

JAZZ PHARMACEUTICALS INC

Form S-1

March 09, 2007

Table of Contents

As filed with the Securities and Exchange Commission on March 8, 2007

Registration No. 333 -

---

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

---

**FORM S-1**  
**REGISTRATION STATEMENT**

*UNDER*

*THE SECURITIES ACT OF 1933*

---

**JAZZ PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

---

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**2834**  
(Primary Standard Industrial  
Classification Code Number)

**05-0563787**  
(I.R.S. Employer  
Identification Number)

---

**3180 Porter Drive**

**Palo Alto, CA 94304**

**(650) 496-3777**

Edgar Filing: JAZZ PHARMACEUTICALS INC - Form S-1

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

---

**Samuel R. Saks, M.D.**

**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:*

**Suzanne Sawochka Hooper, Esq.**

**John M. Geschke, Esq.**

**Cooley Godward Kronish LLP**

**Five Palo Alto Square**

**3000 El Camino Real**

**Palo Alto, CA 94306-2155**

**(650) 843-5000**

**Carol A. Gamble, Esq.**

**Philip J. Honerkamp, Esq.**

**Jazz Pharmaceuticals, Inc.**

**3180 Porter Drive**

**Palo Alto, CA 94304**

**(650) 496-3777**

**Bruce K. Dallas, Esq.**

**Davis Polk & Wardwell**

**1600 El Camino Real**

**Menlo Park, CA 94025**

**(650) 752-2000**

---

**Approximate date of commencement of proposed sale to the public:** As soon as practicable 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. "

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) 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. "

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

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 number of the earlier effective registration statement for the same offering. "

---

### CALCULATION OF REGISTRATION FEE

---

<b>Title of each class of securities</b>	<b>Proposed maximum aggregate</b>	<b>Amount of</b>
<b>to be registered</b>	<b>offering price(1)</b>	<b>registration fee</b>
Common Stock, \$.0001 par value per share	\$172,500,000	\$5,296

---

(1) Estimated solely for the purpose of calculating the amount of the registration fee in accordance with Rule 457(o) under the Securities Act of 1933, as amended. Includes \$22,500,000 of shares that the underwriters have the option to purchase to cover over-allotments, if any.

---

**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. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and we are not soliciting offers to buy these securities in any state where the offer or sale is not permitted.

*PROSPECTUS (Subject to Completion)*

*Issued* , 2007

*Shares*

*COMMON STOCK*

---

*Jazz Pharmaceuticals, Inc. is offering* shares of its common stock. This is our initial public offering and no public market exists for our shares. We anticipate that the initial public offering price will be between \$ and \$ per share.

---

*We have applied to have our common stock listed on the NASDAQ Global Market under the symbol JAZZ .*

---

*Investing in the common stock involves risks. See Risk Factors beginning on page 8.*

---

*PRICE \$ A SHARE*

---

<i>Price to</i>	<i>Underwriting</i>	<i>Proceeds to</i>
<i>Public</i>	<i>Discounts and</i>	<i>Jazz Pharmaceuticals</i>

Edgar Filing: JAZZ PHARMACEUTICALS INC - Form S-1

		<i>Commissions</i>	
<i>Per Share</i>	\$	\$	\$
<i>Total</i>	\$	\$	\$

We have granted the underwriters the right to purchase up to an additional \_\_\_\_\_ shares of common stock to cover over-allotments.

The Securities and Exchange Commission and state securities regulators have not approved or disapproved these securities, or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the shares of common stock to purchasers on \_\_\_\_\_, 2007.

---

**MORGAN STANLEY**

**LEHMAN BROTHERS**

**CREDIT SUISSE**

**NATEXIS BLEICHROEDER INC.**

, 2007

**Table of Contents****TABLE OF CONTENTS**

	<b>Page</b>
<u>Prospectus Summary</u>	1
<u>Risk Factors</u>	8
<u>Special Note Regarding Forward-Looking Statements</u>	32
<u>Use of Proceeds</u>	33
<u>Dividend Policy</u>	35
<u>Capitalization</u>	36
<u>Dilution</u>	38
<u>Selected Consolidated Financial Data</u>	41
<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	43
<u>Business</u>	63
<u>Management</u>	96
	<b>Page</b>
<u>Certain Relationships and Related Party Transactions</u>	123
<u>Principal Stockholders</u>	127
<u>Description of Capital Stock</u>	131
<u>Shares Eligible For Future Sale</u>	136
<u>Material U.S. Tax Consequences for Non-U.S. Holders of Common Stock</u>	138
<u>Underwriters</u>	141
<u>Legal Matters</u>	144
<u>Experts</u>	144
<u>Where You Can Find Additional Information</u>	144
<u>Index to Consolidated Financial Statements</u>	F-1

---

You should rely only on the information contained in this prospectus or any related free writing prospectus we may authorize to be delivered to you. We have not, and the underwriters have not, authorized anyone to provide you with information different from, or in addition to, that contained in this prospectus or any related free writing prospectus. If anyone provides you with different or inconsistent information, you should not rely on it. We are offering to sell, and are seeking offers to buy, shares of common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus or any related free writing prospectus is accurate only as of its date, regardless of its time of delivery, or of any sale of the common stock. Our business, financial conditions, results of operations and prospects may have changed since that date.

**Through and including \_\_\_\_\_, 2007 (25 days after the date of this prospectus), all dealers that buy, sell or trade our common stock, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to the obligation of dealers to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.**

For investors outside of the United States: Neither we nor any of the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. You are required to inform yourselves about and to observe any restrictions relating to this offering and the distribution of this prospectus.

**Table of Contents**

**PROSPECTUS SUMMARY**

*The following summary is qualified in its entirety by, and should be read together with, the more detailed information and financial statements and related notes thereto appearing elsewhere in this prospectus. This summary highlights what we believe is the most important information about us and this offering. Before you decide to invest in our common stock, you should read the entire prospectus carefully, including the Risk Factors section and the financial statements and related notes included in this prospectus.*

**JAZZ PHARMACEUTICALS, INC.**

**Corporate Overview**

We are a specialty pharmaceutical company focused on identifying, developing and commercializing innovative products to meet unmet medical needs in neurology and psychiatry. Our goal is to build a broad portfolio of products through a combination of internal development and acquisition and in-licensing activities and to utilize our specialty sales force to promote our products in our target markets. We apply novel formulations and drug delivery technologies to known drug compounds, and compounds with the same mechanism of action or similar chemical structure as marketed products, to improve patient care by, among other things, improving efficacy, reducing adverse side effects or increasing patient compliance relative to existing therapies. By working with these drug compounds, we believe that we can substantially mitigate the risks and reduce the costs and time associated with product development and commercialization of new therapies with significant market opportunities. Through the application of novel formulations and drug delivery technologies available from third parties, we also explore potential new indications for known drug compounds. Since our inception in 2003, our experienced executive management team has built a commercial operation and assembled a portfolio of products and product candidates that currently includes two marketed products that generated net product sales of \$41.9 million in 2006, one product candidate for which an approvable letter has been issued by the U.S. Food and Drug Administration, or FDA, and five product candidates in various stages of clinical development. We also have additional product candidates in earlier stages of development.

Our most significant marketed product and late-stage product candidates are:

*Xyrem (sodium oxybate oral solution).* Xyrem is the only product approved by the FDA for the treatment of both cataplexy and excessive daytime sleepiness in patients with narcolepsy. According to the National Institutes of Health, 150,000 or more individuals in the United States are affected by narcolepsy. Cataplexy, the sudden loss of muscle tone, is the most well-recognized symptom of narcolepsy. Excessive daytime sleepiness is the most common symptom of narcolepsy and is present in all narcolepsy patients. We promote Xyrem in the United States to neurologists, psychiatrists, pulmonologists and sleep specialists through our 55 person specialty sales force. We have significantly increased domestic net product sales of Xyrem since our acquisition of Orphan Medical, Inc. in June 2005. We have licensed the rights to commercialize Xyrem in 54 countries outside of the United States to UCB Pharma Limited, or UCB, and in Canada to Valeant Canada Limited, or Valeant. UCB has commercially launched Xyrem in 11 countries.

*Luvox CR (fluvoxamine maleate extended release capsules).* Our most advanced product candidate is Luvox CR, an extended release formulation of fluvoxamine, a selective serotonin reuptake inhibitor, or SSRI, which has been developed for the treatment of obsessive compulsive disorder, or OCD, and social anxiety disorder, or SAD. According to the National Institute of Mental Health, OCD and SAD affect approximately 2.2 million and 15 million adults in the United States, respectively. We obtained the U.S. marketing rights to Luvox CR from Solvay Pharmaceuticals, Inc., or Solvay, in January 2007. Solvay submitted a new drug application, or NDA, to the FDA for Luvox CR in April 2006, and, in





---

**Table of Contents**

February 2007, the FDA issued an approvable letter. Subject to the satisfaction of certain requirements set forth in the approvable letter and FDA approval, we expect to commence promotion of Luvox CR in the United States in the first quarter of 2008 through a significantly expanded specialty sales force. During 2007, we expect to make significant expenditures relating to the planned commercial launch of Luvox CR.

*JZP-6 (sodium oxybate).* We are developing a liquid dosage form of sodium oxybate, the active pharmaceutical ingredient, or API, in Xyrem, for the treatment of fibromyalgia syndrome, or FMS. FMS is a chronic pain condition that affects between two and four percent of the U.S. population, according to the American College of Rheumatology. There are currently no products approved by the FDA for the treatment of FMS. We have successfully completed a Phase II clinical trial of this product candidate for the treatment of FMS. We are currently conducting two Phase III pivotal clinical trials and we expect preliminary data from the first Phase III pivotal clinical trial in the second half of 2008. We have granted UCB the commercialization rights to JZP-6 in 54 countries outside of the United States.

In addition to our product candidates in late-stage development, our clinical development pipeline consists of the following product candidates:

*JZP-4 (Type IIa sodium channel antagonist).* JZP-4, a controlled release formulation of an anticonvulsant that is in the same chemical class as Lamictal (lamotrigine), an antiepileptic drug marketed by GlaxoSmithKline, is being developed for the treatment of epilepsy and bipolar disorder. According to the Epilepsy Foundation, approximately 2.7 million people in the United States suffer from epilepsy and, according to the National Institute of Mental Health, approximately 5.7 million people in the United States are affected by bipolar disorder. We plan to commence a Phase II clinical trial of JZP-4 for the treatment of epilepsy in the fourth quarter of 2007.

*JZP-8 (benzodiazepine).* JZP-8, a novel formulation incorporating a benzodiazepine, is being developed for the treatment of acute repetitive seizure clusters, or RSCs, in refractory epilepsy patients. According to an article published in the *New England Journal of Medicine*, approximately 30% of epilepsy patients are refractory to treatment despite being on an effective dose of an antiepilepsy regimen, and a subset of these refractory patients experience RSCs. We have completed development activities to select the API for this product candidate and are conducting further development activities related to formulation, safety and tolerance. We plan to commence a Phase II clinical trial of JZP-8 for the treatment of acute RSCs in refractory epilepsy patients in the third quarter of 2007.

*JZP-7 (dopamine agonist).* JZP-7, a novel formulation incorporating a dopamine agonist, is being developed for the treatment of restless legs syndrome, or RLS. According to the RLS Foundation, up to 10% of the U.S. population suffers from RLS. We have completed development activities to select the API for this product candidate and are conducting further development activities related to formulation, safety and tolerance. We intend to conduct an additional pharmacokinetics study in 2007 prior to commencing Phase II clinical trials for the treatment of RLS.

*JZP-2 (benzodiazepine).* JZP-2, a fast-acting formulation of a benzodiazepine, is being developed for the acute treatment of panic attacks associated with panic disorder. According to the National Institute of Mental Health, approximately six million people in the United States suffer from panic disorder in any given year. We have developed a target formulation for JZP-2 and plan to commence one or more clinical trials of JZP-2 with this formulation in 2007.

We have an ongoing program for generating, identifying and conducting feasibility studies for new product candidates. Our JZP-2, JZP-7 and JZP-8 product candidates resulted from this program. Several other product candidates identified through this program are in various stages of early development, including the use of

## **Table of Contents**

sodium oxybate, the API in Xyrem, for the treatment of movement disorders. In addition, as part of our lifecycle management activities, we are conducting activities directed to developing new forms of sodium oxybate.

Our executive management team has substantial experience in developing and commercializing novel therapeutic products. During their ten years working together as part of the executive management team at ALZA Corporation, a pharmaceutical company acquired by Johnson & Johnson in 2001, our executive management team participated in the successful development and commercialization of a broad portfolio of products and product candidates to address specialized markets.

## **Our Strategy**

Our goal is to be a leading specialty pharmaceutical company developing and commercializing new medicines in neurology and psychiatry and, over the longer term, in additional specialty therapeutic areas. Key elements of our strategy to achieve this goal include:

focusing on specialty markets, particularly neurology and psychiatry, in which a relatively small number of healthcare providers write a large percentage of prescriptions for the indications we target;

expanding and leveraging our U.S. specialty sales force to promote our growing portfolio of commercial products;

mitigating risks and reducing the costs and time associated with the development and commercialization of our products by focusing on known drug compounds, and compounds with the same mechanism of action or similar chemical structure as marketed products, and structuring our development and commercial relationships to minimize financial risk;

expanding our portfolio to include additional products and product candidates that we believe have significant commercial potential through our internal research and development efforts and our acquisition and in-licensing activities; and

leveraging the expertise of our experienced executive management team in developing and commercializing novel therapeutic products.

## **Risks Associated with Our Business**

We are a specialty pharmaceutical company with historical net operating losses, and our operations to date have generated substantial and increasing needs for cash. Our business and our ability to execute on our business strategy are subject to many risks that you should be aware of before you decide to buy our common stock. These risks are discussed more fully in **Risk Factors** beginning on page 8. For example:

Our clinical trials may fail to adequately demonstrate the safety and effectiveness of our product candidates. 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.

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

The regulatory approval process is expensive, time consuming and uncertain and may prevent us or our partners from obtaining regulatory approvals for the commercialization of some or all of our product candidates. If we receive regulatory approval for our product candidates, we will be subject to ongoing significant regulatory obligations and oversight, which may result in significant additional expense and limit our ability to commercialize our products.

Even if approved for sale by the appropriate regulatory authorities, our products may not achieve market acceptance. Market acceptance is dependent upon, among other things, the availability of

## **Table of Contents**

adequate reimbursement by third parties and acceptance by physicians and patients of each of our products as a safe and effective treatment.

We face competition from both generic and branded pharmaceutical products and 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 sales of our products.

Our ability to grow our business is dependent on our ability to successfully develop, acquire or in-license new products and product candidates.

Since our inception in 2003, we have incurred net losses, and we expect to continue to incur net losses for the next several years. We are unable to predict with certainty the extent of any future losses or when we will become profitable. We will also need to raise additional funds to support our operations, and such funding may not be available to us on acceptable terms, if at all. If we are unable to raise additional funds when needed, we may not be able to continue development of our product candidates or we could be required to delay, scale back or eliminate some or all of our development programs and other operations.

## **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®, Antizol®, Luvox® and the Jazz Pharmaceuticals logo as trademarks in the United States and other countries. We have licensed the right to use the registered trademarks Antizol® from Mericon Investment Group, Inc. and Luvox® from Solvay Pharmaceuticals, Inc. All other trademarks or trade names referred to in this prospectus are the property of their respective owners.

## **Market Data**

This prospectus contains market data and industry forecasts that were obtained from industry publications. We have not independently verified any of this information.



Edgar Filing: JAZZ PHARMACEUTICALS INC - Form S-1

the filing of our third amended and restated certificate of incorporation, which will occur immediately prior to the closing of this offering; and

no exercise of the underwriters' over-allotment option.

**Table of Contents****SUMMARY CONSOLIDATED FINANCIAL DATA**

The following table summarizes our financial data. We have derived the following summary of our consolidated statements of operations data for the years ended December 31, 2004, 2005 and 2006 from our audited consolidated financial statements appearing elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that may be expected in the future. The summary of our financial data set forth below should be read together with our consolidated financial statements and the related notes to those statements, as well as

Selected Consolidated Financial Data and Management's Discussion and Analysis of Financial Condition and Results of Operations, appearing elsewhere in this prospectus. The pro forma as adjusted balance sheet data give effect to the conversion of all outstanding shares of convertible preferred stock into common stock immediately prior to the closing of this offering, and to reflect the sale of shares of our common stock in this offering at an assumed initial public offering price of \$ per share, the mid-point of the range reflected on the cover page on this prospectus, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

	Year Ended December 31,		
	2004	2005(1)	2006
(In thousands, except per share data)			
<b>Consolidated Statements of Operations Data:</b>			
Revenues:			
Product sales, net	\$	\$ 18,796	\$ 43,299
Royalties, net		146	594
Contract revenues		2,500	963
Total revenues		21,442	44,856
Operating expenses:			
Cost of product sales		4,292	6,968
Research and development	17,988	45,783	54,956
Selling, general and administrative	7,459	23,551	51,384
Amortization of intangible assets		4,960	9,600
Purchased in-process research and development		21,300	
Total operating expenses	25,447	99,886	122,908
Loss from operations	(25,447)	(78,444)	(78,052)
Interest income	643	1,318	2,307
Interest expense (including \$4,595 and \$9,024 for the years ended December 31, 2005 and 2006, respectively, pertaining to related parties)		(7,129)	(14,129)
Other expense		(901)	(1,109)
Gain on extinguishment of development financing obligation			31,592
Net loss	(24,804)	(85,156)	(59,391)
Beneficial conversion feature			(21,920)
Loss attributable to common stockholders	\$ (24,804)	\$ (85,156)	\$ (81,311)
Loss attributable to common stockholders per share, basic and diluted	\$ (137.80)	\$ (1,216.51)	\$ (572.61)
Weighted-average shares used in computing loss per share attributable to common stockholders, basic and diluted	180	70	142
Pro forma loss attributable to common stockholders per share, basic and diluted (unaudited)(2)			
Pro-forma weighted-average shares used in computing loss per share attributable to common stockholders, basic and diluted (unaudited)(2)			





**Table of Contents**

	As of December 31, 2006 Pro Forma	
	Actual	As Adjusted(3) (Unaudited)
	(In thousands)	
<b>Consolidated Balance Sheet Data:</b>		
Cash and cash equivalents	\$ 78,948	
Working capital	61,043	
Total assets	214,571	
Senior secured notes (including \$51,998 as of December 31, 2006 held by related parties)	74,283	
Convertible preferred stock	263,852	
Common stock subject to repurchase	8,183	
Accumulated deficit	(177,643)	
Total stockholders' equity (deficit)	(176,296)	

- (1) We acquired Orphan Medical on June 24, 2005 and the results of Orphan Medical are included in the consolidated financial statements from that date.
- (2) Assumes the conversion of all outstanding shares of convertible preferred stock outstanding as of December 31, 2006 into common stock.
- (3) Each \$ increase (decrease) in the assumed initial public offering price of \$ per share, would increase (decrease) each of cash and cash equivalents, working capital, total assets and total stockholders' equity (deficit) by approximately \$ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of shares we are offering. Each increase of million shares in the number of shares offered by us, together with a concomitant \$ increase in the assumed initial public offering price of \$ per share, would increase each of cash and cash equivalents, working capital, total assets and total stockholders' equity (deficit) by approximately \$ million. Similarly, each decrease of million shares in the number of shares offered by us, together with a concomitant \$ decrease in the assumed initial public offering price of \$ per share, would decrease each of cash and cash equivalents, working capital, total assets and total stockholders' equity (deficit) by approximately \$ million. The pro forma information discussed above is illustrative only and will adjust based on the actual initial public offering price and other terms of this offering determined at pricing.

**Table of Contents**

**RISK FACTORS**

*You should carefully consider the risks described below, which we believe are the material risks of our business and this offering, before making an investment decision. Additional risks not presently known to us or that we currently deem immaterial may also impair our business operations. Our business could be harmed by any of these risks. The trading price of our common stock could decline due to any of these risks, and you may lose all or part of your investment. In assessing these risks, you should also refer to the other information contained in this prospectus, including our financial statements and related notes.*

**Risks Related to Our Business**

*The FDA may not approve Luvox CR for marketing in the United States, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.*

In January 2007, we licensed from Solvay the exclusive U.S. rights to Luvox CR and Luvox. Luvox CR was developed by Solvay in collaboration with Elan Pharma International Limited, or Elan. In December 2000, Solvay submitted an NDA to the FDA for Luvox CR for the treatment of OCD and SAD. In June 2001, as a result of challenges related to Elan's scale-up of the process to manufacture commercial quantities of Luvox CR, Solvay and Elan mutually agreed to withdraw the NDA for Luvox CR. In April 2006, Solvay resubmitted the Luvox CR NDA to the FDA, requesting approval to market the product for the treatment of OCD and SAD. In February 2007, the FDA issued an approvable letter. Solvay must satisfy the conditions set forth in the letter in order to obtain FDA approval. If Solvay is unable to meet these conditions, or for other reasons, the FDA may not approve Luvox CR for marketing in the United States. The failure to obtain marketing approval for Luvox CR could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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

We are currently conducting two Phase III pivotal clinical trials for the use of JZP-6 to treat FMS, both of which must have statistically significant positive results before we can submit an NDA to the FDA seeking approval of JZP-6 for the treatment of FMS. Our Phase III clinical program for JZP-6 is costly, and we do not expect to complete the program until early 2009. We do not know if our ongoing Phase III pivotal clinical trials will show JZP-6 to be safe and effective for the treatment of FMS, or if the FDA or other regulatory authorities will approve JZP-6 for the treatment of FMS. Favorable results from our prior Phase II clinical trials with JZP-6 for the treatment of FMS may not be indicative of the clinical results from our Phase III pivotal clinical trials. Further, although JZP-6 has the same API as Xyrem, which has been approved by the FDA for the treatment of cataplexy and excessive daytime sleepiness in patients with narcolepsy, this does not assure approval by the FDA, or any other regulatory authorities, of this API for the treatment of FMS. Unsuccessful Phase III pivotal clinical trials or a failure to obtain FDA or other regulatory approval of JZP-6 for FMS could have a material adverse effect on our business, financial condition, results of operations and growth prospects. Even if the FDA approves JZP-6 for the treatment of FMS, the FDA is likely to require us to have a risk management program similar to the one we use for Xyrem. The Xyrem risk management program is labor intensive, complex and expensive. A similar risk management program for JZP-6 could make it difficult for us to effectively supply the FMS market and could limit sales of JZP-6. Moreover, a risk management program for JZP-6 in FMS could make the product less attractive to physicians and patients than other products that are not subject to the same requirements for distribution.

## **Table of Contents**

*Many of our product candidates are in preclinical or early-stage clinical trials. 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 \$40.0 million and \$100.0 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. For example, our Phase III clinical trial of JZP-3, a product candidate for the treatment of general anxiety disorder, was not successful after we incurred significant development costs, and we ceased further development of JZP-3.

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

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

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

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

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

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

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

poor effectiveness of product candidates during clinical trials;

safety issues, including adverse events associated with product candidates;

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

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

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

varying interpretation of data by the FDA or foreign regulatory agencies.

In addition, our product candidates are subject to competition for clinical study sites and patients from other therapies under development that may delay the enrollment in or initiation of our clinical trials. For example, other companies have stated publicly that they are testing product candidates for the treatment of FMS. Some of these companies have more significant financial and human resources than we do.

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

## **Table of Contents**

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

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

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

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

*The commercial success of our products will depend 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 our products by physicians, patients, third party payors and the medical community will depend on:

the clinical indications for which a product is approved;

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

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

perceived advantages over alternative treatments;

relative convenience and ease of administration;

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

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

the availability of adequate reimbursement by third parties.

---

**Table of Contents**

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

We have exclusively licensed to UCB the rights to market and promote Xyrem in 54 countries outside of the United States. If UCB does not obtain regulatory approvals for and launch Xyrem in its licensed countries in the time frames that we expect, or at all, our revenues would be adversely affected. If UCB terminates its relationship with us, we would need to find another party or parties to commercialize Xyrem in UCB's licensed territories. We may be unable to find another party or parties on acceptable terms, or at all, which could materially and adversely affect our business, financial condition, results of operations and growth prospects. In addition, under the terms of our collaboration with UCB, we granted UCB the exclusive right to commercialize JZP-6 for the treatment of FMS in the same territories that UCB has the right to market and promote Xyrem for patients with narcolepsy. We have relied and will continue to rely in part on milestone payments from UCB to reduce our development costs of JZP-6. UCB has the right to terminate our collaboration on 18 months' notice (or less in certain circumstances). If UCB terminates our collaboration, we would need to find another party or parties to commercialize JZP-6 in UCB's territories and may need to execute alternative financing plans to help fund our development of JZP-6. We may be unable to do either of these on acceptable terms, or at all.

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

As a condition of approval of Xyrem, the FDA mandated that we maintain a risk management program for Xyrem under which all Xyrem that we sell in the United States must be shipped directly to patients through a central pharmacy. The process under which patients receive Xyrem under our risk management program is cumbersome. 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 and require FDA approval of the new central pharmacy distributor. In addition, sodium oxybate, the API in Xyrem, is regulated by the U.S. Drug Enforcement Administration, or DEA, as a controlled substance. The new distributor would need to be registered with the DEA and would also need to develop the particular processes, procedures and activities necessary to distribute Xyrem, including the risk management program approved by the FDA. If we change distributors, new contracts might also be required with government and other insurers who pay for Xyrem. Transitioning to a new distributor could result in product shortages, which would adversely affect sales of Xyrem in the United States.

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

The DEA limits the quantity of certain Schedule I and II controlled substances that may be produced in the United States in any given calendar year through a quota system. Because sodium oxybate, the API in Xyrem and JZP-6, is a Schedule I controlled substance, our supplier of the API and our product manufacturer 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 would be difficult and time consuming to obtain and might not ultimately be obtained on a timely basis, or at all. In cooperation with our manufacturing partners, we are seeking to significantly increase their 2007 quotas from the DEA for sodium oxybate, Xyrem and JZP-6 to satisfy the forecasted demand for Xyrem and to conduct our clinical studies of JZP-6. In the future, we intend to seek further increased quotas to supply and manufacture JZP-6 as necessary to complete our clinical trials and, if approved, to commercialize the product. However, our manufacturing partners may not be successful in obtaining increased

---

**Table of Contents**

quotas from the DEA, and without sufficient DEA quotas, there could be shortages of Xyrem for the marketplace or JZP-6 for use in our clinical studies, or both. If our manufacturing partners are unable to obtain increased quotas from the DEA, we may have to reduce the enrollment rate in our Phase III pivotal clinical trials of JZP-6 until additional quantities of JZP-6 are obtained.

*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 APIs. Accordingly, we have entered into manufacturing and supply agreements with single source suppliers and manufacturers for our commercialized products and product candidates. Our suppliers and contract manufacturers may not be able to manufacture our products or product candidates without interruption, or may not comply with their obligations to us under our supply and manufacturing arrangements. We may not have adequate remedies for any breach and their failure to supply us could result in a shortage of our products or product candidates.

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

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

Failure by our third party manufacturers to comply with regulatory requirements could adversely affect their ability to supply products to us. All facilities and manufacturing techniques used for the manufacture of pharmaceutical products must be operated in conformity with cGMP requirements. In complying with cGMP requirements, our suppliers must continually expend time, money and effort in production, record-keeping and





---

**Table of Contents**

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. In addition, under our agreements with UCB and Valeant, we are responsible for the supply of Xyrem and JZP-6 to UCB and Xyrem, and potentially JZP-6, to Valeant. Our failure to meet our contractual obligations to supply UCB and Valeant 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 or Valeant.

***Our product candidates have never been manufactured on a commercial scale and there are risks associated with scaling up manufacturing to commercial scale.***

Our product candidates have never been manufactured on a commercial scale and there are risks associated with scaling up manufacturing to commercial scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, lot consistency and timely availability of raw materials. For example, if Luvox CR is approved for commercial sale, Elan will manufacture Luvox CR for us in commercial quantities in exchange for royalty and milestone payments and supply price payments. Luvox CR has never been produced on a commercial scale, and the NDA for Luvox CR was withdrawn in June 2001 by Solvay and Elan as a result of difficulties encountered during the scale-up of manufacturing of Luvox CR. Although the FDA has issued an approvable letter, there is no assurance that Elan will be able to manufacture Luvox CR to specifications acceptable to the FDA, or if Luvox CR is approved, to produce it in sufficient quantities to meet the requirements for the potential launch of the product or to meet potential future demand. If our manufacturers are unable to produce sufficient quantities of our products for commercialization, our commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

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

From time to time, there is negative publicity about GHB and its effects, including with respect to illegal use, overdoses, serious injury and death and because sodium oxybate, the API in Xyrem, is a derivative of GHB, Xyrem sometimes also receives negative mention in publicity relating to GHB. Because sodium oxybate is a derivative of GHB, patients, physicians and regulators may view Xyrem as the same as or similar to GHB. In addition, there are regulators and some law enforcement agencies that oppose the prescription and use of Xyrem generally. Xyrem's label includes information about adverse events from GHB, and we anticipate that if JZP-6 is approved, its label will include similar information. We could also be adversely affected if any of our products or any similar products distributed by other companies prove to be, or are asserted to be, harmful to consumers. Because of our dependence upon patient and physician perceptions, any adverse publicity associated with illness or other adverse effects resulting from the use or misuse of our products or any similar products distributed by other companies could materially and adversely affect our business, financial condition, results of operations and growth prospects.

---

**Table of Contents**

*An investigation by the U.S. Attorney for the Eastern District of New York concerning Orphan Medical's promotion of Xyrem could result in fines, penalties or other adverse consequences that could result in adverse publicity and could harm our business.*

In April 2006, a physician who was a speaker for Orphan Medical (and for a short time for us) was indicted by a federal grand jury in the U.S. District Court for the Eastern District of New York. The indictment alleges that the physician engaged in a scheme with Orphan Medical sales representatives and other Orphan Medical employees to promote and obtain reimbursement for Xyrem for medical uses not approved for marketing by the FDA. We and Orphan Medical received subpoenas from the U.S. Department of Justice, acting through the U.S. Attorney for the Eastern District of New York, in connection with this indictment and the accompanying investigation. As a result of our acquisition of Orphan Medical, the U.S. government may seek to hold us responsible for Orphan Medical's conduct, and the indictment has resulted in adverse publicity for Xyrem and for us. Companies that have been involved in similar investigations have often paid significant fines and have signed agreements with the U.S. government requiring them to undertake extensive and expensive remedial compliance programs. We have been in discussions with the U.S. Attorney's Office regarding the possible settlement of any potential U.S. government claims against Orphan Medical and/or us, but we cannot assure you that any settlement will be reached on reasonable terms, or at all, and we may be required to make significant monetary payments and to undertake extensive remedial compliance programs at significant expense to us. Even if we reach a settlement agreement with the U.S. Attorney's Office, we might also be subject to regulatory and/or enforcement action by federal agencies, private insurers and states' attorneys general. If we cannot reach a settlement with the U.S. Attorney's Office that is acceptable to us, we could be required to spend significant amounts defending ourselves and Orphan Medical. These matters may involve the filing of criminal charges, as well as criminal and/or civil fines and penalties, against us, or Orphan Medical, or both. We cannot predict or determine the outcome of this matter or reasonably estimate the amount of any fines or penalties that might result from an adverse outcome. However, an adverse outcome could have a material adverse effect on our financial position, liquidity and results of operations.

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

*Xyrem cannot be advertised directly to consumers, which could limit sales.*

Because Xyrem is a derivative of GHB, a known drug of abuse, the FDA has required that Xyrem's label include a box warning regarding the risk of abuse. A box warning is the strongest type of warning that the FDA can require for a drug product and warns prescribers that the drug carries a significant risk of serious or even life-threatening adverse effects. A box warning also means, among other things, that the product cannot be advertised directly to consumers. Competing products may not be subject to this restriction, and the box warning may have a negative effect on Xyrem sales. If JZP-6 is approved by the FDA, we anticipate that the label for JZP-6 will also include a box warning. In addition, Xyrem's type of FDA approval under the FDA's Subpart H regulations requires that all of the promotional materials for Xyrem be provided to the FDA for review at least 30 days prior to the intended time of first use. Competing products may not be subject to these advertising limitations and pre-review requirements, which could result in significant marketing disadvantages for Xyrem and, if approved, JZP-6.

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

Our competitors may obtain FDA or other regulatory approvals for their product candidates more rapidly than we may. For example, Eli Lilly and Company, Pfizer Inc. and Forest Laboratories, Inc., companies with far greater resources than we have, are each conducting Phase III clinical trials of, or have submitted NDAs or supplemental NDAs to the FDA with respect to, product candidates for the treatment of FMS. These product candidates may reach the market before JZP-6, or may be better accepted by physicians and patients. Thus, even if we successfully complete our Phase III clinical trials for JZP-6 for the treatment of FMS and achieve FDA approval, JZP-6 may not result in significant commercial revenues for us.

Our competitors may market their products more effectively than we do. If we are unable to demonstrate to physicians that, based on experience, clinical data, side-effect profiles and other factors, our products are preferable to other therapies, we may not generate meaningful revenues from the sales of our products.

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

Our products are or may become subject to competition from generic equivalents because there is no proprietary protection for some of our products or because our protection has expired or is not sufficiently broad. The FDA has granted orphan drug exclusivity for Xyrem until July 2009 for cataplexy in patients with narcolepsy, and until November 2012 for excessive daytime sleepiness in patients with narcolepsy. Once our orphan drug exclusivity periods for Xyrem expire, other companies could introduce generic equivalents of Xyrem if the generic equivalents do not infringe our existing patents covering Xyrem. Once our orphan drug exclusivity period for Xyrem for the treatment of cataplexy expires in July 2009, prescriptions for Xyrem, or if approved by the FDA, JZP-6, could possibly be filled with generic equivalents that have been approved for the treatment of cataplexy in patients with narcolepsy, even if the patient is diagnosed with excessive daytime sleepiness or FMS. Orphan exclusivity for Antizol for ethylene glycol poisoning expired in 2004 and the orphan exclusivity for Antizol for methanol poisoning will expire in December 2007. Patent protection is not available for the API in most of our products and product candidates, including Xyrem, Luvox CR and JZP-6. Although Xyrem is covered by patents expiring in 2019 with claims covering the formula and process for manufacturing our commercial formulation of Xyrem, it is possible that other companies could manufacture generic equivalents of Xyrem in ways that are not covered by the claims of these patents.

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

competition.

## **Table of Contents**

Luvox CR is covered by a patent application filed by Elan with claims covering the orally administered extended release formulation of fluvoxamine. This patent may not issue, and even if this patent issues, it is possible that other companies could manufacture similar or therapeutically equivalent products in ways that are not covered by the claims of the patent. Further, there may be other patents that we are not aware of that cover some aspect of the Luvox CR formulation and that would prevent launch of the product or require us to pay royalties or other forms of consideration.

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

***We may not be able to enter into acceptable agreements to commercialize our products in international markets.***

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

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

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

***We currently have a small sales organization. If we are unable to appropriately expand our specialty sales force and sales organization in the United States to promote additional products, the commercial opportunity for our products may be diminished.***

Our sales force is currently comprised of 55 sales professionals. Our potential future commercial products, including Luvox CR and JZP-6, will require an expanded sales force and a significant sales support organization, and we will need to commit significant additional management and other resources to the growth of our sales organization before the commercial launch of those product candidates. We may not be able to achieve the necessary growth in a cost-effective manner or realize a positive return on our investment. We will also have to compete with other pharmaceutical and life sciences companies to recruit, hire, train and retain sales and



## **Table of Contents**

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

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

Our success depends in part on our continued ability to attract, retain and motivate highly qualified personnel and on our ability to develop and maintain important relationships with leading academic institutions, clinicians and scientists. We are highly dependent upon our executive management team. The loss of services of any one or more of our members of executive management team or other key personnel could delay or prevent the successful completion of some of our key activities.

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

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

We are a small company with 185 full-time employees as of January 31, 2007, approximately 35% of whom joined us in the last 12 months. To continue our commercialization and development activities, we will need to expand our employee base for managerial, operations, development, regulatory, sales, marketing, financial and other functions. It is particularly difficult to recruit new employees to the San Francisco Bay Area, where our offices are located, in large part due to high housing costs. If we cannot recruit qualified employees when we need them, our key activities could be delayed. Growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees, particularly with respect to the expansion of our sales and marketing organization and related functions for the potential commercialization of Luvox CR and JZP-6. Our future financial performance and our ability to commercialize our products and to compete effectively will depend, in part, on our ability to manage any growth effectively, and our failure to do so could adversely affect our business, financial condition, results of operations and growth prospects.

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

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





## 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 United States and other countries may diminish the value of our intellectual property. Even if we are able to obtain patents covering our products and product candidates, any patent may be challenged, invalidated, held unenforceable or circumvented. The existence of a patent will not necessarily prevent other companies from developing similar or therapeutically equivalent products or protect us from claims of third parties that our products infringe their issued patents, which may require licensing and the payment of significant fees or royalties. Competitors may successfully challenge our patents, produce similar products that do not infringe our patents, or manufacture products in countries where we have not applied for patent protection or that do not respect our patents. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents, our licensed patents or in third party patents.

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

others may be able to make products that are similar to our product candidates but that are not covered by the claims of our patents, or for which we are not licensed under our license agreements;

we or our licensors or partners might not have been the first to make the inventions covered by our issued patents or pending patent applications or the pending patent applications or issued patents of our licensors or partners;

we or our licensors or partners might not have been the first to file patent applications for these inventions;

others may independently develop similar or alternative products without infringing our intellectual property rights;

our pending patent applications may not result in issued patents;

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

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

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

We also may rely on trade secrets and other unpatented proprietary information to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. Although we use reasonable efforts to protect our trade secrets and other unpatented proprietary information, our employees, consultants, advisors and partners may unintentionally or willfully disclose our proprietary information to competitors, and we may not have adequate remedies for such disclosures. If our employees, consultants, advisors and partners develop inventions or processes independently,

## **Table of Contents**

or jointly with us, that may be applicable to our products under development, disputes may arise about ownership or proprietary rights to those inventions and processes. Enforcing a claim that a third party illegally obtained and is using any of our inventions or trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside of the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

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

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

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

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

Furthermore, 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;

Edgar Filing: JAZZ PHARMACEUTICALS INC - Form S-1

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;

## **Table of Contents**

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

discontinue manufacturing or other processes incorporating infringing technology; or

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

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

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

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

## **Risks Related to Our Industry**

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

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



## **Table of Contents**

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

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

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

The federal health care program antikickback 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 antikickback 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



## **Table of Contents**

submitted because of the company's marketing of the product for unapproved, and thus non-reimbursable, uses. The majority of states also have statutes or regulations similar to the federal antikickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a company's products from reimbursement under government programs, criminal fines and imprisonment. Several states now require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products and the reporting of gifts to individual physicians in the states. Other states require the posting of information relating to clinical studies. In addition, California requires pharmaceutical companies to implement a comprehensive compliance program that includes a limit on expenditures for or payments to individual prescribers. Currently, several additional states are considering similar proposals. Compliance with these laws is difficult and time consuming and companies that do not comply with these state laws face civil penalties. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws. Such a challenge could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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

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

We participate in the federal Medicaid rebate program established by the Omnibus Budget Reconciliation Act of 1990, as well as several state supplemental rebate programs. Under the Medicaid rebate program, we pay a rebate to each state Medicaid program for our products that are reimbursed by those programs. The minimum amount of the rebate for each unit of product is set by law at 15.1% of the average manufacturing price, or AMP, of that product, or if it is greater, the difference between AMP 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 AMP 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 AMP 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, or PHS, pharmaceutical pricing program requiring us to sell our products at prices lower than we otherwise might be able to charge. The PHS pricing program extends discounts comparable to the Medicaid rebates to a variety of community health clinics and other

## **Table of Contents**

entities that receive health services grants from the PHS, as well as hospitals that serve a disproportionate share of poor patients and children.

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

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

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

We expect to experience pricing pressures in connection with the sale of our products due to the trend toward managed health care, the increasing influence of health maintenance organizations and additional legislative proposals. If we fail to successfully secure and maintain reimbursement coverage for our products or are significantly delayed in doing so, we will have difficulty achieving market acceptance of our products and our business will be harmed.

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

The market participants to whom we sell Antizol, and to whom we expect to sell most of our future products, including Luvox CR, have undergone significant consolidation, marked by mergers and acquisitions among wholesale distributors and the growth of large retail drugstore chains. As a result, a small number of large wholesale distributors control a significant share of the market, and the number of independent drug stores and small drugstore chains has decreased. In addition, excess inventory levels held by large distributors can lead to



## **Table of Contents**

periodic and unanticipated reductions in our revenues and cash flows. Consolidation of drug wholesalers and retailers, as well as any increased pricing pressure that those entities face from their customers, including the U.S. government, may increase pricing pressure and place other competitive pressures on drug manufacturers, including us.

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

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

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

We recently licensed Xyrem to Valeant to distribute in Canada. Due to government price regulation in Canada, products are generally sold in Canada for lower prices than in the United States. Due to the risk management program for Xyrem and our agreement with Valeant, we believe that it is unlikely that Xyrem will be imported from Canada to the United States.

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

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



## **Table of Contents**

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, the FDA, other government agencies and other entities that have regulatory authority for pharmaceutical sales. Any recall of our products could materially adversely affect our business by rendering us unable to sell that product for some time and by adversely affecting our reputation.

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

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

We have a limited operating history and have incurred significant net losses since our inception in 2003, and we expect to continue to incur net losses for the next several years. Our net loss for the year ended December 31, 2006 was \$59.4 million, and we had an accumulated deficit of \$177.6 million at December 31, 2006. We expect our operating expenses to increase over the next several years as we develop additional products, acquire or in-license additional products, expand clinical trials for our product candidates currently in clinical development, expand our research and development activities, seek regulatory approvals and engage in commercialization preparation activities in anticipation of potential FDA approval of our product candidates. We will need to expand our commercial organization to launch additional products. It is very expensive to launch a product, and many expenses are incurred before revenues are received. We are unable to predict the extent of any future losses or when we will become profitable, if at all.

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

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

As of December 31, 2006, we had approximately \$78.9 million in cash, cash equivalents and marketable securities. During 2006, our cash flows used in operations were approximately \$57.3 million. Substantially all of our \$43.3 million in net product sales during 2006 resulted from sales of Xyrem and Antizol. Sales of either or both products could decrease due to adverse market conditions, introduction of generic products, negative publicity or other events outside our control. We must commit substantial resources to costly and time-consuming research, preclinical testing and clinical trials of our product candidates and significant funds to our commercial operations. While we believe that our current cash,

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

cash equivalents and marketable securities and the anticipated net proceeds from this offering, and interest earned thereon, together with anticipated revenues from product sales, royalties and funding that we expect to receive from our current collaboration arrangement with UCB, will be sufficient to satisfy our current operations through at least the next 12 to 18 months, we expect to raise additional funds within this period of time through development financings, collaborations or public or

private debt or equity financings. We have based this estimate on assumptions that may prove to be wrong, and

**Table of Contents**

we could utilize our available financial resources sooner than we currently expect. Our future capital requirements will depend on many factors, including:

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

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

selling and marketing costs associated with Luvox CR and Xyrem in the United States, including the cost and timing of expanding our marketing and sales capabilities;

revenues from current and potential future development and/or commercial collaboration partners;

the scope, rate of progress, results and costs of our preclinical studies, clinical trials and other research and development activities;

the number and characteristics of product candidates that we pursue;

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

the cost and timing of obtaining regulatory approval;

payments of milestones to third parties;

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

the cost of investigations, litigation and/or settlements related to regulatory activities, in particular the ongoing investigation by the U.S. Attorney for the Eastern District of New York;

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

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

Although we generate product revenues, since our inception in 2003 we have financed our operations primarily through the sale of convertible preferred stock, the issuance of senior secured notes and warrants, a line of credit, development financing related to one of our previous product candidates and our collaboration with UCB related to Xyrem and JZP-6. In addition, our audit report in our 2006 consolidated financial statements contains an explanatory paragraph stating that our recurring losses from operations and cash used in operating activities raise substantial doubt about our ability to continue as a going concern. We believe that the successful completion of this offering will eliminate this doubt and enable us to continue as a going concern; however, if we are unable to successfully complete this offering, we will need to execute alternative financing or operational plans to continue as a going concern.



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

**Table of Contents**

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

As of December 31, 2006, we had total indebtedness of \$82.2 million at face value, substantially all of which we incurred in connection with our acquisition of Orphan Medical. Our substantial debt combined with our other financial obligations and contractual commitments could have other important consequences. For example, it could:

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

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

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

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

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

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

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

Our existing senior secured debt contains, and any future indebtedness would likely contain, a number of restrictive covenants that impose significant operating and financial restrictions on us, including restrictions on our ability to take actions that may be in our best interests. Our existing debt includes covenants, including requirements that we:

generally not borrow additional amounts without the approval of our lenders;

dispose of assets acquired in the Orphan Medical acquisition only in accordance with the terms of our existing senior secured debt;

not impair our lenders' security interests in our assets; and

maintain minimum cash balances.

**Risks Relating to this Offering and 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 in this offering may not be able to sell their shares at or above the initial public offering price. Security prices for companies similar to us experience significant price and volume fluctuations. The following factors, in addition to other risks described in this prospectus, may have a significant effect on our common stock market price:

the success of our development efforts and clinical trials;

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;

**Table of Contents**

actual or expected fluctuations in our operating results, including as a result of fluctuating demand for our commercial products as a result of purchases by wholesalers in connection with product launches, stockpiling or inventory drawdowns by our customers, or otherwise;

changes in the market prices for our products;

the success of our efforts to acquire or in-license additional products or product candidates;

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

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

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

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

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

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

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

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

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

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

the outcome of, and any expenses related to, the U.S. government investigation of the promotion of Xyrem;

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

changes in the market valuation of similar companies;

trading volume of our common stock; and

sales of our common stock by us or our stockholders.

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

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

Sales of a substantial number of shares of our common stock in the public market after this offering, 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. After this offering, we will have \_\_\_\_\_ shares of common stock outstanding, or \_\_\_\_\_ shares if the underwriters exercise their over-allotment option in full.

## **Table of Contents**

All of the shares of common stock sold in this offering will be freely tradable without restrictions or further registration under the Securities Act of 1933, as amended, except for any shares purchased by our affiliates as defined in Rule 144 under the Securities Act of 1933, as amended. The remaining 205,243,938 shares of common stock outstanding after this offering, based on shares outstanding as of December 31, 2006, plus an additional 17,677,564 shares issuable upon the exercise of outstanding options and 8,695,652 shares issuable upon the exercise of outstanding warrants, will be available for sale after the expiration of the contractual lock-up period, subject to volume limitations under Rule 144 under the Securities Act of 1933, as amended. Morgan Stanley & Co. Incorporated and Lehman Brothers Inc., may, in their sole discretion, release all or some portion of the shares subject to lock-up agreements prior to expiration of the lock-up period. See Shares Eligible for Future Sale.

After this offering, the holders of approximately 213,661,357 shares of common stock based on shares outstanding as of December 31, 2006, including 8,695,652 shares underlying outstanding warrants, will be entitled to rights with respect to registration of such shares under the Securities Act of 1933, as amended. In addition, upon exercise of outstanding options by our executive officers, our executive officers will be entitled to rights 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. In addition, prior to the consummation of this offering, we intend to file a registration statement on Form S-8 under Securities Act to register up to shares of our common stock for issuance under our stock option and employee stock purchase plans.

***Our principal stockholders and management own a significant percentage of our stock and will be able to exercise significant influence over matters subject to stockholder approval.***

Our executive officers, directors and principal stockholders, together with their respective affiliates, beneficially owned approximately 83.4% of our capital stock as of January 31, 2007, and we expect that upon completion of this offering they will continue to hold a significant portion of our outstanding capital stock. Accordingly, after this offering, our executive officers, directors and principal stockholders will be 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.

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

The Sarbanes-Oxley Act of 2002 requires, among other things, that we maintain effective internal control over financial reporting and disclosure controls and procedures. In particular, we must perform system and process evaluation and testing of our internal control over financial reporting to allow management and our independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting, as



## **Table of Contents**

required by Section 404 of the Sarbanes-Oxley Act, beginning with our annual report on Form 10-K for the fiscal year ended December 31, 2008. Our compliance with Section 404 of the Sarbanes-Oxley Act will require that we incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. If we are not able to comply with the requirements of Section 404 in a timely manner, or if we or our independent registered public accounting firm identify deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by NASDAQ, the SEC or other regulatory authorities, which would require additional financial and management resources.

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

***We have broad discretion to use the net proceeds from this offering and our investment of these proceeds may not yield a favorable return. We may invest the proceeds of this offering in ways you disagree with.***

Our management has broad discretion as to how to spend and invest the proceeds from this offering and we may spend or invest these proceeds in a way with which our stockholders may disagree. Accordingly, you will need to rely on our judgment with respect to the use of these proceeds. We plan to invest the net proceeds of this offering in short-term, investment-grade, interest bearing securities. These investments may not yield a favorable return to our stockholders.

If we acquire or in-license products or product candidates, or acquire companies that we believe are complementary to our business, the process of integrating the acquired or in-licensed products or product candidates, or acquired companies may result in unforeseen difficulties and expenditures, and may require significant management attention that would otherwise be devoted to our existing business and products. We could fail to realize the anticipated benefits of any acquisition or in-licensing arrangement. Future acquisitions could reduce your percentage of ownership of us or the value of your common stock and could cause us to incur debt and expose us to liabilities.

***An active trading market for our common stock may not develop.***

Prior to this offering, there has been no public market for our common stock. Although we expect that our common stock will be approved for listing on the NASDAQ Global Market, an active trading market for our shares may never develop or be sustained following this offering. The initial public offering price for our common stock was determined through negotiations with the underwriters, and the negotiated price may not be indicative of the market price of the common stock after the offering. This initial public offering price may vary from the market price of our common stock after the offering. As a result of these and other factors, you may be unable to resell your shares of our common stock at or above the initial public offering price.



## **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.*

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, even if doing so would benefit our stockholders. These provisions include:

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

dividing our board of directors into three classes;

limiting the removal of directors by the stockholders;

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

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

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

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

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

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

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

**Table of Contents**

**SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

Some of the statements under Prospectus Summary, Risk Factors, Management's Discussion and Analysis of Financial Condition and Results of Operations and Business and elsewhere in this prospectus contain forward-looking statements. In some cases, you can identify forward-looking statements by the following words: may, will, could, would, should, expect, intend, plan, anticipate, believe, estimate, pr  
continue, ongoing or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. These statements involve risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained in this prospectus, 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. Many important factors affect our ability to achieve our objectives, including:

the success and timing of our product development activities and clinical trials;

our ability to obtain and maintain regulatory approval of our product candidates;

the size and growth potential of the markets for our products, and our ability to serve those markets;

our ability to successfully commercialize our products;

the successful development and expansion of our specialty sales force and commercial organization;

the rate and degree of market acceptance of our current products;

the performance of our single source suppliers and manufacturers;

the success of competing branded and generic drugs;

our ability to identify, develop, acquire and in-license new products and product candidates and to attract appropriate collaboration partners;

the loss of key personnel;

regulatory developments in the United States and foreign countries;

our use of the proceeds from this offering;

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

the accuracy of our estimates regarding revenues, expenses, capital requirements and needs for additional financing, and our ability to obtain additional financing; and

our ability to obtain and maintain intellectual property protection for our products.

In addition, you should refer to the Risk Factors section of this prospectus for a discussion of other important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this prospectus will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law. The Private Securities Litigation Reform Act of 1995 and Section 27A of the Securities Act of 1933 do not protect any forward-looking statements that we make in connection with this offering.

**Table of Contents**

**USE OF PROCEEDS**

We estimate that the net proceeds from the sale of the shares of our common stock in this offering will be approximately \$ \_\_\_\_\_ million, or approximately \$ \_\_\_\_\_ million if the underwriters exercise their over-allotment option in full, based upon an assumed initial public offering price of \$ \_\_\_\_\_ per share, the mid-point of the range reflected on the cover page of this prospectus, and after deducting underwriting discounts and commissions and estimated offering expenses. Each \$ \_\_\_\_\_ increase (decrease) in the assumed initial public offering price of \$ \_\_\_\_\_ per share would increase (decrease) the net proceeds to us from this offering by approximately \$ \_\_\_\_\_ million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same. We may also increase or decrease the number of shares we are offering. Each increase of \_\_\_\_\_ million shares in the number of shares offered by us, together with a concomitant \$ \_\_\_\_\_ increase in the assumed initial public offering price of \$ \_\_\_\_\_ per share, would increase the net proceeds to us from this offering by approximately \$ \_\_\_\_\_ million. Similarly, each decrease of \_\_\_\_\_ million shares in the number of shares offered by us, together with a concomitant \$ \_\_\_\_\_ decrease in the assumed initial public offering price of \$ \_\_\_\_\_ per share, would decrease the net proceeds to us from this offering by approximately \$ \_\_\_\_\_ million. We do not expect that a change in the offering price or the number of shares by these amounts would have a material effect on our uses of the proceeds from this offering, although it may impact the amount of time prior to which we will need to seek additional capital.

We currently expect to use the net proceeds from this offering as follows:

approximately \$ \_\_\_\_\_ million to fund the planned launch and commercialization of Luvox CR, including development and commercial milestone payments to Solvay, activities related to our preparation for marketing and promotion, expansion of our specialty sales force and production of commercial quantities of Luvox CR;

approximately \$ \_\_\_\_\_ million to fund our Phase III pivotal clinical trials of JZP-6;

approximately \$ \_\_\_\_\_ million to fund continued development and feasibility activities related to our portfolio of clinical and early-stage product candidates; and

the remainder to fund working capital, capital expenditures and other general corporate purposes.

We may also use a portion of the proceeds for the potential acquisition or in-licensing of, or investment in, products, product candidates, or companies that complement our business, although we have no current understandings, commitments or agreements to do so.

The expected use of net proceeds of this offering represents our current intentions based upon our present plans and business conditions. As of the date of this prospectus, we cannot specify with certainty all of the particular uses for the net proceeds to be received upon the closing of this offering. Accordingly, our management will have broad discretion in the application of the net proceeds, and investors will be relying on the judgment of our management regarding the application of the proceeds of this offering.

The amount and timing of our expenditures will depend on several factors, including whether and when we obtain regulatory approval of Luvox CR, the success of our research and development programs and clinical trials, expenditures to acquire or in-license additional products or product candidates, our ability to establish and maintain collaborative arrangements that reduce our expenses, resolution of and expenses associated with the U.S. Attorney's Office investigation of Orphan Medical's promotion of Xyrem, future sales growth, cash generated from future operations and actual expenses to operate our business. Pending their uses, we plan to invest the net proceeds of this offering in short- and intermediate-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the

U.S. government.

While we believe that our current cash, cash equivalents and marketable securities and the net proceeds from this offering, and interest earned thereon, together with anticipated revenues from product sales, royalties

**Table of Contents**

and funding that we expect to receive from our current collaboration arrangement with UCB, will be sufficient to satisfy our current operations through at least the next 12 to 18 months, we expect to raise additional funds within this period of time through development financings, collaborations, or public or private debt or equity financings. In addition, we do not expect that our existing capital resources and the net proceeds from this offering will be sufficient to enable us to fund the completion of the development of our current product candidates, and we will need to raise substantial additional capital to fund our operations and to continue to develop our product portfolio, acquire or in-license additional products and product candidates, and launch and market our products.

**Table of Contents**

**DIVIDEND POLICY**

We have never declared or paid any dividends on our common stock or any other securities. We anticipate that we will retain all of our future earnings, if any, for use in the expansion and operation of our business and do not anticipate paying cash dividends in the foreseeable future. In addition, the agreements covering our debt restrict our ability to pay dividends on our common stock. Any future determination relating to our dividend policy will be made at the discretion of our board of directors, based on our financial condition, results of operation, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant.

**Table of Contents****CAPITALIZATION**

The following table sets forth our cash, cash equivalents and capitalization as of December 31, 2006:

on an actual basis; and

on a pro forma as adjusted basis to reflect:

the conversion of all of our outstanding shares of preferred stock into 198,338,205 shares of common stock immediately prior to the closing of this offering and the reclassification of preferred stock warrant liability to additional paid-in capital upon conversion of the preferred stock underlying warrants to common stock; and

the sale of \_\_\_\_\_ shares of common stock in this offering at an assumed initial offering price of \$ \_\_\_\_\_ per share, the mid-point of the range reflected on the cover page of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses.

You should read the information in this table together with Selected Consolidated Financial Data, Management's Discussion and Analysis of Financial Condition and Results of Operations and our consolidated financial statements and related notes included elsewhere in this prospectus.

	As of December 31, 2006	
	Actual	As Adjusted(1) (Unaudited)
	(In thousands, except share data)	
Cash and cash equivalents	\$ 78,948	\$
Senior secured notes (including \$51,998 as of December 31, 2006 held by related parties)	74,283	74,283
Preferred stock warrant liability (including \$5,965 as of December 31, 2006 held by related parties)	8,521	
Convertible preferred stock, \$.0001 par value, issuable in series, 308,236,575 shares authorized, 198,338,205 shares issued and outstanding, actual; no shares authorized, issued and outstanding, pro forma as adjusted.	263,852	
Common stock subject to repurchase	8,183	8,183
Stockholders' equity (deficit):		
Preferred stock, \$.0001 par value, no shares authorized, issued and outstanding, actual; _____ shares authorized, no shares issued and outstanding, pro forma as adjusted.		
Common stock, \$.0001 par value, 252,716,057 shares authorized, 6,905,733 shares issued and outstanding, actual; _____ shares authorized, shares issued and outstanding, pro forma as adjusted		
Additional paid-in capital	1,335	
Accumulated other comprehensive income	12	
Accumulated deficit	(177,643)	
Total stockholders' equity (deficit)	(176,296)	



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

Total capitalization	\$ 178,543	\$
----------------------	------------	----

- 
- (1) Each \$ increase (decrease) in the assumed initial public offering price of \$ per share, the mid-point of the range reflected on the cover page of this prospectus, would increase (decrease) each of additional paid-in capital, total stockholders equity (deficit) and total capitalization by approximately \$ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of shares we are offering. Each increase of million shares in the number of

**Table of Contents**

shares offered by us, together with a concomitant \$ increase in the assumed initial public offering price of \$ per share, would increase each of additional paid-in capital, total stockholders' equity (deficit) and total capitalization by approximately \$ million. Similarly, each decrease of million shares in the number of shares offered by us, together with a concomitant \$ decrease in the assumed initial public offering price of \$ per share, would decrease each of additional paid-in capital, total stockholders' equity (deficit) and total capitalization by approximately \$ million. The as adjusted information discussed above is illustrative only and will adjust based on the actual initial public offering price and other terms of this offering determined at pricing.

The outstanding share information in the table above excludes as of December 31, 2006:

17,677,564 shares of common stock issuable upon the exercise of outstanding options with a weighted average exercise price of \$1.95 per share;

5,378,732 shares of common stock reserved for future issuance under our 2003 Equity Incentive Plan as of December 31, 2006; provided, however, that immediately upon the signing of the underwriting agreement for this offering, our 2003 Equity Incentive Plan will terminate so that no further awards may be granted under our 2003 Equity Incentive Plan;

an aggregate of shares of common stock reserved for future issuance under our 2007 Equity Incentive Plan, 2007 Non-Employee Directors Stock Option Plan and 2007 Employee Stock Purchase Plan, each of which will become effective immediately upon the signing of the underwriting agreement for this offering; and

8,695,652 shares of common stock issuable upon the exercise of outstanding warrants with an exercise price of \$1.84 per share.

We expect to complete a -for- reverse stock split of our common stock and preferred stock before the closing of this offering. All share and per share amounts, other than the shares authorized, have been retroactively adjusted to give effect to this stock split.

**Table of Contents****DILUTION**

If you invest in our common stock in this offering, your ownership interest will be diluted to the extent of the difference between the initial public offering price per share and the pro forma net tangible book value per share of our common stock after this offering. Historical net tangible book value per share is determined by dividing our total tangible assets (total assets less intangible assets), less total liabilities, convertible preferred stock and common stock subject to repurchase, by the number of outstanding shares of our common stock. As of December 31, 2006, we had a historical net tangible book value (deficit) of our common stock of \$(283.6) million, or approximately \$(41.07) per share. The pro forma net tangible book value (deficit) of our common stock as of December 31, 2006 was approximately \$(11.3) million, or approximately \$(0.05) per share, based on the number of shares of common stock outstanding as of December 31, 2006, after giving effect to the conversion of all outstanding convertible preferred stock into shares of common stock and the reclassification of the preferred stock warranty liability to equity immediately prior to the closing of this offering.

Investors participating in this offering will incur immediate, substantial dilution. After giving effect to the sale of common stock offered in this offering at an assumed initial public offering price of \$ \_\_\_\_\_ per share, the mid-point of the range reflected on the cover page of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of December 31, 2006 would have been approximately \$ \_\_\_\_\_ million, or approximately \$ \_\_\_\_\_ per share of common stock. This represents an immediate increase in pro forma as adjusted net tangible book value of \$ \_\_\_\_\_ per share to existing stockholders, and an immediate dilution of \$ \_\_\_\_\_ per share to investors participating in this offering. The following table illustrates this per share dilution:

Assumed initial public offering price per share	\$
Historical net tangible book value (deficit) per share as of December 31, 2006	\$ (41.07)
Pro forma increase in net tangible book value per share attributable to conversion of convertible preferred stock	41.02
Pro forma net tangible book value (deficit) per share before this offering	\$ (0.05)
Pro forma increase in net tangible book value per share attributable to investors participating in this offering	
Pro forma as adjusted net tangible book value (deficit) per share after this offering	
Pro forma dilution per share to investors participating in this offering	\$

Each \$ \_\_\_\_\_ increase (decrease) in the assumed initial public offering price of \$ \_\_\_\_\_ per share would increase (decrease) our pro forma as adjusted net tangible book value (deficit) by approximately \$ \_\_\_\_\_ million, or approximately \$ \_\_\_\_\_ per share, and the pro forma dilution per share to investors in this offering by approximately \$ \_\_\_\_\_ per share, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of shares we are offering. An increase of \_\_\_\_\_ million shares in the number of shares offered by us, together with a concomitant \$ \_\_\_\_\_ increase in the assumed initial public offering price of \$ \_\_\_\_\_ per share, would increase our pro forma as adjusted net tangible book value (deficit) by approximately \$ \_\_\_\_\_ million, or \$ \_\_\_\_\_ per share, and the pro forma dilution per share to investors in this offering by \$ \_\_\_\_\_ per share. Similarly, a decrease of \_\_\_\_\_ million shares in the number of shares offered by us, together with a concomitant \$ \_\_\_\_\_ decrease in the assumed initial public offering price of \$ \_\_\_\_\_ per share, would decrease our pro forma as adjusted net tangible book value (deficit) by approximately \$ \_\_\_\_\_ million, or \$ \_\_\_\_\_ per share, and the pro forma dilution per share to investors in this offering by \$ \_\_\_\_\_ per share. The pro forma as adjusted information discussed above is illustrative only and will adjust based on the actual initial public offering price and other terms of this offering determined at pricing.

**Table of Contents**

If the underwriters exercise their option in full to purchase \_\_\_\_\_ additional shares of common stock in this offering, the pro forma as adjusted net tangible book value per share after the offering would be \$ \_\_\_\_\_ per share, the increase in the pro forma net tangible book value per share to existing stockholders would be \$ \_\_\_\_\_ per share and the pro forma dilution to new investors purchasing common stock in this offering would be \$ \_\_\_\_\_ per share.

The following table summarizes, on a pro forma basis as of December 31, 2006, the differences between the number of shares of common stock purchased from us, the total consideration and the weighted average price per share paid by existing stockholders and by investors participating in this offering at an assumed initial public offering price of \$ \_\_\_\_\_ per share, before deducting underwriting discounts and commissions and estimated offering expenses:

	Shares Purchased		Total Consideration		Weighted
	Number	Percent	Amount	Percent	Average Price Per Share
Existing stockholders before this offering		%	\$	%	\$
Investors participating in this offering					
<b>Total</b>		100%	\$	100%	\$

The above discussion and tables are based on 6,905,733 shares of common stock outstanding as of December 31, 2006. This number excludes, as of December 31, 2006:

17,677,564 shares of common stock issuable upon the exercise of outstanding options with a weighted average exercise price of \$1.95 per share;

5,378,732 shares of common stock reserved for future issuance under our 2003 Equity Incentive Plan; provided, however, that immediately upon the signing of the underwriting agreement for this offering, our 2003 Equity Incentive Plan will terminate so that no further awards may be granted under our 2003 Equity Incentive Plan;

an aggregate of \_\_\_\_\_ shares of common stock reserved for future issuance under our 2007 Equity Incentive Plan, 2007 Non-Employee Directors Stock Option Plan and 2007 Employee Stock Purchase Plan, each of which will become effective immediately upon the signing of the underwriting agreement for this offering; and

8,695,652 shares of common stock issuable upon the exercise of outstanding warrants with an exercise price of \$1.84 per share.

The following table summarizes, on a pro forma basis as of December 31, 2006, after giving effect to the inclusion of 687,536 shares of common stock subject to our right of repurchase and the exercise of all stock options and warrants outstanding as of December 31, 2006, the differences between the number of shares of common stock purchased from us, the total consideration and the weighted average price per share paid by existing stockholders and by investors participating in this offering at an assumed initial public offering price of \$ \_\_\_\_\_ per share, before deducting underwriting discounts and commissions and estimated offering expenses:

Edgar Filing: JAZZ PHARMACEUTICALS INC - Form S-1

	Shares Purchased		Total Consideration		Weighted
	Number	Percent	Amount	Percent	Average Price
		%	\$	%	\$
Existing stockholders before this offering					
Investors participating in this offering					
<b>Total</b>		100%	\$	100%	\$

**Table of Contents**

The number of shares of common stock outstanding in the table above is based on the pro forma number of shares outstanding as of December 31, 2006 and assumes no exercise of the underwriters' option to purchase additional shares. If the underwriters' option to purchase additional shares is exercised in full, the number of shares of common stock held by existing stockholders will be reduced to % of the total number of shares of common stock to be outstanding after this offering, and the number of shares of common stock held by investors participating in this offering will be increased to shares or % of the total number of shares of common stock to be outstanding after this offering.

Effective upon the closing of this offering, an aggregate of shares of our common stock will be reserved for future issuance under our equity benefit plans, and these share reserves will also be subject to automatic annual increases in accordance with the terms of the plans. To the extent that new options are issued under our equity benefit plans or we issue additional shares of common stock in the future, there will be further dilution to investors participating in this offering.

**Table of Contents****SELECTED CONSOLIDATED FINANCIAL DATA**

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

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

	Period from March 20, 2003	Year Ended December 31,		
	(Inception) through December 31, 2003	2004	2005(1)	2006(2)
	(In thousands, except per share data)			
<b>Consolidated Statements of Operations Data:</b>				
Revenues:				
Product sales, net	\$	\$	\$ 18,796	\$ 43,299
Royalties, net			146	594
Contract revenues			2,500	963
Total revenues			21,442	44,856
Operating expenses:				
Cost of product sales			4,292	6,968
Research and development		17,988	45,783	54,956
Selling, general and administrative	2,538	7,459	23,551	51,384
Amortization of intangible assets			4,960	9,600
Purchased in-process research and development			21,300	
Total operating expenses	2,538	25,447	99,886	122,908
Loss from operations	(2,538)	(25,447)	(78,444)	(78,052)
Interest income	10	643	1,318	2,307
Interest expense (including \$4,595 and \$9,024 for the years ended December 31, 2005 and 2006, respectively, pertaining to related parties)			(7,129)	(14,129)
Other expense			(901)	(1,109)
Gain on extinguishment of development financing obligation				31,592
Net loss	(2,528)	(24,804)	(85,156)	(59,391)
Beneficial conversion feature				(21,920)
Loss attributable to common stockholders	\$ (2,528)	\$ (24,804)	\$ (85,156)	\$ (81,311)
Loss attributable to common stockholders per share, basic and diluted	\$ (7.41)	\$ (137.80)	\$ (1,216.51)	\$ (572.61)

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

Weighted-average shares used in computing loss per share attributable to common stockholders, basic and diluted	341	180	70	142
---	-----	-----	----	-----

Pro forma loss attributable to common stockholders per share, basic and diluted (unaudited)(3)				\$
--	--	--	--	----

Pro-forma weighted-average shares used in computing loss per share attributable to common stockholders, basic and diluted (unaudited)(3)				
--	--	--	--	--



**Table of Contents**

- (1) We acquired Orphan Medical, Inc. on June 24, 2005 and the results of Orphan Medical are included in the consolidated financial statements from that date.
- (2) Operating expenses include stock-based compensation expense of \$3.5 million of which \$8,000, \$661,000 and \$2.8 million were charged to cost of product sales, research and development and selling, general and administrative expense, respectively.
- (3) Assumes the conversion of all outstanding shares of convertible preferred stock outstanding as of December 31, 2006 into common stock.

	2003	As of December 31,		2006
		2004	2005	
		(In thousands)		
<b>Consolidated Balance Sheet Data:</b>				
Cash and cash equivalents	\$ 4,460	\$ 33,678	\$ 20,614	\$ 78,948
Working capital	4,488	36,663	8,048	61,043
Total assets	4,900	42,850	164,781	214,571
Senior secured notes (including \$50,620 and \$51,998 as of December 31, 2005 and 2006, respectively, held by related to related parties)			73,629	74,283
Convertible preferred stock	7,076	64,009	163,862	263,852
Common stock subject to repurchase		3,665	5,924	8,183
Accumulated deficit	(2,528)	(27,332)	(118,252)	(177,643)
Total stockholders' equity (deficit)	(2,512)	(30,923)	(118,248)	(176,296)

---

**Table of Contents**

**MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION  
AND RESULTS OF OPERATIONS**

*You should read the following discussion and analysis together with our consolidated financial statements and the notes to those statements included elsewhere in this prospectus. This discussion contains forward-looking statements that involve risks and uncertainties. As a result of many factors, such as those set forth under "Risk Factors" and elsewhere in this prospectus, our actual results may differ materially from those anticipated in these forward-looking statements.*

**Overview**

We are a specialty pharmaceutical company focused on identifying, developing and commercializing innovative products to meet unmet medical needs in neurology and psychiatry. Our goal is to build a broad portfolio of products through a combination of internal development and acquisition and in-licensing activities and to utilize our specialty sales force to promote our products in our target markets. We apply novel formulations and drug delivery technologies to known drug compounds, and compounds with the same mechanism of action or similar chemical structure as marketed products, to improve patient care by, among other things, improving efficacy, reducing adverse side effects or increasing patient compliance relative to existing therapies. By working with these drug compounds, we believe that we can substantially mitigate the risks and reduce the costs and time associated with product development and commercialization of new therapies with significant market opportunities. Through the application of novel formulations and drug delivery technologies available from third parties, we also explore potential new indications for known drug compounds. Since our inception in 2003, our experienced executive management team has built a commercial operation and assembled a portfolio of products and product candidates that currently includes two marketed products that generated net product sales of \$41.9 million in 2006, one product candidate for which an approvable letter has been issued by the U.S. Food and Drug Administration, or FDA, and five product candidates in various stages of clinical development. We also have additional product candidates in earlier stages of development. In March 2007, we sold our rights to a third marketed product that generated net product sales of \$1.4 million in 2006 for cash consideration of \$9.0 million.

In March 2003, we were incorporated in the State of California and began operations. In April 2003, we entered into agreements with investors for a \$15.0 million Series A preferred stock financing, the funds from which were received in 2003 and early 2004. In January 2004, we reincorporated in the State of Delaware. In February 2004, we entered into agreements with investors for a \$250.0 million Series B preferred stock and Series B Prime preferred stock financing led by an affiliate of Kohlberg Kravis Roberts & Co., the funds from which were received in 2004, 2005 and 2006. All of our outstanding preferred stock will convert into common stock in connection with this offering. On June 24, 2005, we acquired Orphan Medical, Inc., including its three marketed products, Xyrem, Antizol and Cystadane, in order to complement our development portfolio with marketed products and to build our commercial organization.

Our marketed products in 2006 were:

*Xyrem (sodium oxybate oral solution).* Xyrem is the only product approved by the FDA for the treatment of both cataplexy and excessive daytime sleepiness in patients with narcolepsy. Net product sales of Xyrem in 2006 were \$29.0 million. We promote Xyrem in the United States to neurologists, psychiatrists, pulmonologists and sleep specialists through our 55 person specialty sales force. Xyrem is distributed in the United States by Express Scripts Specialty Distribution Services, or Express Scripts, a specialty pharmaceutical distribution company, which is our only customer for Xyrem. We have licensed the rights to commercialize Xyrem in 54 countries outside of the United States to UCB Pharma Limited, or UCB, and in Canada to Valeant Canada Limited, or Valeant. In October 2005, the European Agency for the Evaluation of Medical Products, or EMEA, approved Xyrem for the treatment of cataplexy associated with narcolepsy and in March 2007, the EMEA approved the product for the treatment of narcolepsy with

cataplexy in adult patients. UCB has commercially launched Xyrem in 11 countries.

---

**Table of Contents**

*Antizol (fomepizole).* We market Antizol primarily to hospitals and emergency rooms, where it is used to treat both ethylene glycol and methanol poisoning. Net product sales of Antizol in 2006 were \$12.5 million. Antizol is distributed to wholesalers in the United States, and we retain the services of a third party to promote the product. Antizol is marketed by our distributors in Canada and Israel. We also market Antizol-Vet, an injectable formulation of fomepizole approved as an antidote for ethylene glycol poisoning in dogs. Net product sales of Antizol-Vet in 2006 were \$313,000.

*Cystadane (betaine anhydrous).* Cystadane is approved by the FDA for the treatment of homocystinuria, an inherited metabolic disease. Net product sales of Cystadane in 2006 were \$1.4 million. In March 2007, we sold our rights to Cystadane to an unrelated third party for cash consideration of \$9.0 million.

Our late-stage product candidates are:

*Luvox CR (fluvoxamine maleate extended release capsules).* Our most advanced product candidate is Luvox CR, an extended release formulation of fluvoxamine, a selective serotonin reuptake inhibitor, or SSRI, which has been developed for the treatment of obsessive compulsive disorder, or OCD, and social anxiety disorder, or SAD. We obtained the U.S. marketing rights to Luvox CR from Solvay Pharmaceuticals, Inc., or Solvay, in January 2007. Subject to successful completion of certain requirements set forth in an approvable letter issued by the FDA in February 2007 and FDA approval, we expect to commence promotion of Luvox CR in the United States in the first quarter of 2008 through an expanded specialty sales force. During 2007, we expect to make significant expenditures relating to the planned launch and commercialization of Luvox CR, including milestone payments to Solvay, activities related to our preparation for marketing and promotion, expansion of our specialty sales force and production of commercial quantities of Luvox CR.

*JZP-6 (sodium oxybate).* We are developing a liquid dosage form of sodium oxybate, the active pharmaceutical ingredient, or API, in Xyrem, for the treatment of fibromyalgia syndrome, or FMS. We have successfully completed a Phase II clinical trial of this product candidate for the treatment of FMS. We are currently conducting two pivotal Phase III clinical trials, and we expect preliminary data from the first Phase III pivotal clinical trial in the second half of 2008. We have granted to UCB the commercialization rights to JZP-6 in 54 countries outside of the United States.

In addition to our product candidates in late-stage development, our clinical development pipeline consists of the following product candidates:

*JZP-4 (Type IIa sodium channel antagonist).* Subject to the results of proposed and ongoing proof of concept clinical trials and long-term toxicology studies, we plan to commence a Phase II clinical trial of JZP-4 for the treatment of epilepsy in the fourth quarter of 2007. We are also developing JZP-4 for the treatment of bipolar disorder.

*JZP-8 (benzodiazepine).* We plan to commence a Phase II clinical trial of JZP-8 for the treatment of acute repetitive seizure clusters in refractory epilepsy patients in the third quarter of 2007.

*JZP-7 (dopamine agonist).* We intend to conduct an additional pharmacokinetics study of JZP-7 in 2007 prior to commencing Phase II clinical trials for the treatment of restless legs syndrome.

*JZP-2 (benzodiazepine).* We have developed a target formulation for JZP-2 and plan to commence one or more clinical trials of JZP-2 for the acute treatment of panic attacks associated with panic disorder in 2007.

## **Table of Contents**

Although we generate product revenues, we have funded our operations primarily through the sale of convertible preferred stock, the issuance of senior secured notes and warrants, a line of credit, development financing related to one of our previous product candidates and our collaboration with UCB related to Xyrem and JZP-6. Our sources of funding have included the following:

*Equity Financings.* Our preferred stock financings raised gross proceeds of \$265.0 million.

*Debt Financings.* In connection with our acquisition of Orphan Medical, we issued \$80.0 million aggregate principal amount of senior secured notes and warrants to purchase 8,695,652 shares of our Series BB convertible preferred stock. Additionally, in September 2006, we entered into a one year line of credit agreement with a financial institution under which we may borrow up to 80% of eligible accounts receivable, up to a maximum borrowing limit of \$5.0 million.

*Development Financing.* In August 2005, we entered into an agreement with a third party under which the third party agreed to provide \$30.0 million to fund a Phase III clinical trial of JZP-3, a product candidate then in development for the treatment of general anxiety disorder. Under that agreement, we received \$15.0 million in 2005 and \$15.0 million in 2006. In June 2006, following analysis of the results of the Phase III clinical trial, we notified the third party of our intention to discontinue development of the product candidate and not to seek product marketing approval from the FDA. As a result of our notification, we were not obligated to make any payments to the third party that otherwise would have been made upon regulatory approval, launch and commercialization of JZP-3.

*Collaboration.* Under the terms of our agreement with UCB for Xyrem and JZP-6, we received an upfront payment of \$5.0 million and a \$10.0 million payment upon election by UCB to exercise its rights to develop and commercialize JZP-6 for the treatment of FMS. We are also entitled to additional development and commercialization milestone payments of up to \$148.0 million and royalties on all commercial sales of Xyrem and JZP-6 by UCB.

Since our inception, we have incurred significant net losses, and we expect to continue to incur net losses for the next several years as we develop, acquire or in-license additional products or product candidates, expand clinical trials for our product candidates currently in clinical development, expand our research and development activities, seek regulatory approvals and engage in commercialization preparation activities in anticipation of potential FDA approval of our product candidates. We will need to expand our commercial organization to launch additional products. It is very expensive to launch a product, and many expenses are incurred before revenues are received. We are unable to predict the extent of any future losses or when we will become profitable, if at all.

While we believe that our current cash, cash equivalents and marketable securities and the anticipated net proceeds from this offering, and interest earned thereon, together with anticipated revenues from product sales, royalties and funding that we expect to receive from our current collaboration arrangement with UCB, will be sufficient to satisfy our current operations through at least the next 12 to 18 months, we expect to raise additional funds within this period of time through development financings, collaborations, or public or private debt or equity financings.

**Table of Contents****Revenues***Product Sales, Net*

The following is a summary of our product sales, net for the years ended December 31, 2005 and 2006. We had no product sales prior to our acquisition of Orphan Medical in June 2005.

	Year Ended December 31,	
	2005	2006
	(In thousands)	
Xyrem	\$ 11,200	\$ 29,049
Antizol(1)	6,782	12,813
Cystadane	814	1,437
Total	\$ 18,796	\$ 43,299

(1) Includes sales of Antizol-Vet, which were \$99,000 and \$313,000 in 2005 and 2006, respectively.

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

*Antizol (fomepizole).* Revenues from sales of Antizol in the United States represented primarily sales to pharmaceutical wholesalers. Our sales of Antizol to distributors outside of the United States have not been material. The orphan drug exclusivity for Antizol expired for ethylene glycol poisoning in 2004 and is scheduled to expire in December 2007 for methanol poisoning. We expect annual sales to remain at approximately the 2006 level unless generic competition enters the market.

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

*Royalties, Net*

We receive royalties primarily from international distributors of our products, typically based on their net sales of our products, subject to minimum royalty requirements. Approximately half of our 2006 royalties resulted from minimum royalty payments under our agreement with UCB. Royalty income was \$146,000 and \$594,000 in 2005 and 2006, respectively. We had no royalty revenues prior to the acquisition of Orphan Medical in June 2005. Although we do not expect royalty revenues to comprise a substantial portion of our revenues, we expect royalty revenues to increase in the future as UCB launches Xyrem in additional countries and Valeant launches Xyrem in Canada.

*Contract Revenues*

All of our contract revenues relate to upfront or milestone payments received from UCB. During 2005 and 2006, we recorded revenues related to non-refundable development milestone payments of \$2.5 million and \$500,000, respectively. In connection with the expansion of our agreement with UCB in 2006, UCB made an upfront payment of \$5.0 million and subsequently an additional payment of \$10.0 million upon exercise of its rights to develop and commercialize JZP-6 for the treatment of FMS. These payments are being amortized through 2019, the estimated performance period of the contract. This amortization represented the remaining \$463,000 of contract revenues during 2006.

Sales to Express Scripts represented 51% and 65% of our total revenues in 2005 and 2006, respectively. Sales of Antizol and Cystadane to our wholesale customers AmerisourceBergen Corporation in 2005 and Cardinal Health in 2006 represented 15% and 12%, respectively, of our total revenues in those years. Revenues from UCB, including net product sales, net royalties and contract revenues, represented 12% of total revenues in 2005. No other customer accounted for more than 10% of our total revenues in 2005 or 2006.

**Table of Contents****Research and Development Expenses**

Our research and development expenses consist of expenses incurred in identifying, developing and testing our product candidates. These expenses consist primarily of fees paid to contract research organizations and other third parties to assist us in managing, monitoring and analyzing our clinical trials, clinical trial costs paid to sites and investigators' salaries, costs of non-clinical studies, including toxicity studies in animals, costs of contract manufacturing services, costs of materials used in clinical trials and non-clinical studies, fees paid to third parties for development candidates or drug delivery or formulation technologies that we have licensed, allocated expenses, such as facilities and information technology that support our research and development activities, and related personnel expenses, including stock-based compensation. Research and development costs are expensed as incurred, including payments made under our license agreements for product candidates in development.

Conducting a significant amount of research and development is central to our business model. Through December 31, 2006, we had invested more than \$118.0 million in research and development since our formation in 2003, and we plan to continue to make significant investments in research and development for the foreseeable future in order to realize the potential of our portfolio of development candidates and earlier-stage research and development projects. Product candidates in later-stage clinical development generally have higher development costs than those in earlier stages of development, primarily due to the significantly increased size and length of the clinical trials.

The following table summarizes our research and development expenses for each of the years ended December 31, 2004, 2005 and 2006. Prior to 2004, we did not undertake any substantial research and development efforts. We designate development projects to which we have allocated significant research and development resources with the term "JZP" and a unique number. All of the product candidates designated with "JZP" in the following table, other than JZP-3, remain in development. Development projects in addition to JZP-3 that were designated with a JZP number but later terminated are included in "Other terminated projects" in the following table. Earlier-stage development and product lifecycle extension projects are included in "Other projects" in the following table. Early product concept feasibility studies and other research activities are included in "R&D support" in the following table. The expenditures summarized in the following table reflect costs directly attributable to each development candidate and to our "Other projects." We do not allocate salaries, benefits or other indirect costs to our development candidates or "Other projects," and we have included these costs in "R&D support" in the following table.

	Year Ended December 31,			Total
	2004	2005	2006	
	(In thousands)			
Ongoing JZP Projects:				
JZP-6	\$	\$	\$ 14,209	\$ 14,209
JZP-4	2,077	2,141	6,699	10,917
JZP-8		313	1,403	1,716
JZP-7	4	150	1,328	1,482
JZP-2	58	1,570	395	2,023
Terminated Projects:				
JZP-3(1)	12,577	27,305	14,797	54,679
Other terminated projects	1,437	5,878		7,315
Other projects	1	97	2,586	2,684
R&D support	1,834	8,329	13,539	23,702
Total	\$ 17,988	\$ 45,783	\$ 54,956	\$ 118,727

(1) Development has been terminated. This project was partially financed through \$30.0 million of development financing discussed above.



## **Table of Contents**

In July 2004, we commenced our JZP-3 development efforts when we entered into a development and commercialization agreement, a product supply agreement and a technology transfer agreement with a pharmaceutical company and made a \$1.0 million payment to this company. We made additional development milestone payments under these agreements of \$2.0 million and \$5.0 million in 2004 and 2005, respectively. We commenced a Phase III clinical trial of JZP-3 in late 2004. In June 2006, following analysis of the results of the Phase III clinical trial, we discontinued development of JZP-3 and terminated the program.

The process of developing and obtaining FDA approval of products is costly and time consuming. Development activities and clinical trials can take years to complete, and failure can occur any time during the clinical trial process. 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 stages of clinical trials may fail to show the desired safety and efficacy despite having progressed successfully through initial clinical testing. For example, we ceased our development of JZP-3 after its Phase III clinical trial was not successful and after we had incurred significant development costs. Although our program for identifying and developing new product candidates is designed to mitigate risk, the successful development of our product candidates is highly uncertain. Further, even if our product candidates are approved for sale, we may be unable to successfully commercialize them in which case we would not generate the revenues we anticipate. Our ability to successfully develop, obtain FDA approval for and commercialize our products may be affected by a variety of factors including, among others:

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

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;

safety issues, including adverse events associated with product candidates; and

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

Development timelines, probability of success and development costs vary widely among product candidates. As a result, we are unable to determine the time and completion costs related to the development of our product candidates or estimate when, or to what extent, we will generate revenues from the commercialization and sale of any of our product candidates other than Luvox CR, which we expect to commence promoting in the United States in the first quarter of 2008.

## **Critical Accounting Policies and Significant Estimates**

### ***Revenue Recognition***

Revenues are recognized when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed and determinable and collection is reasonably assured. In evaluating arrangements with multiple elements we consider whether components of the arrangement represent separate units of accounting based upon whether certain criteria are met, including whether the delivered element has stand-alone value to the customer and whether there is objective and reliable evidence of the fair value of the undelivered items. This evaluation requires subjective determinations and requires management to make judgments about the fair value of individual elements and whether such elements are separable from other aspects of the contractual relationship. The consideration received in such arrangements is allocated among the separate units of accounting based on their respective fair values when there is reliable evidence of fair value for all elements of the arrangement. If there

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

is no evidence of fair value for all the elements of the arrangement, consideration is allocated based on the residual value method for the delivered elements. Under the residual method, the amount of revenues allocated to the delivered elements equals the total arrangement consideration less the aggregate fair value of any undelivered elements. The applicable revenue recognition criteria are applied to each of the separate units. Payments received in advance of work performed are recorded as deferred revenues and recognized when earned.

## **Table of Contents**

### *Product Sales, Net*

Revenues from sales of Xyrem within the United States are recognized upon transfer of title, which occurs when Express Scripts removes product from our consigned inventory location at its facility for shipment to a patient. Antizol is, and prior to the sale of our rights Cystadane was, shipped to our wholesaler customers in the United States with free on board destination shipping terms, and we recognize revenues when delivery occurs. Our international sales often have customer acceptance clauses and therefore we recognize revenues when we are notified of acceptance or the time to inspect and reject the shipment has lapsed. When sales to international customers do not have acceptance clauses, we recognize revenues when title transfers, which is generally when the product leaves our logistics provider's facilities.

Revenues from sales of products within the United States are recorded net of estimated allowances for prompt payment discounts, wholesaler and specialty distributor fees, government chargebacks and rebates. Significant judgment is inherent in the selection of assumptions and in the interpretation of historical experience, as well as the identification of external and internal factors affecting the estimates. Because Xyrem is sold to one distributor in the United States, allowances and adjustments to estimates for allowances have not historically been material.

### *Royalties, Net*

We receive royalties from third parties based on sales of our products under out-licensing and distributor arrangements. For those arrangements where royalties are reasonably estimable, we recognize revenues based on estimates of royalties earned during the applicable period and adjust for differences between the estimated and actual royalties in the following quarter. Historically, these adjustments have not been material. For those arrangements where royalties are not reasonably estimable, we recognize revenues upon receipt of royalty statements from our licensee or distributor.

### *Contract Revenues*

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

### *UCB Agreement*

In June 2006, we entered into an agreement with UCB that amended and restated a prior agreement between Orphan Medical and UCB. Under the terms of the amended agreement, UCB has the right to market Xyrem for the treatment of narcolepsy and JZP-6 for the treatment of FMS in 54 countries outside of the United States. Under the prior agreement, UCB made a nonrefundable development milestone payment to us of \$2.5 million in November 2005 and a nonrefundable commercial milestone payment of \$500,000 in June 2006, which we recognized upon achievement of the milestones. UCB also made an upfront payment of \$5.0 million upon execution of the amended agreement in June 2006 and an additional payment of \$10.0 million in August 2006 upon exercise of its rights to develop and commercialize JZP-6 for the treatment of FMS. We recognized contract revenues of \$463,000 related to these upfront payments during the year ended December 31, 2006. The remaining \$14.5 million was recorded as deferred revenues as of December 31, 2006 and is being recognized ratably through 2019, the expected performance

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

period under the agreement. The amended agreement requires UCB to make additional milestone payments of up to \$148.0 million, of which up to \$8.0 million relate specifically to Xyrem for the treatment of narcolepsy, up to \$40.0 million relate to the development and approval of JZP-6 for the treatment of FMS and up to \$100.0 million relate primarily to the commercialization of JZP-6 for the treatment of FMS as well as additional sales of Xyrem for the treatment of narcolepsy.

**Table of Contents*****Goodwill and Intangible and Long-Lived Assets***

Goodwill represents the excess of the purchase price over the fair value of assets acquired and liabilities assumed. We have determined that we operate in a single segment and have a single reporting unit associated with the development and commercialization of pharmaceutical products. The annual test for goodwill impairment is a two-step process. The first step is a comparison of the fair value of the reporting unit with its carrying amount, including goodwill. If this step indicates an impairment, then the loss is measured as the excess of recorded goodwill over its implied fair value. Implied fair value is the excess of the fair value of the reporting unit over the fair value of all identified assets and liabilities. We test goodwill for impairment annually in October and have concluded that no impairment existed as of October 1, 2006. We will also test for impairment whenever events or changes in circumstances indicate that the carrying value may not be recoverable. There have been no changes since October 1, 2006 that would cause us to reevaluate our conclusion.

Intangible assets consist primarily of developed technology, agreements not to compete and trademarks. Intangible assets are amortized on a straight-line basis over their estimated useful lives, which range from three to ten years. The estimated useful lives associated with other intangible assets are consistent with underlying agreements, or the estimated lives of the products. Once an intangible asset is fully amortized, the gross costs and accumulated amortization are removed from the consolidated balance sheet. We evaluate purchased intangibles and other long-lived assets, other than goodwill, for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. The amount of any impairment is measured as the difference between the carrying value and the fair value of the impaired asset. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount. The impairment loss, if recognized, would be based on the excess of the carrying value of the impaired asset over its respective fair value, calculated using discounted cash flows. Since our inception, there has been no such impairment.

As a result of our acquisition of Orphan Medical in June 2005, we had recorded goodwill and intangible assets at December 31, 2006 as follows:

	<b>Gross Carrying Amount</b>	<b>Accumulated Amortization (In thousands)</b>	<b>Net Book Value</b>	<b>Weighted Average Remaining Useful Life (Years)</b>
Developed technology	\$ 75,100	\$ 11,970	\$ 63,130	8.0
Agreements not to compete	5,600	2,042	3,558	3.0
Trademarks	2,600	414	2,186	8.0
Other	400	134	266	3.0
Amortizable intangible assets	83,700	14,560	69,140	
Goodwill	38,213			
<b>Total</b>	<b>\$ 121,913</b>			

***Stock-Based Compensation******Stock-Based Compensation Under SFAS 123***

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

Prior to January 1, 2006, we accounted for stock-based employee compensation arrangements using the intrinsic value method of Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* ( APB 25 ) and related interpretations. Prior to January 1, 2006, we complied with the disclosure-only provisions of SFAS No. 123, *Accounting for Stock-Based Compensation*, ( SFAS 123 ) as amended by SFAS No. 148, *Accounting for Stock-Based Compensation, Transition and Disclosure, an amendment to SFAS Statement No. 123*. Under APB 25 compensation expense for employees is based on the excess, if any, of the fair value of our common stock over the exercise price of the option on the date of grant. No stock-based compensation expense was recorded under APB 25 during the years ended December 31, 2004 and 2005.

**Table of Contents***Change in Accounting Principle Stock-Based Compensation Under SFAS 123R*

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

We are using the straight-line method to allocate compensation cost to reporting periods under SFAS 123 and SFAS 123R for stock options granted during each of the three years ended December 31, 2006.

For each of the three years ended December 31, 2004, 2005, 2006, under both SFAS 123 and SFAS 123R we elected to use the Black-Scholes valuation model to calculate the fair value of stock options. The fair value of stock options was estimated at the grant date using the following assumptions:

	Year Ended December 31,		
	2004	2005	2006
Weighted-average volatility	80%	60%	61%
Weighted-average expected term	5	5	6
Range of risk-free rates	3.0-4.0%	3.9-4.4%	4.6-5.1%
Expected dividend yield	0.0%	0.0%	0.0%

The weighted-average grant date fair value per share of employee stock options granted during the years ended December 31, 2004, 2005 and 2006 was \$.81, \$.78 and \$.97, respectively.

*Volatility.* As we do not have any trading history for our common stock, the expected stock price volatility for our common stock was estimated by taking the median historic stock price volatility for industry peers based on daily price observations over a period equivalent to the expected term of the stock option grants. Industry peers consist of several public companies in the biopharmaceutical industry similar in size, stage of life cycle and financial leverage. We did not rely on the implied volatilities of traded options in our industry peers' common stock, because either the term of those traded options was much shorter than the expected term of our stock option grants, or the volume of activity was relatively low.

*Expected Term.* We have very little historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior for our stock option grants. As a result, for stock option grants made during the year ended December 31, 2006, the expected term was estimated using the short-cut method allowed under Securities and Exchange Commission Staff Accounting Bulletin No. 107 *Share-Based Payment*. For stock options granted during the years ended December 31, 2004 and 2005 we estimated the expected term of stock options based on the expected term of options granted by publicly traded industry peers.

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

*Risk-free Rate.* The risk-free interest rate assumption was based on zero coupon U.S. Treasury instruments whose term was consistent with the expected term of our stock option grants.

*Expected Dividend Yield.* We have never declared or paid any cash dividends and do not presently plan to pay cash dividends in the foreseeable future. Consequently, we used an expected dividend yield of zero.



## **Table of Contents**

*Common Stock Fair Value.* The fair value of our common stock during the years 2004 and 2005 was determined by our board of directors with assistance from management. In May 2006, we engaged an independent valuation specialist to perform a valuation of our common stock. The valuation used a two-step methodology that first estimated the fair value of the company as a whole, and then allocated a portion of the enterprise value to our common stock. This approach is consistent with the methods outlined in the AICPA Practice Aid *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. The valuation methodology utilized both the income approach and the market approach to estimate enterprise value. The income approach estimates the fair value of the enterprise based upon a projection of future cash flows while the market approach is based upon comparisons to publicly-held companies in our industry at a similar stage of development. In order to allocate the enterprise value to the various securities that comprise our capital structure, the option-pricing method was used. A discount was applied to account for a lack of marketability. After considering this valuation and other factors, the board of directors determined the fair value of our common stock to be \$1.50 as of June 28, 2006.

In December 2006, we engaged the independent valuation specialist to perform another valuation effective as of December 31, 2006. This valuation was completed in February 2007 and used the same methodology as the previous valuation, except that we also considered the probability-weighted expected return method for allocating enterprise value to the common stock. After considering the valuation and other factors, including valuation estimates prepared by our proposed underwriters, the board of directors determined the fair value of our common stock to be \$1.75 as of February 13, 2007. The board of directors also reviewed our corporate developments from June 28, 2006 to February 13, 2007 and noted that, while there were a number of development milestones reached during the period from June 28, 2006 to December 31, 2006, no such developments occurred in the period from December 31, 2006 to February 13, 2007. Accordingly, we increased the estimated fair value of the common stock ratably from \$1.50 to \$1.75 over the period from June 28, 2006 to December 31, 2006 for purposes of calculating stock-based compensation expense associated with our stock option grants under SFAS 123R.

*Forfeitures.* SFAS 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. In determining our historic forfeiture rate, we have excluded stock option grants totaling 12,548,445 shares issued to executives in February 2004. We believe these stock option grants will not be cancelled due to termination, and therefore have applied a forfeiture rate of 0% for those stock option grants. The annualized forfeiture rate used for the remaining stock option grants was 7%. The forfeiture rate selected did not have a material impact on stock-based compensation expense in 2006. Prior to adoption of SFAS 123R, we accounted for forfeitures of stock option grants as they occurred.

As a result of our Black-Scholes option fair value calculations and the allocation of value to the vesting periods using the straight-line vesting attribution method, we recognized \$3.5 million of stock-based compensation expense in 2006, of which \$8,000, \$661,000, and \$2.8 million were charged to cost of product sales, research and development expenses and selling, general and administrative expenses, respectively. The adoption of SFAS 123R caused basic and diluted net loss per common share to increase by \$24.51 in 2006. No income tax benefit was recognized in the statement of operations for 2006. Compensation cost capitalized as a component of inventory during 2006 was \$18,000.

The total compensation cost related to unvested stock option grants not yet recognized as of December 31, 2006 was \$5.5 million, and the weighted-average period over which these grants are expected to vest is 1.9 years.

### ***Beneficial Conversion Feature***

The Company accounts for potentially beneficial conversion features under Emerging Issues Task Force No. 98-5, *Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios* and EITF Issue No. 00-27, *Application of Issue 98-5 to Certain Convertible Instruments*. In January and December 2006, we issued 35,200,924 and 38,134,349 shares, respectively, of Series B preferred



## **Table of Contents**

stock and Series B Prime preferred stock at a purchase price of \$1.3636 per share. At the time of each of these issuances, the value of the common stock into which the Series B preferred stock and Series B Prime preferred stock is convertible had a fair value greater than the proceeds for such issuances. Accordingly, we recorded a deemed dividend on the Series B preferred stock and Series B Prime preferred stock of \$3.5 million in January 2006 and \$18.4 million in December 2006, which equals the amount by which the estimated fair value of the common stock issuable upon conversion of the issued Series B preferred stock and Series B Prime preferred stock exceeded the proceeds from such issuances.

### ***Accrued Expenses***

As part of the process of preparing financial statements, we are required to estimate accrued expenses. This process involves identifying services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for such service as of each balance sheet date in our financial statements. Examples of estimated accrued expenses include marketing and promotional materials, professional service fees, such as fees to lawyers and accountants, and contract service fees, such as amounts paid to clinical monitors, data management organizations, clinical research organizations and fees paid to contract manufacturers in conjunction with the production of clinical materials. In connection with such service fees, our estimates are most affected by our understanding of the status and timing of services provided relative to the actual levels of services incurred by such service providers. The majority of our service providers invoice us monthly in arrears for services performed. In the event that we do not identify certain costs that have begun to be incurred or we under- or overestimate the level of services performed or the costs of such services, our reported expenses for such period would be too low or too high. The date on which certain services commence, the level of services performed on or before a given date and the cost of such services are often subject to our judgment. We make these judgments based upon the facts and circumstances known to us in accordance with generally accepted accounting principles.

### ***In-Process Research and Development***

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

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

In January 2005, Orphan Medical submitted a supplemental New Drug Application, or sNDA, to the FDA seeking an expanded label indication for Xyrem. At the time of the acquisition, the FDA had not yet approved the sNDA. As a result, we charged the value associated with the additional label indication to in-process research and development, which accounted for 71% of total in-process research and development expense recorded in connection with the acquisition. The discount rate used to calculate the fair value of Xyrem for the new indication of excessive daytime sleepiness in patients with narcolepsy was 26%. At the time of acquisition, Orphan Medical was also conducting a Phase II clinical trial to evaluate the use of sodium oxybate, the API in Xyrem, to treat FMS. The discount rate used to calculate the fair value of this development project was 50%. Positive results for the Phase II trial were determined when the trial was unblinded in August 2005. In August 2006, we initiated a Phase III clinical trial of sodium oxybate for the treatment of FMS.



**Table of Contents****Results of Operations***Comparison of Years Ended December 31, 2005 and 2006*

	2005	2006 (In thousands)	Increase/ (Decrease)	% Increase/ (Decrease)
Product sales, net	\$ 18,796	\$ 43,299	\$ 24,503	130%
Royalties, net	146	594	448	307%
Contract revenues	2,500	963	(1,537)	(61)%
Cost of product sales	4,292	6,968	2,676	62%
Research and development expenses	45,783	54,956	9,173	20%
Selling, general and administrative expenses	23,551	51,384	27,833	118%
Purchased in-process research and development	21,300		(21,300)	N/A(1)
Amortization of intangible assets	4,960	9,600	4,640	94%
Interest income	1,318	2,307	989	75%
Interest expense	7,129	14,129	7,000	98%
Other expense	901	1,109	208	23%
Gain on extinguishment of development financing obligation		31,592	31,592	N/A(1)

(1) No comparable data for comparable year.

*Product Sales, Net*

The increase in product sales, net in 2006 compared to 2005 was primarily due to the inclusion of only approximately six months of product sales in 2005, subsequent to our acquisition of Orphan Medical in June 2005, compared to a full year in 2006. Other factors affecting this increase included:

expansion of the Xyrem sales force from 36 to 55 employees in late 2005;

receipt from the FDA in November 2005 of expanded marketing approval for Xyrem for the treatment of excessive daytime sleepiness in patients with narcolepsy and a corresponding launch of the new indication in early 2006;

increases in the price that we charge our central pharmacy for Xyrem of 6.4% and 7.7% in December 2005 and August 2006, respectively; and

increases in the price that we charge our wholesale customers for Antizol of 4.2% and 5.0% in December 2005 and November 2006, respectively.

*Royalties, Net*

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

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

### *Contract Revenues*

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

## **Table of Contents**

### *Cost of Product Sales*

The increase in the cost of product sales in 2006 compared to 2005 was primarily due to the inclusion of a full year of product sales in 2006 compared to approximately six months of product sales in 2005, subsequent to our acquisition of Orphan Medical in June 2005. Our gross margin increased from 77% in 2005 to 84% in 2006. The primary reason for this increase was a lower fair value adjustment to inventory acquired as part of the acquisition of Orphan Medical in 2006 compared to 2005. Our cost of product sales reflected a fair value adjustment of \$1.6 million and \$775,000 during 2005 and 2006, respectively. This fair value adjustment will not have a material impact on cost of product sales in future periods.

### *Research and Development Expenses*

Higher research and development expenses in 2006 as compared to 2005 resulted primarily from higher spending in 2006 on early phase development and preclinical studies, along with higher salaries and benefits expenses related to a growth in research and development headcount during 2006. Research and development expenses did not increase substantially as a result of the Orphan Medical acquisition. Although total spending on late-stage programs did not change substantially from 2005 to 2006, the components of spending on late-stage programs changed. During 2005, a substantial portion of our research and development expenses related to JZP-3, and, during 2006, a substantial portion of our research and development expenses were attributable to JZP-3 and JZP-6.

### *Selling, General and Administrative Expenses*

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

inclusion of only six months of Xyrem sales and marketing activities in 2005, compared to a full year of activities in 2006;

costs associated with the launch of a new indication for Xyrem in early 2006;

an increase in the Xyrem sales force from 36 at the time of the Orphan Medical acquisition to 55 in November 2005;

outside legal costs of \$5.4 million incurred during 2006 in connection with an investigation by the U.S. Attorney's Office of activities related to the promotion of Xyrem;

building a medical affairs department; and

an increase in headcount and related salaries and benefits.

### *Purchased In-process Research and Development*

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

*Amortization of Intangible Assets*

Our intangible assets consist primarily of developed technology, agreements not to compete and trademarks, all of which were recorded as a result of the acquisition of Orphan Medical in June 2005. We amortize intangible assets on a straight-line basis over their estimated useful lives. Amortization expense was higher in 2006 as compared to 2005 primarily due to the inclusion of only six months of amortization in 2005 as compared to a full year of amortization in 2006.



## **Table of Contents**

### *Interest Income*

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

### *Interest Expense*

Interest expense primarily related to interest on our \$80.0 million principal amount of senior secured notes and interest on the development financing of JZP-3 described above, both of which were recorded using the effective interest method. \$5.6 million of the increase in interest expense in 2006 as compared to 2005 was attributable to the fact the notes were outstanding for the full year in 2006. Interest on the notes was comprised of the accretion of a discount related to warrants that were issued in conjunction with the notes, amortization of debt issuance costs and quarterly cash payments for interest. Interest expense related to the development financing was \$445,000 in 2005, compared with \$1.5 million 2006.

### *Other Expense*

On July 1, 2005, we adopted the provisions of Financial Accounting Standards Board, or FASB, Staff Position No. 150-5, *Issuer's Accounting under Statement No. 150 for Freestanding Warrants and Other Similar Instruments on Shares that are Redeemable*, or FSP 150-5, an interpretation of FASB Statement No. 150, *Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity*, which required us to classify our preferred stock warrants as current liabilities and adjust the carrying value to fair value at the end of each reporting period. This resulted in \$901,000 of expense in 2005 and \$1.1 million of expense in 2006 arising from the increase in value of preferred stock warrants. We will continue to adjust the liability for changes in the fair value of the warrants until the earlier of the exercise of the warrants to purchase shares of convertible preferred stock, at which time the liability will be reclassified to temporary equity, or the conversion of the underlying Series BB preferred stock into common stock, at which time the liability will be reclassified to stockholders' deficit. Upon completion of this offering, any outstanding warrants will automatically become warrants to purchase common stock, and the liabilities will be reclassified to stockholders' deficit.

### *Gain on Extinguishment of Development Financing Obligation*

In August 2005, we entered into an agreement with a third party under which the third party agreed to provide \$30.0 million to fund a Phase III clinical trial of JZP-3, a product candidate then in development. We were obligated to repay the third party \$37.5 million subject to, and conditioned upon, approval by the FDA to market the product in the United States. In addition, we agreed to pay royalties at specified rates based on sales of the product within the United States. Under that agreement, we received \$15.0 million in 2005 and \$15.0 million in 2006. In June 2006, following analysis of the results of the Phase III clinical trial, we notified the third party of our intention to discontinue development of JZP-3 and not to seek product marketing approval from the FDA. As of the date we notified the third party of our intention to discontinue development of JZP-3, we had recorded \$31.6 million for future possible payments as a liability on our balance sheet, of which \$30.0 million related to principal and \$1.6 million related to interest accrued using the effective interest method. As a result of our notification, we were not obligated to make any payments to the third party that otherwise would have been made upon regulatory approval, launch and commercialization of JZP-3, and we recorded a gain of \$31.6 million resulting from the extinguishment of liabilities related to this development financing.



**Table of Contents***Comparison of Years Ended December 31, 2004 and 2005*

	2004	2005	Increase	% Increase
	(In thousands)			
Research and development expenses	\$ 17,988	\$ 45,783	\$ 27,795	155%
Selling, general and administrative expenses	7,459	23,551	16,092	216%
Interest income	643	1,318	675	105%

*Effect of Orphan Medical Acquisition*

Our June 2005 acquisition of Orphan Medical caused a significant change in our business and results of operations. The following line items were not applicable to our 2004 results of operations but became applicable in 2005 as a result of the acquisition:

all product sales, net and cost of product sales during 2005 related to sales of our Xyrem, Antizol and Cystadane products acquired in connection with our acquisition of Orphan Medical;

royalties, net recorded in 2005 related primarily to a product that Orphan Medical had divested in 2003;

contract revenues in 2005 consisted of a \$2.5 million milestone payment from UCB in November 2005, triggered by the approval by the EMEA of Xyrem for the treatment of cataplexy associated with narcolepsy;

acquired in-process research and development charge recorded in 2005 represented the estimated fair value related to three incomplete projects for which, at the time of the Orphan Medical acquisition, technological feasibility had not been established and that had no alternative future use; for additional information regarding this in-process research and development charge, see Note 5 to our financial statements appearing elsewhere in this prospectus;

amortization expense recorded during 2005 related to developed technology, agreements not to compete and trademarks, all of which were recorded as a result of the acquisition of Orphan Medical; see Note 5 to our financial statements appearing elsewhere in this prospectus for more information regarding intangible assets and related amortization;

interest expense during 2005 related to interest on the \$80.0 million principal amount of senior secured notes issued in connection with the Orphan Medical acquisition; and

we adopted the provisions of FSP 150-5 on July 1, 2005, which required us to classify our preferred stock warrants as current liabilities and adjust the carrying value to fair value at the end of each reporting period. This resulted in \$901,000 of expense in 2005 arising from the increase in value of preferred stock warrants.

*Research and Development Expenses*

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

The increase in research and development expenses in 2005 compared to 2004 was primarily due to more activity and higher spending in 2005 on the Phase III clinical development of JZP-3, a product candidate that we initiated in the second half of 2004 and discontinued in mid-2006. We made an initial payment of \$5.0 million to a third party in July 2005 for the North American rights to a product candidate, the development of which was terminated in late 2005. The remainder of the increase primarily related to salaries and benefits expenses associated with increased headcount.

### *Selling, General and Administrative Expenses*

The majority of the increase in 2005 selling, general and administrative expenses compared to 2004 was due to selling expenses incurred following the acquisition of Orphan Medical in June 2005, primarily related to Xyrem promoting and marketing activities in the United States. At the time of the acquisition, we retained all of

**Table of Contents**

the Orphan Medical sales force, consisting of 32 specialty sales consultants and 4 sales managers focused on selling Xyrem. In November 2005, we added 19 additional employees to the sales force. In addition to these expenses, salaries and benefits expenses increased because of increases in headcount in our commercial and general and administrative organizations.

*Interest Income*

The increase in interest income in 2005 as compared to 2004 was driven primarily by higher interest rates in 2005 than in 2004.

**Liquidity and Capital Resources**

Since our inception, we have incurred significant net losses, and, as of December 31, 2006, we had an accumulated deficit of \$177.6 million. We have not achieved profitability, and we anticipate that we will continue to incur net losses for the next several years. We expect that our development, selling, marketing and general and administrative expenses will continue to increase and, as a result, we will need to generate significant net product sales, royalty and other revenues to achieve profitability. Our audit report in our 2006 consolidated financial statements contains an explanatory paragraph stating that our recurring losses from operations and cash used in operating activities raise substantial doubt about our ability to continue as a going concern. We believe that the successful completion of this offering will eliminate this doubt and enable us to continue as a going concern. If we are unable to successfully complete this offering, we will need to execute alternative financing or operational plans to continue as a going concern.

Our operations have been financed primarily through the sale of convertible preferred stock, the issuance of senior secured notes and warrants, a line of credit, development financing related to one of our previous product candidates and our collaboration with UCB related to one of our products and product candidates. In addition to amounts received from UCB, we have raised a total of \$374.4 million (net of issuance costs), as follows:

Date	Amount (In thousands)	Financing
April 2003	\$ 2,078	Series A convertible preferred stock
August 2003	4,998	Series A convertible preferred stock
January 2004	7,850	Series A convertible preferred stock
February 2004	48,683	Series B and B Prime convertible preferred stock
April 2004	400	Series B convertible preferred stock
June 2005	99,853	Series B and B Prime convertible preferred stock
June 2005	77,999	Senior secured notes and warrants(1)
July 2005 February 2006	30,000	Project-specific financing(2)
January 2006	34,990	Series B and B Prime convertible preferred stock
December 2006	65,000	Series B and B Prime convertible preferred stock
September December 2006	2,191	Line of credit(3)

- (1) In June 2005, we issued \$80.0 million aggregate principal amount of 15% senior secured notes and warrants to purchase 8,695,652 shares of our Series BB convertible preferred stock to certain third parties, some of whom are affiliated with investors in our preferred stock. Cash interest payments of \$12.0 million per year are due on the notes, payable quarterly in arrears. The principal of \$80.0 million is due in full in June 2011. Under the terms of the notes we are required to maintain a minimum cash balance of \$12.0 million, which is shown as long-term restricted cash and investments on our consolidated balance sheet. The notes contain customary covenants, including limitations on our ability to pay dividends, make investments or other restricted payments, incur debt, grant liens, sell assets or enter into sale-leaseback transactions. Upon the occurrence of certain events, we may be required to repay the notes at a premium. At our option, the notes can be repaid prior June 2011 by paying a premium, which was 30.0% of the principal amount of the notes as of

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

December 31, 2006 and is reduced to zero ratably over the remaining term of the notes.

- (2) In August 2005, we entered into an agreement with a third party under which the third party agreed to provide \$30.0 million to fund a Phase III clinical trial of JZP-3, a product candidate then in development. Under that agreement, we received \$15.0 million in 2005 and \$15.0 million in 2006. In June 2006, following analysis of the results of the Phase III clinical trial, we notified the third party of our intention to discontinue development of JZP-3 and not to seek product marketing approval from the FDA. As a result of our notification,

**Table of Contents**

we were not obligated to make any payments to the third party that otherwise would have been made upon regulatory approval, launch and commercialization of JZP-3.

- (3) In September 2006, we entered into a one year line of credit agreement with a financial institution under which we may borrow up to 80% of eligible accounts receivable, up to a maximum of \$5.0 million of borrowings. Borrowings under the line of credit bear interest at the financial institution's prime rate, which was 8.25% as of December 31, 2006. At December 31, 2006, \$2.2 million was outstanding under the agreement. See Note 7 to our financial statements appearing elsewhere in this prospectus for additional information.

As of December 31, 2006, we had \$78.9 million in cash and cash equivalents, excluding \$12.3 million in restricted cash required to be retained at all times pursuant to our senior secured notes and certain other agreements, held primarily in obligations of U.S. government agencies, corporate debt securities and money market funds.

The following table shows a summary of our cash flows for each of the three years ended December 31, 2004, 2005 and 2006.

	2004	2005	2006
	(In thousands)		
Cash provided by (used in):			
Operating activities	\$ (21,006)	\$ (52,337)	\$ (57,325)
Purchases of property and equipment	(992)	(1,413)	(1,682)
Acquisition of Orphan Medical		(146,116)	
Other investing activities	(5,946)	(6,050)	150
Financing activities	57,162	192,852	117,191

Net cash used in operating activities in 2006 primarily reflected the net loss, less the gain on extinguishment of development financing, offset in part by depreciation and amortization and changes in working capital. Net cash used in operating activities in 2005 primarily reflected the net loss, which was offset in part by depreciation and amortization, in-process research and development and changes in working capital. Net cash used in investing activities related to the purchase, sale and maturity of short-term investments used to fund the day-to-day needs of the business. Purchases of property and equipment have not been material to date. Net cash provided by financing activities was primarily attributable issuance of stock, notes and project specific financing, as discussed above.

We believe that our current cash, cash equivalents and marketable securities and the anticipated net proceeds from this offering, and interest earned thereon, together with anticipated revenues from product sales, royalties and funding that we expect to receive from our current collaboration arrangement with UCB, will be sufficient to satisfy our current operations through at least the next 12 to 18 months. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available financial resources sooner than we currently expect. Our future capital requirements will depend on many factors, including:

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

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

promotional and marketing costs associated with Luvox CR and Xyrem in the United States, including the cost and timing of expanding our marketing and sales capabilities;

revenues from current and potential future development and/or commercial collaboration partners;

the scope, rate of progress, results and costs of our preclinical studies, clinical trials and other research and development activities;

the number and characteristics of product candidates that we pursue;

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

the cost and timing of obtaining regulatory approval;



**Table of Contents**

payments of milestones to third parties;

hiring of new employees to support our continued growth;

the cost of investigations, litigation and/or settlements, in particular the ongoing investigation by the U.S. Attorney for the Eastern District of New York;

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.

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

**Contractual Obligations**

The following table reflects a summary of our contractual obligations as of December 31, 2006:

	Total	Payments due by period			More than 5 Years
		Less than 1 Year	1-3 Years (In thousands)	3-5 Years	
<b>Contractual Obligations(1)</b>					
Senior secured notes(2)	\$ 80,000	\$	\$	\$ 80,000	\$
Line of credit	2,191	2,191			
Operating lease obligations(3)	2,411	1,227	1,167	17	
Other obligations(4)	1,543	1,543			
<b>Total</b>	<b>\$86,145</b>	<b>\$ 4,961</b>	<b>\$ 1,167</b>	<b>\$ 80,017</b>	<b>\$</b>

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

(2) On June 24, 2005, to partially finance the acquisition of Orphan Medical, we issued \$80.0 million of senior secured notes. The notes bear interest at a rate of 15% per annum, payable quarterly in arrears. The amounts in the table above do not include interest on these notes. See Note 7 to our consolidated financial statements appearing elsewhere in this prospectus for additional information.

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

- (3) Includes the minimum rental payments for our corporate office building in Palo Alto, California and automobile lease payments for the sales force. In March 2007, we entered into a lease agreement for approximately 13,000 square feet of office space in Palo Alto, California, which is not reflected in the table above. The annual lease payments for this space are approximately \$460,000. The fixed term expires in August 2008, after which we may extend the term for up to six months subject to certain conditions.
- (4) Consists of commitments to third party manufacturers of two of our commercial products. Does not include obligations under contracts with a contract research organization that are not cancellable without the payment of liquidated damages of \$3.1 million.

The table above reflects only payment obligations for development products that are fixed and determinable. We also have contractual payment obligations, the amount and timing of which are contingent upon future events.

## **Table of Contents**

Amounts and estimated timing of significant payments related to licensing and other arrangements not included in the contractual obligations table above are as follows:

In January 2007, we entered into a product license agreement with Solvay for the rights to market Luvox and Luvox CR in the United States. Under the terms of the agreement, we made a \$2.0 million payment upon execution of the agreement, and we are required to make additional payments of up to \$138.0 million if various commercial and development milestones are achieved, including up to \$41.0 million to be paid on or prior to commercial launch of Luvox CR which, subject to FDA approval, we expect in the first quarter of 2008, and \$2.0 million payable if we commercially launch Luvox. In addition, we agreed to pay royalties at specified rates based on net product sales.

In October 2004, we entered into an agreement with GlaxoSmithKline to purchase worldwide rights to the API in JZP-4. We paid \$2.0 million upon execution of the agreement and \$3.0 million in July 2006 upon achievement of a development milestone. We also agreed to pay up to \$113.5 million upon the achievement of future development and commercial milestones and royalties at specified rates based on net product sales.

## **Recent Accounting Pronouncements**

In July 2006, the FASB issued Interpretation No. 48, *Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement No. 109*, or FIN 48. FIN 48 clarifies the accounting for uncertainty in income taxes by prescribing the recognition threshold a tax position is required to meet before being recognized in the financial statements. It also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. FIN 48 is effective for fiscal years beginning after December 15, 2006 and is required to be adopted by us effective January 1, 2007. The cumulative effects, if any, of applying FIN 48 will be recorded as an adjustment to retained earnings as of the beginning of the period of adoption. We are currently evaluating the effect that the adoption of FIN 48 will have on our results of operations and financial position.

In September 2006, the SEC issued Staff Accounting Bulletin No. 108, *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements*, or SAB 108. SAB 108 provides guidance on the consideration of the effects of prior year misstatements in quantifying current year misstatements for the purpose of a materiality assessment. SAB 108 establishes an approach that requires quantification of financial statement errors based on the effects on each of our balance sheets and statement of operations and the related financial statement disclosures. SAB 108 will be adopted by us in the first quarter of 2007. We are currently evaluating the effect that the adoption of SAB 108 will have on our results of operations or financial position.

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

## **Off-Balance Sheet Arrangements**

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

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

**Table of Contents**

**Quantitative and Qualitative Disclosures About Market Risk**

Our exposure to market risk is confined to our cash, cash equivalents and restricted cash and investments, all of which have maturities of less than one year. The goals of our investment policy are liquidity and capital preservation. Our investment policy allows us to maintain a portfolio of cash equivalents and short-term investments in a variety of securities, including U.S. government agencies, corporate bonds, commercial paper and money market funds. Our cash and investments as of December 31, 2006 consisted primarily of obligations of United States government agencies and money market funds.

Our senior secured notes have fixed interest payments, and, therefore, we are not subject to market risk with respect to this debt. Our line of credit bears interest at the prime rate of the financial institution from which we borrow, which is subject to change. However, interest expense in connection with this facility is not material.

We have no operations outside the United States, and almost all of our operating expenses and capital expenditures are denominated in United States dollars. We receive royalties on certain net product sales that are denominated in other currencies, primarily in Euro, but these royalties comprise a small portion of our revenues.

---

**Table of Contents****BUSINESS****Overview**

We are a specialty pharmaceutical company focused on identifying, developing and commercializing innovative products to meet unmet medical needs in neurology and psychiatry. Our goal is to build a broad portfolio of products through a combination of internal development and acquisition and in-licensing activities and to utilize our specialty sales force to promote our products in our target markets. We apply novel formulations and drug delivery technologies to known drug compounds, and compounds with the same mechanism of action or similar chemical structure as marketed products, to improve patient care by, among other things, improving efficacy, reducing adverse side effects or increasing patient compliance relative to existing therapies. By working with these drug compounds, we believe that we can substantially mitigate the risks and reduce the costs and time associated with product development and commercialization of new therapies with significant market opportunities. Through the application of novel formulations and drug delivery technologies, we also explore potential new indications for known drug compounds. Since our inception in 2003, our experienced executive management team has built a commercial operation and assembled a portfolio of products and product candidates that currently includes two marketed products that generated net product sales of \$41.9 million in 2006, one product candidate for which an approvable letter has been issued by the U.S. Food and Drug Administration, or FDA, and five product candidates in various stages of clinical development. We also have additional product candidates in earlier stages of development.

Our most significant marketed product and late-stage product candidates are:

*Xyrem (sodium oxybate oral solution).* Xyrem is the only product approved by the FDA for the treatment of both cataplexy and excessive daytime sleepiness in patients with narcolepsy. According to the National Institutes of Health, 150,000 or more individuals in the United States are affected by narcolepsy. We promote Xyrem in the United States to neurologists, psychiatrists, pulmonologists and sleep specialists through our 55 person specialty sales force. We have significantly increased domestic net product sales of Xyrem since our acquisition of Orphan Medical, Inc. We have licensed the rights to commercialize Xyrem in 54 countries outside of the United States to UCB Pharma Limited, or UCB, and in Canada to Valeant Canada Limited, or Valeant. UCB has commercially launched Xyrem in 11 countries.

*Luvox CR (fluvoxamine maleate extended release capsules).* Our most advanced product candidate is Luvox CR, an extended release formulation of fluvoxamine, a selective serotonin reuptake inhibitor, or SSRI, which has been developed for the treatment of obsessive compulsive disorder, or OCD, and social anxiety disorder, or SAD. According to the National Institute of Mental Health, OCD and SAD affect approximately 2.2 million and 15 million adults in the United States, respectively. We obtained the U.S. marketing rights to Luvox CR from Solvay Pharmaceuticals, Inc., or Solvay, in January 2007. Solvay submitted a new drug application, or NDA, to the FDA for Luvox CR in April 2006, and, in February 2007, the FDA issued an approvable letter. Subject to the satisfaction of certain requirements set forth in the approvable letter and FDA approval, we expect to commence promotion of Luvox CR in the United States in the first quarter of 2008 through a significantly expanded specialty sales force. During 2007, we expect to make significant expenditures relating to the planned commercial launch of Luvox CR.

*JZP-6 (sodium oxybate).* We are developing a liquid dosage form of sodium oxybate, the active pharmaceutical ingredient, or API, in Xyrem, for the treatment of fibromyalgia syndrome, or FMS. According to the American College of Rheumatology, between two and four percent of the U.S. population suffers from FMS. There are currently no products approved by the FDA for the treatment of FMS. We have successfully completed a Phase II clinical trial of this product candidate for the treatment of FMS. We are currently conducting two Phase III pivotal clinical trials and we expect preliminary data from the first Phase III pivotal clinical trial in the second half of 2008. In Phase II clinical trials, JZP-6 demonstrated statistically significant improvement in the composite endpoint

---

## **Table of Contents**

accepted by the FDA and the European Agency for the Evaluation of Medicinal Products, or EMEA, as the primary endpoint for our Phase III pivotal clinical trials. Subject to successful completion of Phase III clinical trials, we plan to submit an NDA for JZP-6 by late 2009. If our NDA is approved by the FDA, we would expect to market JZP-6 in the United States to rheumatologists and other specialists who treat FMS patients through an expanded specialty sales force. We have granted UCB the commercialization rights to JZP-6 in 54 countries outside of the United States.

In addition to our product candidates in late-stage development, our clinical development pipeline consists of the following product candidates:

*JZP-4 (Type IIa sodium channel antagonist).* JZP-4, a controlled release formulation of an anticonvulsant that is in the same chemical class as Lamictal (lamotrigine), an antiepileptic drug, or AED, marketed by GlaxoSmithKline, or GSK, is being developed for the treatment of epilepsy and bipolar disorder. According to the Epilepsy Foundation, approximately 2.7 million people in the United States suffer from epilepsy, and, according to the National Institute of Mental Health, approximately 5.7 million people in the United States are affected by bipolar disorder.

*JZP-8 (benzodiazepine).* JZP-8, a novel formulation incorporating a benzodiazepine, is being developed for the treatment of acute repetitive seizure clusters, or RSCs, in refractory epilepsy patients. According to an article published in the *New England Journal of Medicine*, approximately 30% of epilepsy patients are refractory to treatment despite being on an effective dose of an antiepilepsy regimen, and a subset of these refractory patients experience RSCs.

*JZP-7 (dopamine agonist).* JZP-7, a novel formulation incorporating a dopamine agonist, is being developed for the treatment of restless legs syndrome, or RLS. According to the RLS Foundation, up to 10% of the U.S. population suffers from RLS.

*JZP-2 (benzodiazepine).* JZP-2, a fast-acting formulation of a benzodiazepine, is being developed for the acute treatment of panic attacks associated with panic disorder. According to the National Institute of Mental Health, approximately six million people in the United States suffer from panic disorder in any given year.

We have an ongoing program for generating, identifying and conducting feasibility studies for new product candidates. Our JZP-2, JZP-7 and JZP-8 product candidates resulted from this program. Several other product candidates identified through this program are in various stages of early development, including the use of sodium oxybate, the API in Xyrem, for the treatment of movement disorders. In addition, as part of our lifecycle management activities, we are conducting activities directed to developing new forms of sodium oxybate.

Our executive management team has substantial experience in developing and commercializing novel therapeutic products. During their ten years working together as part of the executive management team at ALZA Corporation, a pharmaceutical company acquired by Johnson & Johnson in 2001, our executive management team participated in the successful development and commercialization of a broad portfolio of products and product candidates to address specialized markets.

## **Our Strategy**

Our goal is to be a leading specialty pharmaceutical company developing and commercializing new medicines in neurology and psychiatry and, over the longer term, in additional specialty therapeutic areas. Key elements of our strategy to achieve this goal include:

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

*Focusing on specialty markets of neurology and psychiatry.* We will continue to focus our activities in specialty markets, particularly neurology and psychiatry, where our specialty sales force can establish strong relationships with the relatively small number of healthcare providers who write a large percentage of prescriptions for the indications we target. We have targeted neurology and psychiatry because we believe that these therapeutic areas provide numerous opportunities to improve



## **Table of Contents**

upon existing treatments and to commercialize the products we develop through our commercial organization. In the future, we may seek to expand into additional specialty markets in which we believe there are attractive opportunities to develop novel therapies and to leverage our commercial organization.

*Expanding and leveraging our focused U.S. sales and marketing capabilities.* We currently have a focused and experienced 55 person specialty sales force promoting Xyrem in the United States to neurologists, psychiatrists, pulmonologists and sleep specialists. We expect to expand and leverage this sales force to promote and sell additional products for target indications in which specialists significantly influence the market. For example, we expect to significantly expand our commercial organization, including our sales force, to market Luvox CR to psychiatrists in the United States, subject to receipt of FDA approval. We intend to complete our ongoing Phase III clinical trials of JZP-6 for the treatment of FMS and, subject to regulatory approval, to market this product in the United States to rheumatologists and potentially, through a co-promotion arrangement or contract sales organization, to primary care physicians. For international markets, we intend to establish commercialization partnerships with other pharmaceutical companies to accelerate the introduction of our products outside of the United States and to maximize the commercial opportunity for these products.

*Mitigating risks and reducing the costs and time associated with the development and commercialization of products.* We seek to mitigate the risks and reduce the costs and time associated with product development by focusing on known drug compounds, and compounds with the same mechanism of action or similar chemical structure as marketed products. We intend to continue to apply rigorous development criteria designed to provide us with the basis to make efficient development decisions with respect to each of our product candidates as early as possible in the development process. We also seek to structure our development and commercial relationships, including our strategic licenses and acquisitions of products and product candidates, to minimize financial risk until we can effectively demonstrate a significant likelihood of commercial success.

*Continuing to expand our product portfolio.* We will continue to identify and develop through our internal research and development efforts product candidates that we believe have significant commercial potential. We will also seek to continue to acquire and in-license product candidates and products to complement our portfolio, enabling us to make efficient use of our commercial organization. We continually assess our existing portfolio to ensure a mix of late-stage and earlier-stage opportunities, advancement of product candidates in our target markets and a balance of expected risk and return.

*Leveraging the expertise of our experienced executive management team.* We intend to continue to leverage the expertise of our experienced executive management team in developing and commercializing novel therapeutic products. We will also seek to capitalize on our executive management team's expertise in identifying and pursuing the most effective mix of financings and collaborations to address our capital needs and limit the risk profile of our product pipeline. Since our inception, we have raised over \$400 million from a range of sources, including equity, debt and development financings, and we have engaged in various collaborations related to our product candidates to limit our product development risk.

**Table of Contents****Products and Product Candidates**

Product/Product		Commercialization		
Candidate	API/Mechanism of Action	Primary Indication(s)	Status	Rights
Xyrem	Sodium oxybate	Cataplexy and excessive daytime sleepiness in patients with narcolepsy	Marketed	U.S. and countries not licensed to UCB or Valeant
Antizol	Fomepizole	Ethylene glycol and methanol poisoning	Marketed	Worldwide
Luvox CR	Fluvoxamine maleate	Obsessive compulsive disorder Social anxiety disorder	Approvable letter issued	U.S.
Luvox	Fluvoxamine maleate	Obsessive compulsive disorder	Approvable letter issued	U.S.
JZP-6	Sodium oxybate	Fibromyalgia syndrome	Phase III	U.S. and countries not licensed to UCB
JZP-4	Type IIa sodium channel antagonist	Epilepsy Bipolar disorder	Phase I/II	Worldwide
JZP-8	Benzodiazepine	Repetitive seizure clusters	Phase I/II	Worldwide
JZP-7	Dopamine agonist	Restless legs syndrome	Phase I/II	Worldwide
JZP-2	Benzodiazepine	Panic attacks	Phase I/II	Worldwide

**Marketed Products***Xyrem (sodium oxybate oral solution)*

Xyrem is a sodium oxybate oral solution approved in the United States for the treatment of cataplexy and excessive daytime sleepiness in patients with narcolepsy. Sodium oxybate, the API in Xyrem, is a formulation of  $\gamma$ -hydroxybutyrate, an endogenous neurotransmitter and metabolite of  $\gamma$ -aminobutyric acid. Xyrem is currently the only FDA-approved treatment for both cataplexy and excessive daytime sleepiness in patients with narcolepsy. In 2006, our net product sales of Xyrem were \$29.0 million.

*Market Opportunity*

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

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

*Excessive Daytime Sleepiness.* Excessive daytime sleepiness is the most common symptom of narcolepsy and is present in all narcolepsy patients. Excessive daytime sleepiness results in the individual becoming drowsy or falling asleep, often at inappropriate times and places.

## **Table of Contents**

### *Attributes of Xyrem*

Xyrem is the only product approved by the FDA to treat both cataplexy and excessive daytime sleepiness in patients with narcolepsy. Xyrem is administered at night and quickly metabolized so that during the daytime, very little of the active drug is present in the patient. Xyrem has a well established safety profile. Phase III clinical trial results indicated that Xyrem significantly increased daytime wakefulness and reduced cataplexy attacks in patients with narcolepsy. Approximately 80% of patients in Phase III clinical trials maintained concomitant stimulant use.

### *Product Development*

In June 2005, we obtained the rights to Xyrem as a result of our acquisition of Orphan Medical. Initial FDA approval for Xyrem as a treatment for cataplexy in patients with narcolepsy was obtained in July 2002. In November 2005, the FDA approved a supplemental NDA, or sNDA, for the treatment of excessive daytime sleepiness in patients with narcolepsy.

### *Commercialization*

We promote Xyrem in the United States through our 55 person specialty sales force. Pursuant to an agreement originally executed in 2003 and subsequently amended, we have licensed to UCB the exclusive right to register and market Xyrem for the treatment of narcolepsy in 54 countries throughout Europe, South America, the Middle East and Asia in exchange for milestone and royalty payments to us. Pursuant to the original agreement, UCB and its predecessor paid upfront and milestone payments totaling \$7.5 million in connection with Xyrem for the treatment of narcolepsy. UCB has commercially launched the product in 11 countries and we expect additional commercial launches in 2007. In October 2005, the EMEA approved the product for the treatment of cataplexy in adult patients with narcolepsy, and in March 2007, the EMEA approved the product for the treatment of narcolepsy with cataplexy in adult patients. In December 2006, we licensed to Valeant the Canadian marketing rights to Xyrem for the treatment of narcolepsy, subject to our right to later reacquire these rights. We expect Valeant to launch the product in Canada in 2007.

In June 2006, we significantly expanded the scope of our agreement with UCB to cover JZP-6, our product candidate for the treatment of FMS in exchange for additional upfront and milestone payments. We are entitled to additional commercial milestone payments of up to \$8.0 million specifically associated with Xyrem and royalties on all commercial sales of Xyrem and JZP-6 by UCB under this amended agreement. The term of our agreement with UCB, as it applies to Xyrem, extends to the later of the expiration of our associated patent rights in the territories covered by the agreement or ten years from the date of EMEA approval to commercially promote and distribute the product for the treatment of narcolepsy, subject to automatic extension unless and until UCB terminates the agreement upon not less than 12 months' notice. UCB may terminate our agreement for any reason upon 18 months' notice. We are responsible for supplying Xyrem to UCB and Valeant in exchange for supply price payments. Beginning in 2008, if we are materially unable to comply with our obligations to supply Xyrem to UCB, UCB has the right under certain circumstances to terminate our agreement upon nine months' notice.

The FDA has granted Xyrem orphan drug exclusivity in the United States for both cataplexy and excessive daytime sleepiness in patients with narcolepsy. This provides marketing exclusivity in the United States until July 2009 for the cataplexy indication and November 2012 for the excessive daytime sleepiness indication, which exclusivity periods run concurrently with a period of five-year new chemical entity exclusivity period expiring in July 2007. In addition to orphan drug exclusivity, Xyrem is covered by a formulation patent that is listed in the FDA's approved drug products with therapeutic equivalence evaluation document, or Orange Book, and expires in 2019, and a process patent that expires in 2019. The Orange Book, among other things, lists drug products approved by the FDA and identifies applicable patent and non-patent marketing exclusivities. The listing of our formulation patent in the Orange Book may require potential competitors to certify as to

non-infringement or invalidity of the patent prior to FDA approval of their product candidates.

## **Table of Contents**

We believe that the strict manufacturing and distribution controls imposed by the FDA and the U.S. Drug Enforcement Administration, or DEA, on sodium oxybate, the API in Xyrem, and the complicated risk management procedures required to market and sell the product may make it difficult for other companies to manufacture and market generic formulations of Xyrem. Since Xyrem is classified as a Schedule III controlled substance and approved under the FDA's regulations under Subpart H, its distribution and promotion in the United States is strictly controlled. Unlike typical pharmaceutical products that are distributed by numerous pharmacies, Xyrem is distributed in the United States by a central pharmacy, which is the only source through which Xyrem can be obtained in the United States. Distribution is governed by the FDA's Subpart H regulations and complies with risk-management controls approved by the FDA with input from the DEA and other law enforcement agencies. Every shipment of Xyrem is subject to stringent safeguards to ensure that it reaches only individuals for whom it has been legitimately prescribed. A patent application covering this distribution system is currently pending and, if issued, would expire in 2022. We have contracted separately with third parties to supply the sodium oxybate used to produce Xyrem and to manufacture the product. We rely on a single source for our supply of sodium oxybate. Quotas from the DEA are required in order to manufacture and package sodium oxybate. Since the DEA typically grants quota on an annual basis and requires a detailed submission and justification for the request, obtaining a DEA quota is a difficult and time consuming process.

### *Other Treatments*

As an alternative to Xyrem, cataplexy is often treated with tricyclic antidepressants and SSRIs, although none of these compounds has been approved by the FDA for the treatment of cataplexy. The use of these drugs can often result in somnolence, which exacerbates excessive daytime sleepiness already experienced by all patients with narcolepsy. Other treatments for excessive daytime sleepiness in patients with narcolepsy consist primarily of stimulants and wakefulness promoting agents, including Provigil (modafinil), the only other FDA-approved product for the treatment of excessive daytime sleepiness in patients with narcolepsy.

### *Antizol (fomepizole)*

Antizol, an injectable formulation of fomepizole, is the only FDA-approved antidote for suspected or confirmed ethylene glycol or methanol poisonings in humans. According to the 2005 annual report of the American Association of Poison Control Centers, more than 6,000 exposures to ethylene glycol were reported in the United States in 2005, resulting in 41 fatalities. More than 2,300 exposures to methanol were reported in the United States in 2005, resulting in 13 fatalities. If ingested, ethylene glycol, commonly found in antifreeze, and methanol, commonly found in windshield wiper fluid, can lead to death or permanent, serious physical damage. When administered promptly after ingestion of either of these poisons, Antizol inhibits the formation of toxic metabolites and helps prevent renal damage or death. Guidelines issued by the American Academy of Clinical Toxicologists have established Antizol as the standard of care for such poisonings.

In 2006, our net product sales of Antizol were \$12.5 million. We obtained the rights to Antizol in connection with our acquisition of Orphan Medical. Orphan Medical had obtained the worldwide rights to develop and market Antizol through a sublicense agreement with Mericon Investment Group. The license expires in July 2013, subject to a five-year renewal option that may be exercised by either party. We pay Mericon quarterly royalties on sales of Antizol through the duration of the sublicense.

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

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

We also market Antizol-Vet, an injectable formulation of fomepizole approved as an antidote for suspected or confirmed ethylene glycol poisonings in dogs. In 2006, our net product sales of Antizol-Vet were \$313,000.

## **Table of Contents**

### **Product Candidates**

#### *Luvox CR (fluvoxamine maleate extended release capsules)*

Luvox CR, an extended release formulation of fluvoxamine maleate, developed by Solvay in collaboration with Elan Pharma International Limited, or Elan, is an SSRI for which we are seeking approval from the FDA for the treatment of obsessive compulsive disorder, or OCD, and social anxiety disorder, or SAD. Luvox, an immediate release formulation of fluvoxamine maleate, was previously approved by the FDA and marketed by Solvay for the treatment of OCD, and generic fluvoxamine remains one of the leading treatments for the disorder. Luvox CR incorporates extended release beads designed to provide delivery of fluvoxamine with lower peak plasma levels compared to the immediate-release formulation. In February 2007, the FDA issued an approvable letter for Luvox CR setting forth certain conditions necessary for receiving approval to market Luvox CR for the treatment of OCD and SAD. Subject to satisfaction of the conditions set forth in the approvable letter and approval by the FDA, we expect to commence promotion of Luvox CR in the first quarter of 2008.

#### *Market Opportunity*

*Obsessive Compulsive Disorder (OCD).* OCD is a chronic anxiety disorder characterized by persistent, unwanted thoughts, or obsessions, and repetitive behaviors or rituals, or compulsions. According to the National Institute of Mental Health, OCD affects approximately 2.2 million adults in the United States. According to an article published in the *International Journal of Clinical Practice*, it is estimated that 60% of patients with OCD worldwide receive no treatment for their disorder. As physicians have improved their ability to recognize symptoms, the number of diagnosed cases of OCD has increased by 78% from 1995 to 2005, as measured by the 2005 Physicians Drug and Diagnosis Audit, or PDDA, conducted by Verispan, Inc. Patients with OCD use rituals to help control anxiety related to their obsessive thoughts, and these rituals become disruptive to their daily life. While these patients often realize that their obsessions and compulsions are irrational or excessive, they frequently have little or no control over them. Typical obsessions include concerns with dirt, germs and contamination, fear of acting on violent or aggressive impulses or feeling overly responsible for the safety of others. Rituals adopted by OCD patients may provide them with transient relief from anxiety, but the rituals do not provide sustained comfort. Frequently, the rituals become so overwhelming that patients are unable to function normally in their daily lives. Symptoms of OCD typically appear in childhood, adolescence or early adulthood. According to an article published in the *Journal of Clinical Psychiatry*, a significant portion of OCD patients are believed to have one or more concomitant psychiatric disorders, such as depression or social anxiety disorder.

*Social Anxiety Disorder (SAD).* SAD is characterized by the fear and avoidance of social or performance situations where patients feel that others may scrutinize them and they may embarrass themselves. According to the National Institute of Mental Health, SAD affects approximately 15 million adults in the United States. Despite the prevalence of the disorder, social anxiety disorder remains underdiagnosed and undertreated by clinicians. SAD patients have anticipatory anxiety about these situations, and this anxiety can become so pronounced that patients cannot function normally in their daily lives. Social anxieties can be limited to a particular situation or apply to a variety of situations. In addition to anxiety, patients experience physical symptoms including blushing, sweating, trembling, and nausea. Symptoms of SAD typically appear in childhood or adolescence with a mean age of onset of approximately 13 years, and the symptoms are often preceded by a history of social inhibition or shyness. According to an article published in the *Journal of Clinical Psychiatry*, mood and other anxiety disorders are prevalent among SAD patients.

#### *Current Treatments*



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

SSRIs have become the standard treatment for anxiety disorders, including OCD and SAD. According to the Pharmaceutical Audit Suite, or PHAST, published by Wolters Kluwer Health, more than 142 million total prescriptions were written for SSRIs and serotonin-norepinephrine reuptake inhibitors, or SNRIs, in the United States in 2006, accounting for approximately \$16 billion in sales. Since the approval of Prozac (fluoxetine) in the

## **Table of Contents**

United States in 1987, the use of SSRIs and SNRIs has increased dramatically due to their efficacy and reduced side effect profile relative to previously approved antidepressants. Based on available market data, we estimate that the majority of SSRI and SNRI prescriptions are for the treatment of depression and that OCD and SAD constitute approximately three percent of total SSRI and SNRI prescriptions.

There are currently five SSRI products approved by the FDA for the treatment of OCD, including fluvoxamine, the generic formulation of Luvox. The use of these various agents for the treatment of OCD has varied over the past ten years. Based on PDDA data, we estimate that fluvoxamine use represented approximately 11% of total drug usage for the treatment of OCD in 2005. Prior to the introduction of generic fluvoxamine in 2001, Luvox was considered one of the preferred SSRIs for the treatment of OCD, with what we estimate, based on PDDA data, to be 21% of total drug usage for the treatment of OCD in 1999. Generic competitors are currently available for the three SSRIs most commonly prescribed for the treatment of OCD.

There are currently four products that are approved by the FDA for the treatment of SAD. The existence of co-morbid psychiatric disorders is an important consideration in the selection of the pharmacologic agents to treat SAD. For these patients, an SSRI or SNRI with demonstrated efficacy in multiple indications is the preferred treatment option. Generic competitors are currently available for the two SSRIs most commonly prescribed for the treatment of SAD.

Although SSRIs have a favorable side-effect profile compared to other classes of agents, the current SSRI products used to treat OCD and SAD, particularly those formulated for immediate release, all have significant adverse side effects. Adverse side effects associated with SSRIs include nausea, sleep disturbances, sexual dysfunction, weight gain, adverse drug interactions, risk of hypertension and, in adolescents, increased suicidal tendencies. SSRIs are known to have little effect on patients' disease condition during the initial six to eight weeks of therapy. As a result, multiple psychotropic drugs are often prescribed during this time period to provide patients with more immediate relief. Additional adverse effects associated with immediate release formulations of SSRIs include significant incidence of nausea and reduced compliance as a result of multiple daily dosing.

### *Attributes of Luvox CR*

We believe that there is a significant market opportunity for the reintroduction of the Luvox brand for the treatment of OCD, and its introduction for the treatment of SAD, and that Luvox CR offers a compelling opportunity to improve upon existing formulations of fluvoxamine in treating these disorders. Fluvoxamine, the API in Luvox, is already a broadly prescribed therapy for the treatment of OCD. The market potential for fluvoxamine is demonstrated by its significant ongoing prescription rates for the generic formulation despite the absence of active marketing and sales activity for Luvox since 2001. No extended release fluvoxamine products have been approved by the FDA, and if approved by the FDA, Luvox CR would be the first fluvoxamine product approved for the treatment of SAD.

In a Phase III clinical trial for OCD, patients taking Luvox CR demonstrated a statistically significant improvement compared to patients receiving placebo as assessed by the Yale-Brown Obsessive Compulsive Scale, or Y-BOCS, as early as week two of the trial. In Phase III clinical trials for SAD, patients receiving Luvox CR demonstrated statistically significant improvement compared to patients receiving placebo as assessed by the Liebowitz Social Anxiety Scale, or LSAS, total score as early as week four of the trial. Patients taking Luvox CR also did not show an increase in hypertension.

We believe the once-a-day dosing regimen afforded by the extended release formulation of Luvox CR could significantly improve compliance and patient acceptability. Furthermore, we believe that Luvox CR has a favorable tolerability profile as a result of its altered pharmacokinetic profile and lower maximum plasma concentration of fluvoxamine.



**Table of Contents***Product Development*

In January 2007, we licensed the exclusive U.S. rights to Luvox CR and Luvox from Solvay. Solvay submitted an NDA for Luvox CR in December 2000. As a result of difficulties associated with manufacturing large-scale batches of the product candidate, Solvay and Elan mutually agreed to withdraw the NDA for Luvox CR in June 2001. We believe that Solvay and Elan have adequately addressed these manufacturing difficulties and that Elan, the party responsible for the manufacturing of Luvox CR, will be able to manufacture the product in commercial quantities. In April 2006, Solvay resubmitted the NDA for Luvox CR for treatment of OCD and SAD. In February 2007, the FDA issued an approvable letter for Luvox CR. The approvable letter sets forth the requirements that must be met in order for the FDA to approve Luvox CR for marketing in the United States. The requirements set forth in the approvable letter include the completion of certain toxicology studies on the impurities that are generated by fluvoxamine maleate, the API in Luvox CR, and the submission of additional information relating to the chemistry, manufacturing and controls section of the NDA. The approvable letter also requires Solvay to re-analyze certain data set forth in the NDA. We will need to commit to conducting certain post-approval, or Phase IV, studies, including a pediatric study for SAD and a long-term safety study. We (with Solvay) will also need to finalize product labeling with the FDA. Pursuant to the terms of our license agreement, Solvay is responsible for conducting the additional toxicology studies and submitting the information to the FDA. We expect that Solvay will submit its response to the requests in the approvable letter to the FDA in the second or third quarter of 2007.

*OCD Phase III Clinical Trial Results.* Solvay conducted one Phase III pivotal clinical trial with Luvox CR for the treatment of OCD. Since fluvoxamine is currently approved for the treatment of OCD, the FDA only requires one successful Phase III trial for approval of the extended release formulation for use in OCD. In the 12-week, multi-center, placebo-controlled trial of roughly 250 patients, patients receiving Luvox CR demonstrated statistically significant improvements on the Y-BOCS compared to patients receiving placebo as early as week two of the study. The Y-BOCS is a ten-item clinician-administered scale developed to assess the severity of obsessions and compulsions, independent of the number and type of obsessions or compulsions present. The Y-BOCS has been the primary outcome measure in virtually all multi-center clinical trials of SSRIs for the treatment of OCD. The Luvox CR group mean total change from baseline on the Y-BOCS was -8.5 compared to -5.6 for placebo, for a p-value of  $p < 0.001$  at 12 weeks. A p-value is a statistical measure intended to predict when a result of a study is likely the result of an intended outcome, such as a drug having a therapeutic effect in a clinical trial, and not by random chance. A value of  $p < 0.05$  means the likelihood of a result by chance is less than five in 100. As p-values become smaller, the probability of a result by chance decreases and the standard convention is to consider a p-value of 0.05 or less a statistically significant result.

*SAD Phase III Clinical Trial Results.* The effectiveness of Luvox CR in the treatment of SAD was demonstrated in two 12-week, multi-center, placebo-controlled Phase III clinical trials in over 550 patients. In both studies, the effectiveness of Luvox CR compared to placebo was evaluated on the basis of change from baseline in the LSAS. The LSAS was the first clinician-administered scale to evaluate the wide range of social situations that are difficult for individuals with social phobia. The scale contains 24 items, 13 concerning performance anxiety and 11 concerning social situations. The LSAS is used as an outcome measure in most pharmacological trials for social phobia, as well as in many studies of cognitive-behavioral treatment. Patients receiving Luvox CR demonstrated statistically significant improvement compared to patients receiving placebo as assessed by the LSAS total score as early as week four of the study. In one study of 279 patients, mean change in LSAS total score was -26.7 for Luvox CR and -12.9 for placebo, for a p-value of  $p < 0.001$  at 12 weeks. In the other study of 300 patients, mean change in LSAS total score was -36.1 for Luvox CR and -27.3 for placebo, for a p-value of  $p < 0.02$  at 12 weeks.

*Commercialization Strategy*

If Luvox CR is approved by the FDA, we anticipate launching it in the United States in the first quarter of 2008. To effectively market Luvox CR we intend to expand our already established specialty sales force. A

## **Table of Contents**

substantial majority of prescriptions for the treatment of OCD and SAD are written by psychiatrists. We believe that this concentration provides an attractive, focused market opportunity for us.

Through our agreement with Solvay, we have the right to distribute and market Luvox CR in the United States. Solvay retains the right to market Luvox CR outside of the United States. In the event that Solvay decides not to pursue marketing of Luvox CR in any countries to which it has retained rights, we have a right of first offer with respect to any license of rights to market Luvox CR in such countries. Solvay is responsible for providing us with the API necessary to manufacture Luvox CR. In addition, Solvay has assigned its rights under its agreement with Elan. Pursuant to that agreement, Elan will manufacture Luvox CR for us in commercial quantities. We paid Solvay \$2.0 million upon signing of the agreement, and will pay Solvay up to \$138.0 million in developmental and commercial milestone payments associated with Luvox CR as well as royalties on commercial sales. Up to \$41.0 million of the milestone payments are payable at or prior to commercial launch. We will pay Elan royalties on commercial sales and supply price payments.

We expect Luvox CR will receive three years of new marketing exclusivity if approved by the FDA. In addition, a patent application has been filed by Elan covering the orally administered formulation of extended-release fluvoxamine that requires the release of fluvoxamine over a period of not less than 12 hours. If this patent issues in the United States, it could provide patent protection for this formulation until 2020.

### ***Luvox (fluvoxamine maleate)***

Luvox, an immediate release formulation of fluvoxamine maleate, was approved by the FDA for the treatment of OCD in 1994. However, Solvay withdrew Luvox from the market in 2002 as a result of discrepancies in data identified by the FDA. Solvay resubmitted the NDA for Luvox to the FDA in June 2002 and received an approvable letter from the FDA in February 2004. In May 2006, Solvay submitted its response to the approvable letter and in November 2006, the FDA issued a second approvable letter for Luvox setting forth certain conditions necessary for receiving approval to market Luvox for treatment of OCD. The second approvable letter requires certain standard toxicology studies on the impurities present in the drug product to be conducted. No carcinogenicity or other studies are required. Because numerous generic formulations of fluvoxamine are on the market, and no serious adverse events associated with toxicity have been reported, we do not believe that the required testing poses a significant risk for the ultimate approval of Luvox. Pursuant to the terms of our license agreement, Solvay is responsible for conducting the additional tests and submitting the information to the FDA. We expect that Solvay will submit the additional data to the FDA in the second or third quarter of 2007.

Through our agreement with Solvay, we have the right to distribute and market Luvox in the United States, but we have not yet determined if we will market Luvox if it is approved by the FDA for the treatment of OCD. In the event we market Luvox in the United States, we will make a milestone payment to Solvay of \$2.0 million and royalties on commercial sales.

### ***JZP-6 (sodium oxybate)***

We are developing a liquid dosage form of sodium oxybate, the API in Xyrem, for the treatment of fibromyalgia syndrome, or FMS. We are currently conducting two Phase III pivotal clinical trials for JZP-6 in FMS. We have completed a Phase II clinical trial for JZP-6 in which FMS patients taking sodium oxybate achieved a statistically significant improvement compared to placebo on the composite endpoint accepted by the FDA and the European Agency for the Evaluation of Medicinal Products, or EMEA, as the primary endpoint for our Phase III pivotal clinical trials.

*Market Opportunity*

FMS is a chronic pain syndrome defined by widespread pain lasting at least three months. According to the American College of Rheumatology, or ACR, between two and four percent of the U.S. population suffers from

## **Table of Contents**

FMS. FMS is believed to be a central nervous system condition. In addition to pain, FMS patients often suffer from a combination of muscle stiffness, fatigue, disturbed sleep, restless legs and impaired memory and concentration. Although physicians do not understand the cause of FMS, it may be triggered by physical trauma, emotional stress or infection. The criteria established by the ACR for the classification of fibromyalgia require the application of pressure at 18 different points on the body and measurement of pain induced by such pressure. If at least 11 of the 18 points are painful and have been painful for three months, the patient is diagnosed with FMS.

### *Current Treatments*

There are currently no products approved by the FDA for the treatment of FMS. In clinical practice, a variety of drugs is often prescribed to address individual symptoms of FMS, including antidepressants, opioid analgesics, COX-2 analgesics, muscle relaxants, hypnotics and anticonvulsants. Based on available market data, we estimate that more than 5.7 million total prescriptions were written to treat FMS symptoms in 2005, of which approximately 42% were for antidepressants, 29% were for opioids and 18% were for muscle relaxants. Physicians generally prescribe one or more drug therapies based on the dominant symptom or symptoms of FMS in a particular patient. This polypharmacy approach has significant limitations as none of the current therapies used to address the symptoms of FMS is designed to comprehensively address the syndrome and many of its related symptoms.

In addition to JZP-6, there are currently four programs that have completed or are in Phase III clinical development for the treatment of FMS. These include Lyrica (pregabalin), an anticonvulsant being developed by Pfizer, which has previously been approved by the FDA for the treatment of partial seizures, post herpetic neuralgia and diabetic peripheral neuropathy. In December 2006, Pfizer submitted a supplemental NDA seeking FDA approval of Lyrica for the treatment of FMS, or certain symptoms associated with FMS.

### *Attributes of JZP-6*

JZP-6 is being developed to provide an effective treatment for FMS and pain associated with FMS. While the primary symptom of FMS is widespread pain, fatigue and mood disturbances are also common symptoms. We believe that JZP-6 will provide significant advantages over current treatments by offering improvements in pain relief and physical functioning that may address the overall syndrome and many of its related symptoms.

The primary endpoint for our pivotal trials measuring the efficacy of JZP-6 is a composite of change from baseline in three co-primary measures of patients' pain: the pain visual analog scale, the fibromyalgia impact questionnaire and patient global impression of change. This composite of change endpoint was accepted by the FDA and the EMEA as the primary endpoint for our Phase III pivotal clinical trials. An efficacious response by a patient in the trial for each of the three co-primary measures of patient's pain is defined as a greater than 20% reduction in the pain visual analog scale, a greater than 20% improvement in the fibromyalgia impact questionnaire score and a self-rating describing themselves as very much better or much better on the patient global impression of change.

### *Product Development*

*Phase II Clinical Trial Results.* In August 2005, we completed a Phase II clinical trial of 195 patients with FMS in a randomized, double blind placebo-controlled safety and efficacy study. Patients received a fixed dose of 4.5 grams of sodium oxybate divided into two nightly doses, 6.0 grams of sodium oxybate divided into two nightly doses, or placebo twice nightly for an eight-week period. The primary endpoint for this trial

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

was a composite of change from baseline in three co-primary measures of patients' pain: the pain visual analog scale, the fibromyalgia impact questionnaire and patient global impression of change. Secondary endpoints included measurement of a tender point count, tender point index, Epworth sleepiness scale, Jenkins scale for sleep, global score on the functional outcome of sleep questionnaire, severity of fatigue and clinical global impression of



## **Table of Contents**

change. The Phase II clinical trial demonstrated significant improvement in the composite endpoint results in both dosage strengths. In addition, the study demonstrated significant improvements in secondary measures of fatigue, sleepiness and sleep quality. There were no unexpected adverse events in the study.

JZP-6 also demonstrated statistically significant improvement in each of the co-primary measures that comprise the composite endpoint in either one or both dosage strengths. The visual analog scale is a self-assessed measurement of pain in which zero is no pain at all and 100 is the worst pain experienced. The baseline pain for the FMS patients in the trial was roughly 65. Patients on both dosage strengths experienced a statistically significant improvement in pain at eight weeks. In addition, the study measured pain throughout the day. Patients experienced pain relief in the morning, at midday and in the evening, which represents an important clinical benefit for patients. The fibromyalgia impact questionnaire is a 20 item questionnaire that asks patients to assess their ability to complete activities of daily living such as shopping, preparing a meal, visiting or doing housework. The total score is normalized to 100 points. The questionnaire also has a single inquiry about anxiety and depression. The Phase II clinical trial results demonstrated that patients on both dosage strengths experienced statistically significant improvement in the total score. The patient global impression of change is a seven point scale on which patients assess how much better or worse they feel throughout the trial. Our Phase II clinical trial demonstrated a statistically significant improvement for this measure for patients on the 4.5 gram dose.

*Ongoing Phase III Clinical Trials.* We are currently conducting two Phase III pivotal clinical trials, each in approximately 525 patients, and an open-label continuation trial in approximately 500 patients, to confirm the results of our Phase II clinical trial. The primary endpoint in both of our ongoing Phase III pivotal clinical trials is the same as in our Phase II clinical trial. Each of our Phase III pivotal clinical trials involve randomized, double blind studies. The first of these trials commenced in September 2006 and is ongoing in 45 sites located exclusively in the United States. As of March 2007, more than 80 patients had been enrolled in the first trial. Screening for the second trial commenced in February 2007. Between 30% and 40% of the subjects for the second trial are expected to reside outside of the United States. We expect to commence clinical pharmacology studies in the third quarter of 2007. Dosages being studied in the ongoing Phase III trials are consistent with our Phase II clinical trial with the exception that subjects assigned to higher doses will be titrated from the lower dose to the higher dose over a period of two weeks. We believe this titration regimen will provide for a more clinically relevant comparison of the relative safety, efficacy and tolerability of the dosages being studied and assist in determining the benefits, if any, of flexible dosing.

We expect preliminary data from the first Phase III pivotal clinical trial in the second half of 2008. Based on the results of our Phase III clinical trials and further discussions with the FDA, we will determine when and if we will submit an NDA for JZP-6 for the treatment of FMS or other, more limited indications such as pain associated with FMS.

### *Commercialization Strategy*

If JZP-6 is approved by the FDA, we believe that the majority of prescriptions for the product to treat FMS will be written by rheumatologists, with some prescriptions written by neurologists and psychiatrists. Because the number of rheumatologists in the United States is relatively small we expect to be able to expand our specialty sales force to promote JZP-6 in the United States. We may also identify one or more pharmaceutical company partners or a contract sales organization to promote JZP-6 to other audiences, including primary care physicians who are treating patients with FMS.

In 2006, we amended our agreement with UCB to grant UCB the right to market JZP-6 for the treatment of FMS in 54 countries throughout Europe, South America, the Middle East and Asia. Under the terms of the amended agreement, UCB paid us \$15.0 million to develop and commercialize JZP-6 for the treatment of FMS. We are entitled to up to \$40.0 million in additional developmental milestone payments associated with JZP-6, and additional commercial milestone payments of up to \$100.0 million related primarily to JZP-6 for the treatment of FMS as well as Xyrem for the treatment of narcolepsy. The term of our agreement with UCB, as it



## **Table of Contents**

applies to JZP-6, extends to the earlier of the expiration of our associated patent rights in the territories covered by the agreement or ten years from the date of EMEA approval to commercially promote and distribute the product for the treatment of FMS, subject to automatic renewals of one year unless UCB provides 12 months' notice. UCB may terminate our agreement for any reason upon 18 months' notice. We are responsible for supplying commercial quantities of JZP-6 to UCB in exchange for supply price payments. If we are unable to comply with our obligations to supply JZP-6 to UCB, UCB has the right under certain circumstances to terminate our agreement upon nine months' notice.

Pursuant to our agreement with Valeant, Valeant has the option to acquire the rights to market JZP-6 for treatment of FMS in Canada if it is then commercializing Xyrem for narcolepsy in Canada, subject to our right to later reacquire these rights. We are responsible for supplying commercial quantities of JZP-6 to Valeant in exchange for supply price payments.

We have contracted with our current supplier of sodium oxybate for the manufacture of Xyrem and our current manufacturer of Xyrem for the manufacture of JZP-6 to conduct our clinical trials. Because sodium oxybate is a controlled substance requiring manufacturing quotas from the DEA, our current API supplier and contract manufacturer may be unable to provide us with sufficient clinical and commercial quantities. In cooperation with our manufacturing partners, we intend to seek increased quotas from the DEA to supply and manufacture JZP-6 to complete our clinical trials and, if it is approved, to commercialize the product. We expect that the manufacture and distribution of JZP-6 will be subject to similar restrictions and risk management policies as our existing processes in place for Xyrem. These restrictions may present a meaningful obstacle for the eventual introduction of generic versions of JZP-6.

We expect that our patents associated with Xyrem will cover JZP-6. In addition, we hold a U.S. patent and patents in 29 other countries that cover the use of sodium oxybate for the treatment of FMS. Our U.S. patent expires in 2017 and our patents in other countries expire in 2018.

### ***JZP-4 (type IIa sodium channel antagonist)***

We are developing JZP-4, a controlled release formulation of an anticonvulsant that has a similar chemical structure and is believed to work through the same mechanism of action as Lamictal (lamotrigine), an AED marketed by GSK for the treatment of epilepsy and bipolar disorder. We have completed a number of preclinical studies related to antiepileptic activity that suggest that JZP-4 may be effective in treating epilepsy. Subject to the results of proposed and ongoing proof of concept clinical trials and long-term toxicology studies, we plan to commence a Phase II clinical trial for the treatment of epilepsy in the fourth quarter of 2007.

### ***Market Opportunity***

***Epilepsy.*** Epilepsy, a seizure disorder, is a serious neurological illness affecting people of all ages. A seizure is a sudden surge of electrical activity in the brain that affects how a person feels or acts for a short time. According to the Epilepsy Foundation, approximately 2.7 million people in the United States suffer from epilepsy. In 2005, over \$6.0 billion of seizure disorder drugs were sold in the United States as measured by PHAST. Based on available market data, we estimate that approximately \$2.3 billion of these drugs were prescribed for the treatment of epilepsy. Epileptic seizures are classified as either partial or generalized depending upon how the abnormal brain activity begins. Partial seizures begin with abnormal activity in part of the brain. Generalized seizures have abnormal activity in most or all of the brain. Seizure symptoms may be hardly noticeable, such as confusion and staring, or totally disabling, such as convulsions, shaking and falling down.

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

*Bipolar disorder.* Bipolar disorder is a serious, chronic psychiatric disorder that causes shifts in mood, energy and ability to function. According to National Institute of Mental Health, approximately 5.7 million people in the United States are affected by bipolar disorder. Based on available market data, we estimate that approximately \$1.3 billion of AEDs were sold for the treatment of bipolar disorder in 2005. People suffering

## Table of Contents

from the condition experience dramatic mood swings from an overly high mania state to an overly low or depressive state, often with periods of normal mood in between.

### *Current Treatments*

*Epilepsy.* Seizures in epileptic patients are typically controlled by treatment with one or more AEDs. In 2006, there were approximately 6.2 million prescriptions written for Lamictal. While up to 70% of epilepsy patients respond to therapy and become seizure-free with chronic treatment with AEDs, the remaining patients fail treatment either because the drugs do not stop their seizures or because they cannot tolerate the side effects. These patients usually end up taking more than one AED at a time and are therefore more susceptible to adverse effects associated with drug interactions. Selection of the appropriate medication for an individual patient is typically based on the type of epilepsy from which a patient suffers, the genesis of the disease, and the patient's age and gender. Although there are many AEDs available that work in different ways, no single drug is well tolerated and controls seizures in a majority of patients. Side effects and tolerability are significant concerns with currently available AEDs. Side effects for most AEDs include sleepiness, cognitive impairment, weight gain, mood changes, dizziness and potentially life-threatening immune system reactions. Doctors generally start their patients on a low dose of AEDs, and titration may take up to 12 weeks. During this period, patients often continue to suffer from epileptic seizures of various severities.

*Bipolar Disorder.* Bipolar disorder is typically managed with drugs from a variety of different drug classes. While treatment duration varies for each patient, treatment of an acute phase of the disease generally lasts approximately three weeks, followed by a continuation phase of approximately two months, and a maintenance phase of up to 18 months. Generally, the treatment is chosen based on the mood episode a patient is experiencing at a particular time. Treatment for patients in the acute mania phase includes a mood stabilizer, such as lithium or an AED, in addition to an atypical antipsychotic. Patients in the acute depression phase are initially treated with Lamictal, Symbyax (olanzapine and fluoxetine HCl capsules), a combination antidepressant and antipsychotic, or Seroquel (quetiapine), an antipsychotic. For long-term maintenance, the same medications that were effective for the acute episodes are typically continued at the same or lower doses. Many of the drugs currently used in the treatment of bipolar disorder have adverse drug interactions affecting each drug's efficacy and safety as well as adverse tolerability and other negative side effects such as sedation, weight gain, involuntary movements, tremors, stiffness orthostatic hypotension and potentially life-threatening immune system reactions. These side effects discourage compliance and may pose serious health risks. Antidepressants are also often prescribed to treat bipolar depression, even though they are not indicated for such treatment and there is a risk that such antidepressants can induce a bipolar patient to switch from depression to mania.

### *Attributes of JZP-4*

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

### *Product Development*

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

We acquired the worldwide rights to the API in JZP-4 from GSK in 2004. Since acquiring these rights, we have completed our initial early preclinical development to show that the drug can be formulated as a once-a-day

## **Table of Contents**

product, and we have conducted preclinical studies which we believe have confirmed studies previously completed by GSK showing that the drug has central nervous system activity comparable to Lamictal and other AEDs.

Our preclinical development has involved a range of preclinical studies to determine how the API in JZP-4 works and its potential to treat epilepsy. The results of these studies indicate that the API in JZP-4 is a broad spectrum AED with sodium and calcium channel blockade as the primary mechanisms of action. From the results of these preclinical studies, we believe that the API has a broad spectrum of activity, which indicates that it may be effective in treating many different types of epileptic seizures. We have also completed preliminary toxicology and pharmacology tests that have provided early indications of safety and a low potential for adverse drug interactions. These tests involved exposure of more than 170 healthy individuals in eight single dose and multi-dose studies. We have developed a prototype formulation and tested it in a pharmacokinetic study which confirmed the viability of once-a-day dosing. Following completion of this study we began development activities for a once-a-day formulation, and we currently expect to complete these activities in the second quarter of 2007.

In addition, we have designed two proof of concept clinical trials designed to provide evidence of therapeutic activity for JZP-4. The first, a transcranial magnetic stimulation, or TMS study, is a non-randomized, single blind placebo-controlled study of JZP-4 in healthy volunteers with lamotrigine as a positive control. The TMS model is predictive of central nervous system activity and efficacy in partial epilepsy. Three patients have completed all four doses of JZP-4 and one dose of lamotrigine. Results from these subjects indicate potential central nervous system activity of JZP-4. The second, a photic-induced paroxysmal electroencephalographic study in photosensitive epilepsy patients, is a non-randomized, single blind placebo-controlled study of JZP-4 with a higher dose of baseline AED as a positive control. The results from this study will provide information on the effective dose range in epilepsy patients and possible adverse drug interactions with other AEDs. Initial dosing for this study is expected to commence in the second quarter of 2007.

Our completed toxicology studies support use of the API in JZP-4 in humans for up to 13 weeks. We began additional long-term toxicology studies in March 2006 and expect to receive results from these studies in the first quarter of 2007. Subject to satisfactory results from these long-term toxicology studies, a proof of concept study and certain drug-drug interaction studies, we plan to commence a Phase II clinical trial of JZP-4 for the treatment of epilepsy beginning in the fourth quarter of 2007. We believe that the initial results of this trial will be available in early 2008.

### *Commercialization Strategy*

Our strategy to market any approved formulation of JZP-4 will depend on the outcome of our clinical trials, the nature of any indications it is approved to treat and the specialties of the physicians most likely to prescribe the product. Any such sales efforts may involve the utilization of our internal sales force, collaborations with partners, or a combination of both. Pursuant to our agreement with GSK, we have paid upfront and developmental milestone payments of \$5.0 million and will pay up to \$113.5 million in additional developmental and commercial milestone payments as well as royalties on commercial sales.

We have identified and are in the process of qualifying a manufacturer to produce clinical trial materials for all late-stage clinical trials of JZP-4. Following development of our once-a-day formulation we intend to seek a contract manufacturer for commercial quantities of JZP-4.

The composition of matter for the API in JZP-4 is covered by patents in 53 countries, including in the United States and countries in Europe. The U.S. composition of matter patent expires in 2018. In addition, we hold a U.S. patent covering the use of the API in JZP-4 for the treatment of bipolar disorder that expires in 2018, and a U.S. patent that covers the process used for preparing of the API in JZP-4 that expires in 2021. A patent application covering a sustained release composition for delivering the API in JZP-4 is currently pending in the U.S. Patent and

Trademark Office and would, if issued, expire in 2026.



## **Table of Contents**

### *JZP-8 (benzodiazepine)*

We are developing JZP-8, a novel formulation incorporating a benzodiazepine, for the treatment of acute repetitive seizure clusters, or RSCs, in refractory epilepsy patients. Our initial development work suggests that JZP-8 has the potential to provide fast-acting efficacy associated with currently available therapies while addressing problems associated with administration that make such therapies largely impractical to employ.

### *Market Opportunity*

RSCs are increased bouts of acute seizure activity within a 24-hour period in adults and a 12-hour period in children. According to the Epilepsy Foundation, approximately 2.7 million people in the United States have epilepsy. According to an article published in the *New England Journal of Medicine*, approximately 30% of epilepsy patients are refractory to treatment despite being on an effective dose of an antiepilepsy regimen, and a subset of these refractory patients experience RSCs. RSCs are an acute and repetitive reaction to the abnormal electrical activity that builds up and releases in the brain. Epilepsy patients and their caregivers are usually able to distinguish between a regular seizure and the first seizure in a RSC series.

### *Current Treatments*

Quick identification and treatment of the first seizure in an RSC can often interrupt the ongoing seizure, reduce its severity, and prevent subsequent seizures. Interrupting a seizure cluster may also lessen the severity of post-seizure symptoms. In the United States, Diastat (diazepam rectal gel), marketed by Valeant Pharmaceuticals, is the only FDA-approved, acute, outpatient treatment for patients on stable AEDs who experience bouts of increased seizure activity. In 2005, sales of Diastat totaled approximately \$65.0 million in the United States as measured by PHAST. Although generally considered safe and effective for patients of all ages, because it is a rectally administered gel, Diastat is currently prescribed primarily for children under the age of ten and is administered to them by caregivers or parents. Diastat's rectal administration has made it impractical for most of the adolescent, adult and elderly population. Patients with seizure clusters who do not use Diastat have no other outpatient treatment option and thus, typically, are treated through the emergency medical system.

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

### *Attributes of JZP-8*

JZP-8 is being developed as a fast-acting benzodiazepine. Like other benzodiazepines, JZP-8 will likely be regulated as a controlled substance by the DEA if approved for marketing by the FDA. We believe JZP-8 will provide a far easier means of administration while patients are actively seizing and a delivery form that will be accepted for use by adolescent and adult patients as well as caregivers. In addition, we believe that JZP-8 will have sufficient duration of action to prevent recurrence of subsequent seizures.

*Product Development*

We have completed development activities to select the API for this product candidate and are conducting further development activities related to formulation, safety and tolerance. We have completed a pharmacokinetics and pharmacodynamics, or PK/PD, study in healthy volunteers. Pharmacokinetics deals with the absorption, distribution, biotransformation and excretion of drugs, which, coupled with dosage, determines the concentration of a drug in the body and, hence, the intensity of its effects as a function of time. Pharmacodynamics is the study of the biochemical and physiological effects of drugs and their mechanisms of

## **Table of Contents**

action. These PK/PD results demonstrate that JZP-8 has an acceptable plasma profile. We plan to commence a Phase II clinical trial of JZP-8 for the treatment of acute RSCs in refractory epilepsy patients in the third quarter of 2007. Subject to satisfactory results from this clinical trial, we plan to begin Phase III clinical trial activities for JZP-8 in the first quarter of 2008.

### *Commercialization Strategy*

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

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

We have contracted for the supply of the API in JZP-8 in sufficient quantities to complete clinical trials. We intend to seek a contract manufacturer for commercial quantities of JZP-8.

### *JZP-7 (dopamine agonist)*

We are developing JZP-7, a novel formulation incorporating a dopamine agonist, for the treatment of restless legs syndrome, or RLS. Based on our preclinical development, we believe JZP-7 offers the potential for effective treatment of RLS while reducing adverse effects associated with existing treatments.

### *Market Opportunity*

RLS is a common, underdiagnosed neurological disorder that frequently manifests itself as a sleep disorder. According to the RLS Foundation, up to ten percent of the U.S. population suffers from RLS. A study published in the May 2004 issue of Sleep Medicine indicated that approximately ten percent of patients visiting primary care physicians in the United States and four European countries experience RLS symptoms at least weekly, with approximately two percent of patients visiting primary care physicians suffering from symptoms severe enough to disrupt their quality of life. Patients who suffer from RLS experience an irresistible urge to move their legs. This urge is usually accompanied by unpleasant sensations of burning, creeping, tugging or tingling inside the patients' legs, ranging in severity from uncomfortable to painful. These RLS-related symptoms typically begin or worsen during periods of rest or inactivity, particularly when lying down or sitting, and may be temporarily relieved by movement such as walking or massaging the legs. Symptoms often worsen at night and disturbed sleep is a common result of RLS. Left untreated, RLS may cause exhaustion, daytime fatigue, inability to concentrate and impaired memory.

### *Current Treatments*

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

Requip (ropinirole), marketed by GSK, was the first product approved by the FDA for the treatment of RLS. In 2006, Mirapex (pramipexole), marketed by Boehringer Ingelheim, was approved by the FDA for the treatment of moderate to severe RLS. Schwarz Pharma is also developing a rotigotine transdermal patch for RLS under the trade name Neupro, for which the FDA has issued an approvable letter. The symptoms of RLS are also currently treated by dopamine agonists, opioids, benzodiazepines and anticonvulsants. While Requip and Mirapex have been shown to be effective in treating RLS, they have been associated with adverse side effects, including nausea, vomiting, orthostatic hypotension and sudden onset of sleep. In a study of patients on dopamine agonist treatments reported in the *Archives of Neurology*, approximately 48% of patients who had continued treatment for longer than six months developed augmentation, with approximately 22% of these patients having severe augmentation. Augmentation refers to the earlier onset of symptoms, increase in symptoms, and spread of

## **Table of Contents**

symptoms to involve other extremities. For these patients, physicians often add an additional, earlier dose of the existing treatment, increase dosage, or switch to an alternative therapy.

### *Attributes of JZP-7*

We are developing JZP-7 as a novel formulation incorporating a dopamine agonist to provide the effective treatment of RLS while addressing adverse events associated with current therapies. We are seeking to develop JZP-7 as a once daily formulation. We believe this formulation has the potential to significantly reduce the titration schedule associated with Requip and adverse events associated with more commonly dosed products, including nausea, vomiting, orthostatic hypotension and sudden onset of sleep. JZP-7 may also have the potential to provide extended relief of RLS for those patients needing longer symptom relief than may be provided by existing oral therapies.

### *Product Development*

We have completed development activities to select the API for this product candidate and are conducting further development activities related to formulation, safety and tolerance. We have completed a PK/PD study in healthy volunteers. These PK/PD results demonstrated that our JZP-7 product has a PK profile consistent with our development target. We intend to conduct an additional PK study in 2007 prior to commencing Phase II clinical trials for the treatment of RLS.

### *Commercialization Strategy*

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

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

We have contracted for the supply of the API in JZP-7 in sufficient quantities to complete clinical trials. We intend to seek a contract manufacturer for commercial quantities of JZP-7.

### *JZP-2 (benzodiazepine)*

We are developing JZP-2, a fast-acting formulation of a benzodiazepine, for the acute treatment of panic attacks associated with panic disorder. There are currently no products approved for the treatment of panic attacks.

*Market Opportunity*

A panic attack is an isolated period of intense fear or discomfort that is associated with numerous symptoms, including feelings of imminent danger, heart palpitations, sweating, shortness of breath, chest pain, nausea and a fear of dying. According to the National Institute of Mental Health, approximately 6.0 million people in the United States suffer from panic disorder in any given year. A panic attack typically starts without warning, building to maximum intensity within ten to 15 minutes. A panic attack is distinguished from other forms of anxiety by its intensity and its sudden occurrence. To be diagnosed with panic disorder, patients must have two or more unexpected panic attacks, and develop persistent concerns or worries about having subsequent attacks.

## **Table of Contents**

### *Current Treatments*

Currently there is no drug approved for the acute treatment of a panic attack. The current leading treatments for panic disorder are SSRIs taken prophylactically on a daily basis. Alternative treatments to SSRIs include drugs in other classes, such as benzodiazepines, tricyclic antidepressants, or TCAs and monoamine oxidase inhibitors, or MAOs. Based on PDDA data, we estimate that approximately 27% of drug usages for benzodiazepines are taken on an as-needed basis, indicating a level of ineffective treatment with SSRIs alone. In addition, patients initiating SSRI drug therapy often take several weeks to experience therapeutic effects and during this time, continue to experience panic attacks. According to an article published in the American Family Physician, approximately 30% of patients treated with SSRIs cannot tolerate these medications or will have an unfavorable or incomplete response to treatment. Adverse side effects associated with SSRIs include nausea, sleep disturbances, sexual dysfunction, weight gain, adverse drug interactions, risk of hypertension and, in adolescents, increased suicidal tendencies. Benzodiazepines are well-understood drugs, and physicians continue to prescribe them despite the availability of a number of SSRIs in the market. Long-term benzodiazepine use is considered to be safe and effective treatment for panic disorder patients who have no history of substance abuse. We believe that some physicians may prescribe oral benzodiazepines for patients to take as needed, when they feel a panic attack coming on, or during an attack. However, because the symptoms of a panic attack typically have a rapid onset and last less than 30 minutes, we believe oral benzodiazepines often do not work quickly enough to provide patients with adequate relief. In addition, patients treated with benzodiazepines often develop increased tolerance to the activity of the drug over time, requiring substantial increases in dosages to obtain and maintain clinical effectiveness.

### *Attributes of JZP-2*

We believe that JZP-2 has the potential to provide rapid relief from a panic attack and enable the patient to quickly resume functionality after an attack. We are developing JZP-2 as a fast-acting formulation of a benzodiazepine. Like other benzodiazepines, JZP-2 will likely be regulated as a controlled substance by the DEA if approved for marketing by the FDA. We believe JZP-2 could be used as an adjunct to chronic treatment with SSRIs. In addition, severe panic disorder patients continue to experience multiple panic attacks per week while on chronic SSRI treatment and other therapies. JZP-2 could be used as a supplementary therapy on an as-needed basis for patients on chronic medication who continue to experience panic attacks. Patients using JZP-2 on an as-needed basis would have reduced exposure to the API. As a result, we believe that JZP-2 has the potential to have a favorable tolerance profile.

### *Product Development*

We have developed a target formulation for JZP-2 and plan to commence one or more clinical trials of JZP-2 in 2007 with this formulation for the acute treatment of panic attacks associated with panic disorders. The first clinical trial will evaluate how fast the product gets into the bloodstream in human subjects. Subject to the successful completion of this trial, the second clinical trial will evaluate the product in patients undergoing an artificially induced panic attack. If successful, the outcome from these clinical trials will be used to determine clinical endpoints for Phase II and Phase III clinical trials. The focus of our completed and ongoing preclinical studies on JZP-2 has been to identify the preferred formulation of benzodiazepine and most effective delivery technology while balancing sedative effects, panic alleviation, risks and speed of action.

### *Commercialization Strategy*

Our marketing strategy for JZP-2 will depend on the outcome of our clinical trials, the nature of any indications JZP-2 is approved to treat, and the specialties of the physicians most likely to prescribe the product. Any sales efforts may involve the utilization of our internal sales force,

collaborations with partners, or a combination of both.



## **Table of Contents**

We have entered into an agreement with a technology provider to conduct feasibility studies associated with the formulation and method of delivery of JZP-2. If these studies are successful, we have the option to enter into a license agreement that will provide for the payment of royalties to our technology provider on commercial sales.

We currently have an agreement for supply of the API in JZP-2 and ongoing manufacture of the drug product in sufficient quantities to complete clinical trials. Pursuant to our agreement, our technology provider will manufacture commercial quantities of JZP-2.

## **New Product Candidate Identification and Development**

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

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

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

Our JZP-2, JZP-7 and JZP-8 product candidates resulted from this program. We currently have several other product candidates identified through this program in various stages of early development, including the use of sodium oxybate, the API in Xyrem, for the treatment of movement disorders. We are also conducting activities intended to develop new dosage forms of sodium oxybate.

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

## **Sales and Marketing**

We have a specialty sales force consisting of 55 full-time sales professionals, including five regional sales managers, who promote Xyrem. Our sales representatives are experienced, with an average of five years of specialty selling experience. Our sales management team has an average of nine years of specialty sales

## **Table of Contents**

management experience. Our sales force calls on neurologists, psychiatrists, pulmonologists and sleep specialists. In the near term, we anticipate more than doubling our specialty sales force to prepare for the commercial launch, subject to receipt of FDA approval, of Luvox CR, with additional sales professionals focusing on psychiatrists who treat OCD and SAD. If JZP-6 is approved by the FDA, we expect to further expand our specialty sales force to include additional sales professionals who would focus on rheumatologists treating FMS.

We have established marketing and commercial operations departments to support our sales efforts. Our marketing and commercial operations departments consist of marketing professionals who are responsible for brand management and market research, and commercial operations professionals who are responsible for business analytics and commercial technology, commercial administration, training and development, pharmacy relations and patient affairs. Our marketing team develops and implements brand strategies to maximize product uptake and adoption with our target physician audiences in accordance with our approval labeling. We expect to significantly expand commercial operations in 2007 to accommodate promotional and marketing activities necessary to prepare for the potential commercial launch of Luvox CR, including the addition of a trade relations team and a national accounts, or managed care, team. We also employ numerous third party vendors, such as advertising agencies, market research firms and suppliers of marketing and other sales support related services.

## **Medical Affairs Department**

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

## **Manufacturing**

We do not have, and do not intend to establish in the near term, any of our own manufacturing capability for our products or product candidates, or their APIs, or the capability to perform packaging of our products. We have entered into manufacturing and supply agreements with third parties for our marketed products. For each of our marketed products, we utilize a single supplier for the API and a separate drug product manufacturer. We have agreements with these suppliers and manufacturers for Xyrem, Antizol and Antizol-Vet. We supply all quantities of Xyrem to UCB and Valeant. We believe that qualified suppliers and manufacturers for our marketed products will continue to be available in the future, at a reasonable cost to us, although there can be no assurance that this will be the case.

We are also seeking, have identified or have entered into manufacturing and supply arrangements for our product candidates. In particular, if Luvox CR is approved, Solvay will supply us with the API and Elan will manufacture our commercial requirements for Luvox CR. We have contracted with our existing contract manufacturers of Xyrem for the API and drug product for our clinical requirements of JZP-6. As with Xyrem, we will be responsible for supplying JZP-6 to UCB and, if applicable, to Valeant. We are also seeking or have identified qualified suppliers and contract manufacturers for JZP-4, JZP-8, JZP-7 and JZP-2.

Because sodium oxybate is a controlled substance subject to manufacturing quotas by the DEA, our supplier and contract manufacturer of Xyrem and JZP-6 may be unable to provide us with sufficient quantities necessary to complete our clinical trials or, if approved, commercialize the product. The DEA requires substantial evidence and documentation of expected need before assigning quotas to manufacturers. Therefore, obtaining sufficient quotas can be very difficult and time consuming, which may provide a meaningful obstacle for the introduction of generic

formulations of Xyrem and the eventual introduction of generic versions of JZP-6.

## **Table of Contents**

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

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

## **Government Regulation**

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

## ***Drug Approval Process***

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

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

preclinical laboratory tests and animal tests;

submission to the FDA of an Investigational New Drug Application, or IND, for human clinical testing, which must become effective before human clinical trials commence;

adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug product for each indication;

the submission to the FDA of an NDA;

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

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

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

FDA review and approval of the NDA.

Preclinical studies may include laboratory evaluations of the product chemistry, toxicity, and formulation, as well as animal studies to assess the potential safety and efficacy of the product candidate. The conduct of the preclinical tests and formulation of the compounds for testing must comply with federal regulations and requirements. The results of the preclinical studies, together with manufacturing information and analytical data, are submitted to the FDA as part of the IND, which must become effective before clinical trials may be

---

**Table of Contents**

commenced. The IND will become effective automatically 30 days after receipt by the FDA, unless the FDA raises concerns or questions about the conduct of the clinical trials as outlined in the IND prior to that time. In this case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can proceed.

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

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

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

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

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

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

## Table of Contents

The applicant must submit to the FDA the results of the preclinical and clinical trials, together with, among other things, detailed information on the manufacture and composition of the product candidate and proposed labeling, in the form of an NDA, including payment of a user fee. The FDA reviews all NDAs submitted before it accepts them for filing and may request additional information rather than accepting an NDA for filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, the FDA has ten months in which to complete its initial review of a standard NDA and respond to the applicant, and six months for a priority NDA. The FDA does not always meet its PDUFA goal dates for standard and priority NDAs. The review process and the PDUFA goal date may be extended by three months if the FDA requests or the NDA sponsor otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date. If the FDA's evaluations of the NDA and the clinical and manufacturing procedures and facilities are favorable, the FDA may issue either an approval letter or an approvable letter, which contains the conditions that must be met in order to secure final approval of the NDA. If and when those conditions have been met to the FDA's satisfaction, the FDA will issue an approval letter, authorizing commercial marketing of the drug for certain indications. If the FDA's evaluation of the NDA submission and the clinical and manufacturing procedures and facilities is not favorable, the FDA may refuse to approve the NDA and issue a not approvable letter. Sponsors that receive either an approvable letter or a not approvable letter may submit to the FDA information that represents a complete response to the issues identified by the FDA. Such resubmissions are classified under PDUFA as either Class 1 or Class 2. The classification of a resubmission is based on the information submitted by an applicant in response to an action letter. Under the goals and policies agreed to by the FDA under PDUFA, the FDA has two months to review a Class 1 resubmission, and six months to review a Class 2 resubmission. The FDA may also refer an application to the appropriate advisory committee, typically a panel of clinicians, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendations of the advisory committee.

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

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

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

report certain adverse reactions to the FDA;

submit annual and periodic reports summarizing product information and safety data;

comply with certain requirements concerning advertising and promotional labeling for their products; and

continue to have quality control and manufacturing procedures conform to cGMP after approval.



## **Table of Contents**

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

### ***Section 505(b)(1) New Drug Applications***

The approval process described above is premised on the applicant being the owner of, or having obtained a right of reference to, all of the data required to prove the safety and effectiveness of a drug product. This type of marketing application, sometimes referred to as a full or stand-alone NDA, is governed by Section 505(b)(1) of the FDCA. A Section 505(b)(1) NDA contains full reports of investigations of safety and effectiveness, which includes the results of preclinical studies and clinical trials, together with detailed information on the manufacture and composition of the product, in addition to other information.

### ***Section 505(b)(2) New Drug Applications***

As an alternate path to FDA approval of, for example, new indications or improved formulations of previously-approved products, a company may submit a Section 505(b)(2) NDA, instead of a stand-alone or full NDA filing under Section 505(b)(1). Section 505(b)(2) of the FDCA was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch-Waxman Act. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. For example, the Hatch-Waxman Act permits the applicant to rely upon the FDA's findings of safety and effectiveness for an approved product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new drug product for all or some of the label indications for which the referenced product has been approved, or for a new indication sought by the Section 505(b)(2) applicant.

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

the listed patent has expired;

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

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

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

If the applicant has provided a paragraph IV certification to the FDA, the applicant must also send notice of the paragraph IV certification to the holder of the NDA and the relevant patent holders once the 505(b)(2) NDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a legal challenge to the paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of their receipt of a paragraph IV certification automatically prevents the FDA from approving the Section 505(b)(2) NDA until the

## **Table of Contents**

earliest of 30 months, expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the Section 505(b)(2) applicant. For drugs with five-year exclusivity, such as Xyrem, if an action for patent infringement is initiated after year four of that exclusivity period, then the 30-month stay period is extended by such amount of time so that 7.5 years has elapsed since the approval of the NDA with the five-year exclusivity period. This period could be extended by six months if the NDA sponsor obtains pediatric exclusivity. Thus, a Section 505(b)(2) applicant may invest a significant amount of time and expense in the development of its products only to be subject to significant delay and patent litigation before its products may be commercialized. Alternatively, if the listed patent holder does not file a patent infringement lawsuit within the required 45-day period, the applicant's 505(b)(2) NDA will not be subject to the 30-month stay.

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

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

### ***The Hatch-Waxman Act***

Under the Hatch-Waxman Act, newly-approved drugs and indications may benefit from a statutory period of non-patent marketing exclusivity. The Hatch-Waxman Act provides five-year marketing exclusivity to the first applicant to gain approval of an NDA for a new chemical entity, meaning that the FDA has not previously approved any other new drug containing the same active moiety. The Hatch-Waxman Act prohibits the submission of an abbreviated new drug application, or ANDA, or a Section 505(b)(2) NDA for another version of such drug during the five-year exclusive period; however, as explained above, submission of an ANDA or Section 505(b)(2) NDA containing a paragraph IV certification is permitted after four years, which may trigger a 30-month stay of approval of the ANDA or Section 505(b)(2) NDA. Protection under the Hatch-Waxman Act will not prevent the submission or approval of another full NDA; however, the applicant would be required to conduct its own preclinical and adequate and well-controlled clinical trials to demonstrate safety and effectiveness. The Hatch-Waxman Act also provides three years of marketing exclusivity for the approval of new and supplemental NDAs, including Section 505(b)(2) NDAs, for, among other things, new indications, dosages, or strengths of an existing drug, if new clinical investigations that were conducted or sponsored by the applicant are determined by the FDA to be essential to the approval of the application.

In addition to non-patent marketing exclusivity, the Hatch-Waxman Act amended the FDCA to require each NDA sponsor to submit with its application information on any patent that claims the API, drug product (formulation and composition), and method-of-use for which the applicant submitted the NDA and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. Generic applicants that wish to rely on the approval of a drug listed in the Orange Book must certify to each listed patent, as discussed above. We intend to submit for Orange Book listing all relevant patents for our product candidates, and to vigorously defend any Orange Book-listed patents for our approved drug products.

The Hatch-Waxman Act also permits a patent term extension of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, a patent term extension cannot extend the remaining term of a patent beyond a total of 14 years after the FDA approves a marketing application. The patent term extension period is generally equal to the sum of one-half the time between the effective date of an IND and the submission date of an NDA, and all of the time between the submission date of an NDA and the approval of that application, up to a total of five years. Only one patent applicable to an approved drug, that represents the first commercial marketing of that API, is eligible for the extension, and it



## **Table of Contents**

must be applied for prior to expiration of the patent. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for patent term extension. We will consider applying for a patent term extension for some of our patents, to add patent life beyond the expiration date, depending on our ability to meet certain legal requirements permitting such extension, and the expected length of clinical trials and other factors involved in the submission of an NDA.

### ***Orphan Drug Designation and Exclusivity***

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

Xyrem is currently protected by five years of new chemical entity exclusivity, which expires in July 2007. The FDA designated and approved Xyrem as an orphan drug for each of cataplexy and excessive daytime sleepiness in patients with narcolepsy. The periods of orphan drug exclusivity, which run concurrently with the period of five-year new chemical entity exclusivity, expire in July 2009 and November 2012, respectively for cataplexy and excessive daytime sleepiness in patients with narcolepsy. We anticipate receiving three years of marketing exclusivity for Luvox CR if the FDA approves the marketing application for Luvox CR, and if the FDA determines that the requirements for granting three-year exclusivity are met.

### ***Pediatric Exclusivity***

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

### ***Fast Track Designation***

The FDA's fast track program is intended to facilitate the development and to expedite the review of drugs that are intended for the treatment of a serious or life-threatening condition and that demonstrate the potential to address unmet medical needs. Under the fast track program, applicants

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

may seek traditional approval for a product based on data demonstrating an effect on a clinically meaningful endpoint, or approval based on a well-established surrogate endpoint. The sponsor of a new drug candidate may request the FDA to designate the drug

## **Table of Contents**

candidate for a specific indication as a fast track drug at the time of original submission of its IND, or at any time thereafter prior to receiving marketing approval of a marketing application. The FDA will determine if the drug candidate qualifies for fast track designation within 60 days of receipt of the sponsor's request.

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

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

## ***Other Regulatory Requirements***

In addition to regulation by the FDA and certain state regulatory agencies, the DEA imposes various registration, recordkeeping and reporting requirements, procurement and manufacturing quotas, labeling and packaging requirements, security controls and a restriction on prescription refills on certain pharmaceutical products under the Controlled Substances Act. A principal factor in determining the particular requirements, if any, applicable to a product is the actual or potential abuse profile. The DEA regulates drug substances as Schedule I, II, III, IV or V substances, with Schedule I substances considered to present the highest risk of substance abuse and Schedule V substances the lowest risk. Sodium oxybate in its base form is regulated by the DEA as a Schedule I controlled substance but when contained in a drug product approved by FDA it is regulated as a Schedule III controlled substance. Xyrem is a Schedule III controlled substance and JZP-6, along with certain of our early-stage product candidates, contains sodium oxybate. These product candidates, if approved for marketing by FDA, will also likely be Schedule III controlled substances. In addition, JZP-8, JZP-2 and certain of our early-stage product candidates will likely be regulated as controlled substances if approved for marketing by the FDA. Controlled substances are subject to DEA regulations relating to manufacturing, storage, distribution and physician prescription procedures, and the DEA regulates the amount of the scheduled substance that would be available for clinical trials and commercial distribution. Sodium oxybate, as a Schedule I substance, is subject to additional controls, including quotas on the amount of product that can be manufactured. As a Schedule III drug, Xyrem is subject to limitations on prescription refills. The third parties who perform our clinical and commercial manufacturing for Xyrem and JZP-6 have received necessary registrations from the DEA. The DEA periodically inspects facilities for compliance with its rules and regulations. Failure to comply with current and future regulations of the DEA could lead to a variety of sanctions, including revocation or denial of renewal of DEA registrations, fines, injunctions, or civil or criminal penalties, and could harm our business and financial condition.

We are also subject to a variety of foreign regulations governing clinical trials and the marketing of other products. Outside of the United States, our ability to market a product depends upon receiving a marketing authorization from the appropriate regulatory authorities. The requirements governing the conduct of clinical trials, marketing authorization, pricing and reimbursement vary widely from country to country. In any country, however, we will only be permitted to commercialize our products if the appropriate regulatory authority is satisfied that we have presented adequate evidence of safety, quality and efficacy. Whether or not FDA approval has been obtained, approval of a product by the comparable regulatory authorities of foreign countries must be obtained prior to the commencement of marketing of the product in those countries. The time needed to secure approval may be longer or shorter than that required for FDA approval. The regulatory approval and oversight





## **Table of Contents**

process in other countries includes all of the risks associated with regulation by the FDA and certain state regulatory agencies as described above.

### **Pharmaceutical Pricing and Reimbursement**

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

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

controls on government funded reimbursement for drugs;

controls on healthcare providers;

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

reform of drug importation laws; and

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

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

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

**Patents and Proprietary Rights**

We actively seek to patent, or to obtain licenses to or to acquire third party patents, to protect our products, inventions and improvements that we consider important to the development of our business. We own seven issued U.S. patents. In addition to the issued U.S. patents, we own or have rights to 13 pending U.S. patent applications and more than 100 issued and pending foreign patents and patent applications. Our owned and licensed patents and patent applications cover formulations of our products and product candidates, uses of our products and product candidates to treat particular conditions, drug delivery technologies and delivery profiles

**Table of Contents**

relating to our products and product candidates and methods for producing our products and product candidates. However, patent protection is not available for the APIs in most of our products and product candidates, including Xyrem, Luvox CR and JZP-6. Patents extend for varying periods according to the date of the patent filing or grant and the legal term of patents in the various countries where patent protection is obtained. The actual protection afforded by a patent, which can vary from country to country, depends on the type of patent, the scope of its coverage and the availability of legal remedies in the country. The patents and patent applications that relate to our products and product candidates include the following:

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

*Luvox CR.* Luvox CR is covered by a U.S. patent application filed by Elan with claims covering the orally administered formulation of extended release fluvoxamine that requires the release of fluvoxamine over a period of not less than 12 hours that, if issued, would expire on May 10, 2020.

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

*JZP-4.* JZP-4 is covered by a U.S. composition of matter patent that we acquired from GSK that will expire on February 26, 2018. The JZP-4 composition of matter is covered by patents in 52 other countries that expire in 2018. In addition, we hold a U.S. patent that covers the use of JZP-4 for the treatment of bipolar disorder, pain or functional bowel disorder that will expire on February 26, 2018, and a U.S. patent that covers the preparation of the API in JZP-4 that will expire on May 2, 2021. Further, we have filed a U.S. patent application with claims covering a sustained release composition for delivering JZP-4 that, if issued, would expire on February 14, 2026.

*JZP-8.* We have filed a provisional U.S. patent application with claims covering JZP-8. A patent claiming priority from this application would, if issued, expire in 2027. The claims do not cover the JZP-8 composition of matter.

*JZP-7.* We have filed a provisional U.S. patent application with claims covering JZP-7. A patent claiming priority from this application would, if issued, expire in 2027. The claims do not cover the JZP-7 composition of matter.

*JZP-2.* We have an option for an exclusive license to four U.S. formulation patents covering JZP-2 from the technology provider with which we are conducting feasibility studies associated with JZP-2. These patents will expire on August 1, 2017.

Because the patent positions of pharmaceutical companies are highly uncertain and involve complex legal and factual questions, the patents we own and license, or any further patents we may own or license, may not prevent other companies from developing similar or therapeutically equivalent products or ensure that others will not be issued patents that may prevent the sale of our products or require licensing and the payment of significant fees or royalties. In addition, we cannot be certain that any of our patent applications, or those of our licensors, will result in issued patents. Furthermore, to the extent that any of our future products or methods is not patentable or infringe the patents of third parties, or in the event that our patents or future patents fail to give us an exclusive position in the subject matter claimed by those patents, our business could be adversely affected. We may be unable to avoid infringement of third party patents and may have to obtain a license, defend an infringement action, or challenge the validity of the patents in court. A license may be unavailable on terms and conditions acceptable to us, if at all. Patent litigation is costly and time consuming, and we may be unable to prevail in any such patent litigation or devote sufficient resources to even pursue such litigation. If we do not obtain a license under necessary patents, are found liable for infringement, or are not able to have such patents



## **Table of Contents**

declared invalid, we may be liable for significant money damages, encounter significant delays in bringing products to market, or be precluded from participating in the manufacture, use or sale of products or methods of treatment requiring such licenses.

We have also applied for a number of trademarks and service marks to further protect the proprietary position of our products. We own 25 registered trademarks and service marks in the United States and 29 registered trademarks and service marks in other countries. We also have 13 pending trademark and service mark applications in the United States and 11 pending trademark and service mark applications in other countries. We also rely on our trade secrets and those of our licensors, as well as other unpatented proprietary information, to protect our products. To the extent that our products have a competitive edge as a result of our reliance on trade secrets and unpatented know-how, our competitive position may be compromised if others independently develop products using the same or similar technologies or trade secrets. We seek to protect our trade secrets and proprietary knowledge in part through confidentiality agreements with our employees, consultants, advisors and collaboration partners. Nevertheless, these agreements may not effectively prevent disclosure of our confidential information and may not provide us with an adequate remedy in the event of unauthorized disclosure of our confidential information. If our employees, consultants, advisors or collaboration partners develop inventions or processes independently or jointly with us that may be applicable to our products under development, disputes may arise about ownership or proprietary rights to those inventions and processes. Such inventions and processes will not necessarily become our property, but may remain the property of those third parties or their employers. Protracted and costly litigation could be necessary to enforce and determine the scope of our proprietary rights. Failure to obtain or maintain patent and trade secret protection, for any reason, could have a material adverse effect on our business.

## **Competition**

The pharmaceutical industry is highly competitive and characterized by a number of established, large pharmaceutical companies, as well as smaller companies. Some of these companies have financial resources, marketing capabilities and experience in obtaining regulatory approvals for product candidates, product line acquisition capabilities and market share substantially greater than ours. Our products and product candidates may also compete with new products currently under development by others, alternate therapies during the period of patent protection, and generic equivalents once patent protection is no longer available. Any products that we develop are likely to be in a highly competitive market and many of our competitors may succeed in developing products that may render our products obsolete or noncompetitive. For a detailed description of current products that compete with Xyrem, please see [Marketed Products Xyrem \(sodium oxybate oral solution\) Other Treatments](#). For detailed descriptions of current products that may be competitive with our product candidates, please see the descriptions under the headings [Current Treatments](#) for each our product candidates described under [Product Candidates](#). With respect to our current and potential future product candidates, we believe that our ability to successfully compete will depend on, among other things:

efficacy, safety and reliability of our product candidates;

the timing and scope of regulatory approvals;

product acceptance by physicians and other health care providers;

our ability to expand and grow our specialty sales force;

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

the speed at which we develop product candidates;

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

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

obtaining reimbursement for product use in approved indications;

## **Table of Contents**

our ability to recruit and retain skilled employees; and

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

Our ability to remain competitive in the marketplace is also impacted by our ability to compete successfully with other specialty pharmaceutical companies for product and product candidate acquisition and in-licensing opportunities.

## **Employees**

As of January 31, 2007, we had 185 full-time employees. Of the full-time employees, 74 were engaged in sales and marketing, 69 were engaged in product development and clinical activities, and 42 were engaged in general and administrative activities. We plan to continue to expand our product development programs and product commercialization activities. To support this growth, we will need to expand managerial, operations, development, manufacturing, regulatory, sales, marketing, financial and other functions. In particular, our potential future commercial products, including Luvox CR and JZP-6, will require a significantly expanded sales force and a significant sales support organization. None of our employees is represented by a labor union, and we consider our employee relations to be good. We currently utilize TriNet Employer Group, Inc., an employer services company, to provide human resource services. TriNet is the employer of record for payroll, benefits, employee relations and other employment-related administration.

## **Facilities**

Our corporate headquarters are located in Palo Alto, California, where we occupy approximately 44,000 square feet of office space. The annual lease payments for corporate headquarters building are approximately \$735,000. Thereafter, at our option, we may extend the term for up to an additional nine years to August 2017. We also lease approximately 13,000 square feet of additional office space in Palo Alto, California. The annual lease payments for this space are approximately \$460,000. The fixed lease term expires in August 2008, after which we may extend the term for up to six months subject to certain conditions. We believe that the facilities that we currently lease are sufficient for approximately the next year and that anticipated future growth thereafter can be accommodated by leasing additional space near our current facilities.

## **Legal Proceedings**

In April 2006, a physician who was a speaker for Orphan Medical (and for a short time for us), was indicted by a federal grand jury in U.S. District Court for the Eastern District of New York. The indictment alleges that the physician engaged in a scheme with Orphan Medical sales representatives and other Orphan Medical employees to promote and obtain reimbursement for Xyrem for medical uses not approved for marketing by the FDA. Also in April 2006, the U.S. Department of Justice, acting through the U.S. Attorney for the Eastern District of New York, issued to us and Orphan Medical subpoenas for documents relating to Xyrem. We are cooperating with this investigation and have provided documents to the U.S. Attorney's Office. As a result of our acquisition of Orphan Medical, the U.S. government may seek to hold us responsible for Orphan Medical's conduct. We have been in discussions with the U.S. Attorney's Office regarding the possible settlement of any potential U.S. government claims against Orphan Medical and/or us. We cannot assure you that any such settlement will be reached on reasonable terms, or at all, and if a settlement is reached, we may, among other things, be required to make significant monetary payments and to undertake extensive remedial compliance programs at significant expense to us. Even if we reach a settlement agreement with the U.S. Attorney's Office, we might also be subject to regulatory and/or enforcement action by federal agencies, private insurers and states' attorneys general. If we do not reach a settlement we could be required to spend significant amounts to defend ourselves and Orphan Medical. These matters may involve the filing of criminal charges, as well as criminal and/or civil fines and penalties, against us, Orphan Medical, or both. We

cannot predict or determine the outcome of this matter or reasonably estimate the amount of any fines or penalties that might result from an adverse



**Table of Contents**

outcome. However, an adverse outcome could have a material adverse effect on our financial position, liquidity and results of operations.

In April 2006, Little Gem Life Sciences LLC, individually and purportedly on behalf of a class of persons similarly situated, filed a complaint against Orphan Medical, John H. Bullion, and Timothy G. McGrath in the U.S. District Court for the District of Minnesota. The case is captioned Little Gem Life Sciences LLC v. Orphan Medical, Inc., John H. Bullion, and Timothy G. McGrath, Civ. Action No. 06-CV-1377 (ADM/AJB). The complaint alleges that the defendants made false and misleading statements in the proxy statement prepared by Orphan Medical in connection with the solicitation of proxies to be voted at the special meeting of Orphan Medical stockholders held on June 22, 2005 for the purpose of considering and voting upon a proposal to adopt the definitive merger agreement pursuant to which we acquired Orphan Medical. The plaintiff seeks damages for itself and the putative class, in an unspecified amount, together with interest, litigation costs and expenses, and its attorneys' fees and other disbursements, as well as unspecified other and further relief. On October 25, 2006, the defendants filed a motion to dismiss the complaint and oral argument on the motion was heard by the U.S. District Court for the District of Minnesota. On February 16, 2007, the U.S. District Court for the District of Minnesota granted the defendants' motion to dismiss the complaint, but granted the plaintiff a one-month leave to amend the plaintiff's complaint. We are unable to predict the outcome of this lawsuit and amounts ultimately payable, if any, resulting from an adverse outcome in this lawsuit cannot be reasonably estimated at this time.

**Table of Contents****MANAGEMENT****Directors and Executive Officers**

The following table sets forth certain information concerning our directors and executive officers as of March 1, 2007:

<b>Name</b>	<b>Age</b>	<b>Position</b>
Bruce C. Cozadd	43	Executive Chairman and Director
Samuel R. Saks, M.D.	52	Chief Executive Officer and Director
Robert M. Myers	43	President
Matthew K. Fust	42	Senior Vice President and Chief Financial Officer
Carol A. Gamble	54	Senior Vice President, General Counsel and Corporate Secretary
Janne L.T. Wissel	51	Senior Vice President of Development
Adam H. Clammer	37	Director
Samuel D. Colella(2)(3)	67	Director
Bryan C. Cressey	57	Director
Michael W. Michelson(2)	55	Director
James C. Momtazee(1)(3)	35	Director
Kenneth W. O Keefe(1)	40	Director
Alan M. Sebulsky(1)	48	Director
James B. Tananbaum, M.D.(2)	43	Director

(1) Member of audit committee.

(2) Member of compensation committee.

(3) Member of nominating and corporate governance committee.

**Executive Officers**

*Bruce C. Cozadd* is a co-founder and has served as our Executive Chairman since 2003. From 2001 to 2003, he served as a consultant to companies in the biopharmaceutical industry and worked on a part-time basis for Prospect Ventures Partners and Versant Ventures, both venture capital firms. 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, The Nueva School and Stanford Hospital and Clinics, both non-profit organizations, as well as the Stanford Molecular Imaging Advisory Board. He received a B.S. from Yale University and an M.B.A. from the Stanford Graduate School of Business.

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

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

*Robert M. Myers* is a co-founder and was appointed as our President in March 2007. From 2003 until 2007, he served as our Executive Vice President and Chief Business Officer. From 2002 until 2003, he served as Executive Vice President, Pharmaceuticals at Exelixis, Inc., a biotechnology company. He previously held various positions with ALZA Corporation from 1992 to 2001, most recently as its Senior Vice President.

## **Table of Contents**

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.

*Matthew K. Fust* was appointed as our Senior Vice President in 2004 and has served as our Chief Financial Officer since 2003. From 2002 to 2003, he served as Chief Financial Officer at Perlegen Sciences, a biopharmaceutical company. He previously held various positions with ALZA Corporation from 1996 to 2002, most recently as its Chief Financial Officer. He serves on the board of Sunesis Pharmaceuticals, a biopharmaceutical company. He received a B.A. from the University of Minnesota and an M.B.A. from the Stanford Graduate School of Business.

*Carol A. Gamble* was appointed as our 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, Inc., a biopharmaceutical company acquired by Nektar Therapeutics. From 1988 to 2000, she held various positions with ALZA Corporation, most recently as its Senior Vice President and Chief Corporate Counsel. She received a B.S. from Syracuse University and a J.D. from the University of California, Berkeley, Boalt Hall.

*Janne L. T. Wissel* has served as our Senior Vice President of Development since 2004. From 2003 to 2004, she served as our Vice President of Development. From 1981 to 2003, she held various positions at ALZA Corporation, most recently as its Senior Vice President, Operations, with responsibility for ALZA Corporation's global regulatory, quality, general operations and manufacturing activities. She has led the development, registration and launch of more than 20 pharmaceutical products in the neurology, pediatric psychiatry, endocrinology, urology and oncology areas. She received a B.S. from the University of California, Davis and an M.B.A. from the University of Phoenix.

## **Directors**

*Adam H. Clammer* has served as a member of our board of directors since 2004. Since 1995, he has been employed by Kohlberg Kravis Roberts & Co. L.P., where he is a Member of its general partner, KKR & Co. L.L.C. He serves on the boards of MedCath Corporation, a cardiovascular services company and several privately-held technology companies. He received a B.S. from the University of California 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 pharmaceutical company, Genomic Health Inc., a molecular diagnostics company, Symyx Technologies, Inc., a research technology company, Thermage, Inc., a aesthetic medicine 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.

*Bryan C. Cressey* has served as a member of our board of directors since 2006. Since 1998, he has been a Partner of Thoma Cressey Bravo, Inc., a private equity firm, of which he is a founder. He serves on the boards of Belden CDT, Inc., a division of Belden Cable, a 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.

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

*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 of its general partner, KKR & Co. L.L.C. and also serves on KKR's Investment and Operating committees. He serves on the boards of Alliance Imaging, Inc., a diagnostic imaging services company, HCA Inc., a healthcare services company, and Accellant

## **Table of Contents**

Inc., a manufacturing and engineering services 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 Director. He serves on the boards of Alliance Imaging, Inc., a diagnostic imaging services company, 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.

*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., a biopharmaceutical company, Infinity Pharmaceuticals, Inc., a drug discovery company, Novavax, Inc., a biotechnology company, and Vanda Pharmaceuticals Inc., a biopharmaceutical company, as well as several private 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.

## **Board Composition**

Our board of directors currently consists of ten members. Our board of directors has determined that all of our directors, other than Mr. Cozadd and Dr. Saks, are independent within the meaning of applicable NASDAQ listing standards.

Effective upon the completion of this offering, we will divide our board of directors into three classes, as follows:

Class I, which will consist of \_\_\_\_\_, and whose term will expire at our annual meeting of stockholders to be held in 2008;

Class II, which will consist of \_\_\_\_\_, and whose term will expire at our annual meeting of stockholders to be held in 2009; and

Class III, which will consist of \_\_\_\_\_, and whose term will expire at our annual meeting of stockholders to be held in 2010.

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

At each annual meeting of stockholders to be held after the initial classification, the successors to directors whose terms then expire will serve until their successors are duly elected and qualified at the third annual meeting following their election. The authorized number of directors may be changed only by resolution of the board of directors. Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. This classification of the board of directors may have the effect of delaying or preventing changes in our control or management. Under Delaware law, our directors may be removed for cause by the affirmative vote of the holders of a majority of our voting stock.

## **Table of Contents**

### **Board Committees**

Our board of directors currently has an audit committee, a compensation committee and a nominating and corporate governance committee. The composition and primary responsibilities of each committee are described below.

*Audit Committee.* The members of our audit committee are Messrs. Momtazee, O Keefe and Sebulsky. Mr. O Keefe chairs the audit committee. Our board of directors has determined that Messrs. O Keefe and Sebulsky meet the independence requirements of Rule 10A-3 of the Exchange Act and NASDAQ listing standards. Our board of directors has also determined that Mr. O Keefe qualifies as an audit committee financial expert within the meaning of SEC regulations and the NASDAQ listing standards. In making this determination, our board of directors considered the nature and scope of experience Mr. O Keefe has had with reporting companies and his employment in the corporate finance sector.

The primary purpose of the audit committee is to discharge the responsibilities of our board of directors with respect to our accounting, financial and other reporting and internal control practices and to oversee our independent registered public accounting firm. Specific responsibilities of our audit committee include:

evaluating the performance of our independent registered public accounting firm and determining whether to retain or terminate their services;

determining and pre-approving the engagement of our independent registered public accounting firm to perform audit services and any permissible non-audit services, other than immaterial aggregate amounts of non-audit services as excepted under applicable laws and rules;

reviewing and discussing with management and our independent registered public accounting firm the results of the annual audit and the independent registered public accounting firm's review of our annual and quarterly financial statements and reports;

reviewing with management and our independent registered public accounting firm significant issues that arise regarding accounting principles and financial statement presentation;

conferring with management and our independent registered public accounting firm regarding the scope, adequacy and effectiveness of our internal control over financial reporting; and

establishing procedures for the receipt, retention and treatment of complaints received by us regarding accounting, internal control or auditing matters.

*Compensation Committee.* The members of our compensation committee are Messrs. Colella and Michelson and Dr. Tananbaum. Mr. Michelson chairs the compensation committee. Each member of the compensation committee is independent within the meaning of applicable NASDAQ listing standards, is a non-employee director as defined in Rule 16b-3 promulgated under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and is an outside director as that term is defined in Section 162(m) of the Internal Revenue Code of 1986, as amended. The purpose of our compensation committee is to discharge the responsibilities of our board of directors to oversee our compensation policies, plans and programs and to review and determine the compensation to be paid to our executive officers and other senior management. Specific responsibilities of our compensation committee include:



determining the compensation and other terms of employment of our executive officers and senior management and reviewing and approving corporate performance goals and objectives relevant to such compensation;

evaluating and recommending to our board of directors the compensation plans and programs advisable for us, and evaluating and recommending the modification or termination of existing plans and programs; and

reviewing and approving the terms of any employment agreements, severance arrangements, change of control protections and any other compensatory arrangements for our executive officers and other senior management.

## **Table of Contents**

*Nominating and Corporate Governance Committee.* The members of our nominating and corporate governance committee are Messrs. Colella and Momtazee. Mr. Colella chairs the nominating and corporate governance committee. Each member of the nominating and corporate governance committee is independent within the meaning of applicable NASDAQ listing standards. The specific responsibilities of our nominating and corporate governance committee include:

identifying, reviewing, evaluating and recommending for selection candidates for membership to our board of directors;

reviewing, evaluating and considering the recommendation for nomination of incumbent members of our board of directors for reelection to our board of directors and monitoring the size of our board of directors;

evaluating nominations by stockholders of candidates for election to our board of directors;

reviewing, discussing and reporting to our board of directors an assessment of our board's performance;

recommending director compensation; and

determining adherence to our corporate governance documents.

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

In 2006, our compensation committee consisted of Messrs. Colella and Michelson and Dr. Tananbaum. David Mayer, one of our former directors, served on the compensation committee until his resignation from our board of directors in October 2006. None of the members of the compensation committee is currently or has been at any time one of our officers or employees. None of our officers currently serves, or has served during the last completed fiscal year, as a member of the board of directors or compensation committee of any entity that has one or more officers serving as a member of our board of directors or compensation committee.

## **Executive Compensation**

### ***Compensation Discussion and Analysis***

#### *Overview*

Our executive compensation program is designed to help us attract, as needed, talented individuals to manage and operate all aspects of our business, to reward those individuals fairly over time, and to retain those individuals who continue to meet our high expectations. The goals of our executive compensation program are to align our executive officers' compensation with our business objectives and the interests of our stockholders, to incentivize and reward our executive officers for our success, and to reflect the teamwork philosophy of our executive management team. Specifically, we have created an executive compensation program that combines short and long-term components, cash and

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

equity, and fixed and contingent payments, in the proportions that we believe are the most appropriate to incentivize and reward our executive officers for achieving our objectives. Our executive compensation program is also intended to make us competitive in the San Francisco Bay Area, and in the pharmaceutical and biotechnology industry, where there is significant competition for talented employees, and to be fair relative to other professionals within our organization. We believe that we must provide competitive compensation packages to attract and retain executive officers and to help our executive management function as a stable team over the longer term.

As discussed in further detail below, our executive compensation program consists of the following three principal components:

*Base Salary.* Base salary for our executive officers is set each year, effective March 1. For 2006, our executive officers' base salaries were set by reviewing their then current salaries in light of 2005

## Table of Contents

company performance and individual performance, base salary benchmarking against comparable companies, and general economic factors. We also considered, as we have since our inception, compensation equity among our executive officers.

*Bonus.* We have an annual cash bonus plan for our employees under which bonuses may be paid shortly after the end of each year, at the discretion of our board of directors, based on our performance in meeting our corporate objectives for the year and each individual's performance and contribution in meeting our corporate objectives.

*Stock Option Grants.* Our employees and executive officers receive stock option grants as long-term incentives to ensure that a portion of compensation is linked to our long-term success.

The compensation committee does not have any formal policies for allocating compensation among salary, bonus and stock option grants. However, the compensation of our executive officers is based in part on the terms of employment agreements we entered into with each of our executive officers in February 2004 which set forth the initial base salaries for our executive officers as well as the target bonuses under our annual cash bonus plan (subject, in each case, to increases approved by our board of directors or compensation committee).

### *Role of the Compensation Committee in Setting Executive Compensation*

The compensation committee determines the salary, annual cash bonus awards and stock option grants for our executive officers. The compensation committee considers recommendations from Samuel Saks, our Chief Executive Officer, and Bruce Cozadd, our Executive Chairman, in determining executive compensation. While Dr. Saks and Mr. Cozadd discuss their recommendations with the compensation committee, they do not participate in determining their own compensation or that of one another. In making their recommendations, Dr. Saks and Mr. Cozadd receive input from our Human Resources department and have access to various third party compensation surveys and compensation data of publicly-traded we obtained from SEC filings. This information is also available to our compensation committee. Carol Gamble, our General Counsel, participates in compensation committee meetings, but does not participate in any discussions of her own compensation. None of our other executive officers participates in the compensation committee's executive compensation discussions. The compensation committee does not delegate any of its functions to others in determining executive compensation.

The compensation committee has not historically engaged consultants with respect to executive compensation matters. However, the compensation committee engaged Compensia, Inc., a compensation consulting firm located in San Jose, California, to provide the compensation committee with certain benchmarking material to assist it in determining appropriate salary, bonus and long-term equity compensation for our executive officers for 2007. Compensia provided the compensation committee with compensation data for 17 publicly-traded companies in the pharmaceuticals and biotechnology industry, some smaller than our company, some of similar size, and some larger, including Alexza Pharmaceuticals, Inc., Alkermes, Inc., CV Therapeutics, Inc., Endo Pharmaceuticals Holdings, Inc., Indevus Pharmaceuticals, Inc., InterMune, Inc., Medics Pharmaceutical Corporation and Theravance, Inc. The companies in the survey were chosen because they were generally similar to ours in terms of industry, capital structure, financial attributes, geographic location and/or competition for talent. However, because certain aspects of our business and management team are unique, the compensation committee used the peer company data as one resource in determining executive compensation for 2007 and not as a stand-alone tool. The compensation committee reviewed the data from Compensia and discussed it, along with other publicly-available compensation data, with Compensia, Dr. Saks and Mr. Cozadd in determining compensation for our executive officers for 2007.

### *Executive Compensation Program*

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

Our executive compensation program consists of three principal components: base salary, annual cash bonuses (if approved by our board of directors) and long-term incentive compensation in the form of stock

## Table of Contents

options. Our executive officers are also eligible to participate, on the same basis as other employees, in our 401(k) plan and our other benefit programs generally available to all employees. Our executive officers do not receive any perquisites.

*Base Salary.* Each of our executive officers entered into an employment agreement with us in February 2004 that provides for an initial base salary, subject to annual increases determined by the compensation committee. We review company and individual performance annually, shortly after the end of each calendar year. As discussed above, Dr. Saks and Mr. Cozadd review the executive officers' salaries with the compensation committee in connection with that annual performance review. For 2006, our executive officers' base salaries were set by reviewing their then current salaries against company and individual performance, base salary benchmarking against comparable companies, as well as general economic factors. We also considered, as we have since our inception, compensation equity among our executive officers. Since our inception, we have reviewed the compensation of our executive officers as a group, and have minimized the differences among their salaries. One of the core values of our company is fostering the teamwork philosophy of our management team, which is reflected in our policy of providing compensation equity among our executive officers.

Our compensation committee targets our executives' base salaries as a group in the 75th percentile of salaries for executive officers in similar positions with similar responsibilities at companies of similar size in our industry that have both commercial products and significant product development activities. Our compensation committee believes this is appropriate for several reasons. We have a complex business model and are pursuing multiple commercial and product development opportunities simultaneously with a relatively small organization relative to our level of investment in research and development. We do not have laboratories or manufacturing facilities, and therefore we conduct our development, manufacturing and clinical activities through arrangements with third parties. As a result, our executives are required to manage both internal and significant external resources. Competition for executive talent is intense in our industry and in our geographic area. Our executives have many years of valuable experience in our industry, and their continued leadership is critical to our short-term and long-term success.

*Cash Bonuses.* We have an annual cash bonus plan under which cash bonuses may be paid annually to all of our employees, including our executive officers, shortly after the end of the calendar year. Target bonus levels under the plan are assigned based on various categories of employees and with respect to our executive officers, are based on the terms of the employment agreements we entered into with them. For 2006, the target bonus level for our Executive Chairman, Chief Executive Officer and Executive Vice President was 50% of base salary; for Senior Vice Presidents, the target was 40% of salary; for Vice Presidents, 20-35% of salary; and lower percentage ranges for directors, managers and others. The actual bonus awarded in any year, if any, may be more or less than the target, depending on individual performance and the achievement of our corporate objectives. Whether or not a bonus is paid for any year is within the discretion of our board of directors. Our compensation committee also determines the size of the total bonus pool under the plan, which is based in large part on our board of directors' determination of our success in achieving our corporate objectives for the plan year. The compensation committee determines the portion of the pool, if any, that will be allocated to the executive officers as a group and the bonuses for each of our executive officers and vice presidents. Dr. Saks and Mr. Cozadd provide input to the compensation committee with respect to bonuses for executive officers.

For 2006, our corporate objectives fell generally in the following categories: achieving certain sales targets, reaching certain development milestones, achieving certain financial targets (for example, spending and EBITDA), completing important milestones in employee training and development and achieving and sustaining company-wide ethical and compliant behavior. The bonus plan does not give a particular weight to any particular corporate objective, nor does it set any formula for determining bonuses. Each employee, including each executive officer, has individual objectives for the year which are designed to contribute to the achievement of our corporate objectives.

The compensation committee has not determined whether it would attempt to recover bonuses from our executive officers if the performance objectives that led to the bonus determination were to be restated, or found

---

**Table of Contents**

not to have been met to the extent originally believed by the compensation committee. However, as a public company, if we are required to restate our financial results due to our material noncompliance with any financial reporting requirements under the federal securities laws, as a result of misconduct, our Chief Executive Officer and Chief Financial Officer may be legally required to reimburse us for any bonus or other incentive-based or equity-based compensation they receive in accordance with the provisions of Section 304 of the Sarbanes-Oxley Act of 2002.

We have not paid any significant signing or promotion bonuses to our executive officers, nor have we guaranteed any bonuses to our executive officers.

*Long-term Equity Compensation.* Our salary and bonus programs are intended to compensate our executive officers for short-term performance. We also have an equity incentive program intended to reward longer-term performance and to help align the interests of our executive officers with those of our stockholders. We believe that long-term performance is achieved through an ownership culture that rewards such performance by our executive officers through the use of equity incentives. Our current long-term incentives consist solely of stock option grants under our 2003 Equity Incentive Plan. However, our executive officers have also acquired equity in our company through direct investment in our common stock and in our prior preferred stock offerings. The common stock acquired directly by our executive officers is subject to our right of repurchase which lapses on a vesting schedule over a period of four years as described under Executive Employment Agreements Unvested Share Repurchase Right below. Vested shares are also subject to our repurchase right until February 2009 upon specified termination events as described under Executive Employment Agreements Vested Share Repurchase Right; Executive Put Right below. The compensation committee believes that the use of stock options offers the best approach to achieve our compensation goals with respect to long-term compensation and currently provides tax and other advantages to our employees relative to other forms of equity compensation. We believe that our stock option program is an important retention tool for our employees. With respect to determining the size of stock option grants, the compensation committee has approved target ranges of stock options for new vice presidents, directors, managers and others, and it reviews those ranges at least annually. The target ranges are intended to set appropriate stock option incentive levels for the various levels of responsibility.

Our executive officers were granted stock option options under our 2003 Equity Incentive Plan in February 2004, which will be fully vested in February 2008 (but any vested shares acquired upon exercise of the options are subject to our repurchase right until February 2009). In connection with its compensation review for 2007, the compensation committee granted additional stock options to our executive officers in February 2007 as described in more detail under Compensation Actions for our Executive Officers below. These options vest as to one-third of the shares subject to the option in February 2010, and the remaining two-thirds of the shares subject to the option vest monthly over two years thereafter. The exercise price of the options is equal to the fair market value of our common stock as determined by the compensation committee on the date of grant. In the absence of a public trading market for our common stock, the compensation committee determined the fair market value of our common stock in good faith based upon consideration of a number of relevant factors including the status of our development and commercialization efforts, results of operations, market conditions and the valuation we received from an independent valuation firm with respect to the fair market value of our common stock as of December 31, 2006. In determining the number of stock options granted to the executive officers, the compensation committee took into account each executive officer's position, scope of responsibility, ability to affect stockholder value, the individual's historic and recent performance, and our policy of providing compensation equity among our executive officers.

In connection with this offering, our board of directors has adopted new equity benefit plans described under Employee Benefit Plans below. The 2007 Equity Incentive Plan will replace our existing 2003 Equity Incentive Plan immediately upon the signing of the underwriting agreement for this offering. In connection with our transition to a publicly-traded company, the compensation committee intends to evaluate an annual stock option grant program for executive officers to continue aligning the interests of our executive officers with those

**Table of Contents**

of our stockholders. Participation in our 2007 Employee Stock Purchase Plan that we have adopted and that will become effective immediately upon the signing of the underwriting agreement for this offering will also be available to all executive officers following this offering on the same basis as our other employees.

*Employment Agreements.* Our executive officers, each of whom is a party to an employment agreement with us, will continue, following this offering, to be parties to these agreements in their current form until such time as our compensation committee agrees with the executive officers to revise the employment agreements, or until they expire in February 2009. The material terms of these employment agreements are described under *Executive Employment Agreements* below.

*Severance and Change of Control Benefits.* Under their employment agreements, our executive officers are entitled to certain severance and change of control benefits, the terms of which are described in detail below under *Executive Employment Agreements Severance and Change of Control Benefits*. With respect to change of control benefits, we provide severance compensation if an executive officer is terminated in connection with a change of control transaction to further promote the ability of our executive officers to act in the best interests of our stockholders even though they could be terminated as a result of the transaction. We also believe that the other severance benefits are appropriate, particularly with respect to a termination by us without cause since in that scenario, we and the executive have a mutually-agreed-upon severance package that is in place prior to any termination event which provides us with more flexibility to make a change in executive management if such a change is in our stockholders' best interests.

*Other Benefits.* We have a 401(k) plan in which substantially all of our employees are entitled to participate. Employees contribute their own funds, as salary deductions, on a pre-tax basis. Contributions may be made up to plan limits, subject to government limitations. The plan permits us to make matching contributions if we choose; however, to date, we have not made any matching contributions. We provide health care, dental and vision benefits to all full-time employees, including our executive officers. We also have a flexible benefits healthcare plan and a flexible benefits childcare plan under which employees can set aside pre-tax funds to pay for qualified health care expenses and qualified childcare expenses not reimbursed by insurance. These benefits are available to all employees, subject to applicable laws.

*Compensation Actions for Our Executive Officers*

*Samuel Saks, M.D. Chief Executive Officer.* Dr. Saks' base salary effective as March 1, 2006 was \$410,000, or a 5% increase over his base salary for the prior 12-month period. After review of the data from Compensia and other publicly-available compensation data, including chief executive officer salaries of public companies in our industry and other companies in the San Francisco Bay Area, the compensation committee increased Dr. Saks' salary to \$450,000 effective March 1, 2007. Dr. Saks received a bonus of \$102,000 for 2006. In setting the bonus pool for 2006, our board of directors determined that we had met many of our important objectives, but not all of our 2006 objectives, and approved a bonus payout of 56% of the total target bonus pool. The compensation committee determined Dr. Saks' bonus to be approximately 50% of target based on his performance and contributions to meeting our objectives for 2006, as well as his leadership during key challenges, and, at his and Mr. Cozadd's suggestion, the allocation of a portion of the available bonus pool to executives other than Dr. Saks and Mr. Cozadd that could have otherwise been awarded to Dr. Saks and Cozadd. In February 2007, the compensation committee granted Dr. Saks an option to purchase 450,000 shares of common stock with the vesting schedule described above. The option has an exercise price of \$1.75 per share, the fair market value of our common stock determined by the compensation committee on the date of grant. As with all of our executive officers, this option was granted in part due to the fact that Dr. Saks had not received any stock option grants since February 2004, and Dr. Saks' option granted in 2004 will be fully vested in February 2008 (but any vested shares acquired upon exercise of the options are subject to our repurchase right until February 2009). The new stock option is intended to provide a strong retention incentive well into the future, and to help align Dr. Saks' long-term interests with those of our stockholders.



---

**Table of Contents**

*Bruce Cozadd Executive Chairman.* Mr. Cozadd's base salary effective March 1, 2006 was \$310,000, or a 6% increase over his base salary for the prior 12-month period. Mr. Cozadd currently devotes 75% of his professional time to his role as our Executive Chairman. Since our inception in 2003, Mr. Cozadd and Dr. Saks have had approximately the same salary on a full-time equivalent basis. Mr. Cozadd's salary effective as of March 1, 2007 is \$338,000 for 75% time. Mr. Cozadd's base salary was determined by the compensation committee as part of its compensation review described above, with reference to Dr. Saks' base salary. Mr. Cozadd's bonus for 2006 was \$77,000, or approximately 50% of his target bonus. The bonus for Mr. Cozadd was determined by the compensation committee based on his performance, contributions and leadership in 2006 and, at his and Dr. Saks' suggestion, the allocation of a portion of the available bonus pool to executives other than Dr. Saks and Mr. Cozadd that could have otherwise been awarded to Dr. Saks and Cozadd. In February 2007, the compensation committee granted Mr. Cozadd an option to purchase 450,000 shares of common stock with the vesting schedule described above. The option has an exercise price of \$1.75 per share, the fair market value of our common stock determined by the compensation committee on the date of grant.

*Robert Myers President.* Mr. Myers' base salary effective March 1, 2006 was \$410,000, or a 5% increase over his salary for the prior 12-month period. Mr. Myers received a 4% salary increase effective March 1, 2007. Mr. Myers' bonus for 2006 was \$120,000, or approximately 60% of his target bonus. The bonus for Mr. Myers was determined by the compensation committee based on Mr. Myers' leadership of our commercial team through a number of key transactions during the year, the expansion of our sales and marketing activities and the significant achievements of our commercial organization during 2006. In February 2007, partly in recognition of his promotion from Executive Vice President and Chief Business Officer to President, the compensation committee granted Mr. Myers an option to purchase 350,000 shares of common stock with vesting schedule described above. The option has an exercise price of \$1.75 per share, the fair market value of our common stock determined by the compensation committee on the date of grant.

*Senior Vice Presidents.* The base salary effective March 1, 2006 for each of our remaining executive officers was \$330,000, or a 5.6% increase over their salaries for the prior 12-month period. They received a 4% salary increase effective March 1, 2007. The 2006 bonuses for these executive officers, as determined by the compensation committee and based on the recommendations of Dr. Saks and Mr. Cozadd, were \$70,000 for Mr. Fust, \$80,000 for Ms. Gamble and \$66,000 for Ms. Wissel. With these bonuses, the Compensation Committee recognized the efforts of each of these executive officers in connection with our key corporate objectives for 2006. In February 2007, the compensation committee granted each of these executive officers an option to purchase 250,000 shares of common stock with the vesting schedule described above. The options have an exercise price of \$1.75 per share, the fair market value of our common stock determined by the compensation committee on the date of grant.

*Accounting and Tax Considerations*

Effective January 1, 2006, we adopted the fair value provisions of Financial Accounting Standards Board Statement No. 123(R) (revised 2004), Share-Based Payment, or SFAS 123R. Under SFAS 123R, we are required to estimate and record an expense for each award of equity compensation (including stock options) over the vesting period of the award. The compensation committee has determined to retain for the foreseeable future our stock option program as the sole component of its long-term compensation program, and, therefore, to record this expense on an ongoing basis according to SFAS 123R. The compensation committee has considered, and may in the future consider, the grant of restricted stock to our executive officers in lieu of stock option grants in light of the accounting impact of SFAS 123R with respect to stock option grants and other considerations.

Section 162(m) of the Internal Revenue Code of 1986 limits our deduction for federal income tax purposes to not more than \$1 million of compensation paid to certain executive officers in a calendar year. Compensation above \$1 million may be deducted if it is performance-based compensation. The compensation committee has not yet established a policy for determining which forms of incentive compensation awarded to our executive



**Table of Contents**

officers shall be designed to qualify as performance-based compensation. To maintain flexibility in compensating our executive officers in a manner designed to promote our objectives, the compensation committee has not adopted a policy that requires all compensation to be deductible. However, the compensation committee intends to evaluate the effects of the compensation limits of Section 162(m) on any compensation it proposes to grant, and the compensation committee intends to provide future compensation in a manner consistent with our best interests and those of our stockholders.

**Summary Compensation Table**

The following table sets forth all of the compensation awarded to, earned by, or paid to our principal executive officer, principal financial officer and our four other highest paid executive officers for the year ended December 31, 2006. The officers listed in the table below are referred to in this prospectus as the named executive officers.

**2006 Summary Compensation Table**

Name and Principal Position	Year	Salary (\$)	Option Awards (\$)(1)	Non-Equity	All	Total (\$)
				Incentive Plan Compensation (\$)(2)	Other Compensation (\$)(3)	
Bruce C. Cozadd(4) Executive Chairman	2006	307,236	605,818	77,000	234	990,288
Samuel R. Saks, M.D. Chief Executive Officer	2006	406,853	605,818	102,000	234	1,114,905
Robert M. Myers President	2006	406,853	605,818	120,000	234	1,132,905
Matthew K. Fust Senior Vice President and Chief Financial Officer	2006	327,159	231,268	70,000	234	628,661
Carol A. Gamble Senior Vice President, General Counsel and Corporate Secretary	2006	327,159	231,268	80,000	234	638,661
Janne L.T. Wissel Senior Vice President of Development	2006	327,159	231,268	66,000	234	624,661

- (1) We did not grant any stock option awards to our named executive officers in 2006. The dollar amounts in this column represent the compensation cost for the year ended December 31, 2006 of stock option awards granted in prior years. These amounts have been calculated in accordance with FASB Statement No. 123 (revised), Share-Based Payment, or SFAS No. 123R, using the Black-Scholes option-pricing model. Pursuant to SEC rules, the amounts shown exclude the impact of estimated forfeitures related to service-based vesting conditions. For a discussion of valuation assumptions, see Note 14 to our consolidated financial statements included elsewhere in this prospectus.
- (2) See footnote (1) to the 2006 Grants of Plan-Based Awards Table below.
- (3) Represents group term life insurance premiums paid by us.
- (4) Mr. Cozadd currently devotes 75% of his professional time to his role as our Executive Chairman.

**Table of Contents*****Grants of Plan-Based Awards in Fiscal 2006***

The following table sets forth certain information regarding grants of plan-based awards to the named executive officers during the year ended December 31, 2006.

**2006 Grants of Plan-Based Awards Table**

<b>Name</b>	<b>Estimated Possible Payouts Under</b>	
	<b>Non-Equity</b>	
	<b>Incentive Plan Awards Target</b>	
	<b>(\$)(1)</b>	
Bruce C. Cozadd		153,618
Samuel R. Saks, M.D.		203,427
Robert M. Myers		203,427
Matthew K. Fust		130,864
Carol A. Gamble		130,864
Janne L.T. Wissel		130,864

(1) This column sets forth the target bonus amount for each named executive officer for the year ended December 31, 2006 under our annual cash bonus plan established by our board of directors, which for Dr. Saks and Messrs. Cozadd and Myers was 50% of their respective salaries earned for fiscal year ended December 31, 2006. The target bonus amount for Mr. Fust, Ms. Gamble and Ms. Wissel was 40% of their respective salaries earned for fiscal year ended December 31, 2006. The actual cash bonus award earned for the year ended December 31, 2006 for each named executive officer is set forth in the 2006 Summary Compensation Table above. As such, the amounts set forth in this column do not represent additional compensation earned by the named executive officers for the year ended December 31, 2006. For a description of our annual cash bonus plan, please see Compensation Discussion and Analysis Executive Compensation Program Cash Bonuses above.

***Executive Employment Agreements******General***

In February 2004, we entered into employment agreements with each of our named executive officers. Each of the employment agreements provides for an initial annual base salary subject to annual increases approved by our board of directors. The employment agreements set forth an initial base salary of \$375,000 for Mr. Cozadd, \$375,000 for Dr. Saks, \$375,000 for Mr. Myers and \$300,000 for each of Mr. Fust, Ms. Gamble and Ms. Wissel. Mr. Cozadd's annual base salary is pro-rated based on full-time employment. Mr. Cozadd currently devotes 75% of his professional time to his role as our Executive Chairman. Dr. Saks and Messrs. Cozadd and Myers are each eligible to receive an annual performance bonus determined in accordance with our annual cash bonus plan and targeted at 50% of their respective annual base salaries, subject to increases approved by our board of directors. Mr. Fust, Ms. Gamble and Ms. Wissel are each eligible to receive an annual performance bonus determined in accordance with our annual cash bonus plan and targeted at 40% of their respective annual base salaries, subject to increases approved by our board of directors. Each of the named executive officers is also eligible to participate in our general employee benefits plans for executives or key management employees in accordance with the terms and conditions of these plans.

*Term*

Each employment agreement provides that the terms and conditions of the agreement will apply to the named executive officers' employment until the fifth anniversary of the date of the agreement. However, each employment agreement also provides that the employment of the named executive officer may be terminated at any time by us or by the named executive officer, subject to the named executive officer's right to receive certain severance and other benefits, and our right to repurchase shares of our common stock held by the named executive officer.

## **Table of Contents**

### *Unvested Share Repurchase Right*

In the event a named executive officer's employment is terminated by us or the named executive officer, we have the right to repurchase at cost all or any portion of the shares of common stock that were held by the named executive officer on the date of the employment agreement, which we refer to in this prospectus as the founder shares. Our right of repurchase with respect to the founder shares lapses on an equal monthly basis over a period of four years, subject to acceleration in certain termination scenarios as described under Severance and Change of Control Benefits and subject to our right to repurchase vested shares as described under Vested Share Repurchase Right; Executive Put Right.

### *Vested Share Repurchase Right; Executive Put Right*

In the event a named executive officer is terminated by us for cause or is terminated by the named executive officer without good reason, as those terms are defined in the employment agreements, we have the right to repurchase any vested shares of common stock held by the named executive officer at the lesser of cost or fair market value. If the named executive officer's employment is terminated without cause or for good reason, we have the right to repurchase the named executive officer's vested shares at fair market value. Finally, if the named executive officer's employment is terminated because of death or disability, we have the right to repurchase, and the named executive officer (or his or her estate) has the right to require us to repurchase, the named executive officer's vested shares at fair market value. Our right to repurchase these vested shares terminates in February 2009, or earlier upon the completion of a change of control event; however, our vested share repurchase rights terminate on the date one year after our initial public offering as to 20% of the vested shares then held by each named executive officer.

### *Severance and Change of Control Benefits*

*Cash Severance Payments.* In the event a named executive officer is terminated by us without cause or is terminated by the named executive officer for good reason, the named executive officer is entitled, subject to our receipt of an effective waiver and release of claims executed by the named executive officer, to the following cash severance payments:

an amount, payable in accordance with our customary payroll practices, equal to 1/12<sup>th</sup> of the named executive officer's base salary at the time of termination for each month in a severance period of up to 24 months;

COBRA premiums for the number of months in a severance period of up to 24 months, payable on a monthly basis;

an amount, payable when bonus payments for the year of termination are paid to other employees, equal to the sum of:

the product of the named executive officer's base salary at the time of termination (prorated to reflect the number of days remaining in the year of termination after the date of termination) multiplied by the lesser of (a) the named executive officer's historical bonus rate (based on the average ratio of bonus paid to salary paid) or (b) the named executive officer's target bonus rate for the year of termination (which may be reduced based on the ratio of bonuses paid to target bonuses for the remaining named executive officers in the year of termination), which lesser amount we refer to in this prospectus as the severance bonus rate, plus

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

the product of the named executive officer's base salary at the time of termination (prorated to reflect the number of days elapsed in the year of termination including the date of termination) multiplied by one-half of the severance bonus rate; and

an amount, payable when bonus payments for the year following the year of termination are paid to other employees, equal to the product of the named executive officer's base salary at the time of termination (prorated to reflect the number of days elapsed in the year of termination including the date

**Table of Contents**

of termination) multiplied by the lesser of (a) the named executive officer's historical bonus rate or (b) the named executive officer's target bonus rate for the year of following termination (which may be reduced based on the ratio of bonuses paid to target bonuses for the remaining named executive officers in the year following termination).

The employment agreements also provide for the payment of the cash severance payments described above if a named executive officer voluntarily terminates his or her employment within one year after the effective date of (a) a change of control event or (b) in the case of the named executive officers other than Dr. Saks, a significant transaction, such as our acquisition of another entity, where the members of our board of directors prior to the significant transaction constitute a majority of the board of directors after the transaction and the employment of 50% or more of the existing members of our executive management team, including our Chief Executive Officer, is terminated in connection with the significant transaction.

The following table estimates the amount of compensation payable to each named executive officer in the event of a termination described above, in each case as if the named executive officer's employment had terminated on December 29, 2006, the last business day of our prior fiscal year. The actual amounts that would be paid out in any termination event can only be determined at the time of the termination of the named executive officer's employment with us.

Name	Salary	COBRA	Bonus Payment for the	Bonus Payment for the Year
	Continuation	Premiums	Year of Termination	Following Termination
	(\$)	(\$)	(\$)	\$(1)
Bruce C. Cozadd	465,000	21,320	24,823	49,104
Samuel R. Saks, M.D.	615,000	33,049	30,735	60,801
Robert M. Myers	615,000	25,485	44,323	87,679
Matthew K. Fust	495,000	6,043	29,676	58,706
Carol A. Gamble	495,000	21,228	22,926	45,352
Janne L.T. Wissel	467,500	12,493	22,926	45,352

(1) For purposes of calculating the amounts set forth in this column, applicable bonus rates in the year of termination and the year following termination are assumed to be the same.

The employment agreements further provide that if a named executive officer's employment is terminated (a) by the named executive officer due to a relocation of our executive office of more than 20 miles from our current executive office, (b) without cause by us or for good reason by the named executive officer in connection with a change of control or a significant transaction, or (c) in the case of the named executive officers other than Dr. Saks, without cause by us or for good reason by the named executive officer prior to the first anniversary of the effective date of a significant transaction in connection with which the employment of 50% or more of the existing members of our executive management team, including our Chief Executive Officer, is terminated, then, and in each such case, the named executive officer is entitled, subject to our receipt of an effective waiver and release of claims executed by the named executive officer, to the following cash severance payments:

a single lump sum payment equal to 1/12<sup>th</sup> of the named executive officer's base salary at the time of termination for each month in a severance period of up to 24 months;

a single lump sum payment equal to the product of the named executive officer's base salary at the time of termination (prorated to reflect the number of days elapsed in the year of termination including the date of termination) multiplied by the named executive officer's historical bonus rate;



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

a single lump sum payment equal to the product of (a) 1/12<sup>th</sup> of the named executive officer's base salary at the time of termination multiplied by (b) the named executive officer's historical bonus rate multiplied by (c) the number of months in a severance period of up to 24 months; and

COBRA premiums for the number of months in a severance period of up to 24 months, payable on a monthly basis.

**Table of Contents**

The following table estimates the amount of compensation payable to each named executive officer in the event of a termination described above, in each case as if the named executive officer's employment had terminated on December 29, 2006, the last business day of our prior fiscal year. The actual amounts that would be paid out in any termination event can only be determined at the time of the termination of the named executive officer's employment with us.

Name	Lump Sum Salary	COBRA	Lump Sum Bonus
	Payment	Premiums	Payment
	(\$)	(\$)	(\$)
Bruce C. Cozadd	465,000	21,320	123,167
Samuel R. Saks, M.D.	615,000	33,049	152,505
Robert M. Myers	615,000	25,485	219,922
Matthew K. Fust	495,000	6,043	147,249
Carol A. Gamble	495,000	21,228	113,754
Janne L.T. Wissel	467,500	12,493	109,954

In the event a named executive officer's employment is terminated by reason of death or disability, the named executive officer will be entitled to a cash payment equal to the named executive officer's accrued bonus (if any) at the rate in effect at the time of termination. As described above, each of named executive officer (or his or her estate) would also be entitled to require us to repurchase the named executive officer's vested shares at fair market value. The following table estimates the amount of compensation payable to each named executive officer in the event of a termination by reason of death or disability, in each case as if the named executive officer's employment had terminated on December 29, 2006, the last business day of our prior fiscal year. The actual amounts that would be paid out in any termination event can only be determined at the time of the termination of the named executive officer's employment with us.

Name	Accrued Bonus	Executive Put Right
	(\$)	\$(1)
Bruce C. Cozadd	76,578	
Samuel R. Saks, M.D.	101,441	
Robert M. Myers	119,342	
Matthew K. Fust	69,616	
Carol A. Gamble	79,562	
Janne L.T. Wissel	65,638	

(1) The value of the put right is calculated assuming a price per share of \$ \_\_\_\_\_, which is the mid-point of the range reflected on the cover page of this prospectus, with respect to vested shares of common stock.

*Vesting Acceleration.* The employment agreements provide that if the named executive officer's employment is terminated (a) without cause by us or for good reason by the named executive officer in connection with change of control or significant transaction, or within 12 months following a change of control, or (b) in the case of the named executive officers other than Dr. Saks, without cause by us or for good reason by the named executive officer prior to the first anniversary of the effective date of a significant transaction in connection with which the employment of 50% or more of the existing members of our executive management team, including our Chief Executive Officer, is terminated, then all unvested founder shares will immediately vest and our unvested share repurchase right will immediately lapse with respect to those shares. These provisions also govern the terms of the stock options granted to our named executive officers under our 2003 Equity Incentive Plan such that in the event of one of these termination scenarios, the options granted to our named executive officers under our 2003 Equity Incentive Plan would immediately vest and become exercisable and would no longer be subject to our unvested share repurchase right.

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

In addition, the employment agreements provide that if the named executive officer's employment is terminated without cause by us or for good reason by the named executive officer prior to and not in connection

**Table of Contents**

with or more than 12 months following, a change in control, then 1/4<sup>th</sup> of the founder shares (or the actual number of unvested founder shares immediately prior to the termination, if less) will immediately vest and our unvested share repurchase right will immediately lapse with respect to those shares. These provisions are not applicable to the stock options granted to our named executive officers under our 2003 Equity Incentive Plan.

The following table estimates the value of the vesting acceleration provisions described above with respect to each named executive officer in the event of a termination described above, in each case as if the named executive officer's employment had terminated on December 29, 2006, the last business day of our prior fiscal year. The actual value of vesting acceleration in any termination event can only be determined at the time of the termination of the named executive officer's employment with us.

Name	Full Vesting Acceleration Founder Share		Partial Vesting Acceleration	
	Acceleration (\$)(1)	Option Acceleration (\$)(2)	Founder Share Acceleration (\$)(1)	Option Acceleration (\$)
Bruce C. Cozadd				
Samuel R. Saks, M.D.				
Robert M. Myers				
Matthew K. Fust				
Carol A. Gamble				
Janne L.T. Wissel				

- (1) The value of vesting acceleration is calculated assuming a price per share of \$ \_\_\_\_\_, which is the mid-point of the range reflected on the cover page of this prospectus, with respect to unvested founder shares subject to acceleration.
- (2) The value of vesting acceleration is calculated assuming a price per share of \$ \_\_\_\_\_, which is the mid-point of the range reflected on the cover page of this prospectus, with respect to unvested option shares subject to acceleration minus the exercise price of these unvested option shares.

**Employee Benefit Plans***2003 Equity Incentive Plan*

Our board of directors adopted, and our stockholders approved, the 2003 Equity Incentive Plan, or 2003 plan, in March 2003. An aggregate of 23,517,858 shares of our common stock is reserved for issuance under the 2003 plan. The 2003 plan provides for the grant of incentive stock options, nonstatutory stock options, stock appreciation rights, stock issuances and cash awards. As of December 31, 2006, options to purchase 17,677,564 shares of our common stock at a weighted average exercise price per share of \$1.96 remained outstanding under the 2003 plan. No stock appreciation rights, stock issuances, or cash awards have been granted under the 2003 plan. As of December 31, 2006, 5,378,732 shares of our common stock remained available for future issuance under the 2003 plan.

Our board of directors has the authority to administer the 2003 plan and the awards granted under it. Upon the signing of the underwriting agreement for this offering, the 2003 plan will terminate so that no further awards may be granted under the 2003 plan. Although the 2003 plan will terminate, all outstanding awards will continue to be governed by their existing terms.

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

*Stock Options.* The 2003 plan provides for the grant of incentive stock options under the federal tax laws or nonstatutory stock options. Incentive stock options may be granted only to employees. Nonstatutory stock options may be granted to employees, non-employee directors and consultants. The exercise price of incentive stock options may not be less than 100% of the fair market value of our common stock on the date of grant. The exercise price of nonstatutory stock options may not be less than 85% of the fair market value of our common stock on the date of grant. Shares subject to options under the 2003 plan generally vest in a series of installments over an optionee's period of service, with a minimum vesting rate as to non-executive employees of at least 20% per year over five years from the date of grant.

**Table of Contents**

In general, the maximum term of options granted under the 2003 plan is ten years. Unless the terms of an optionee's stock option agreement provide otherwise, if an optionee's service relationship with us, or any of our affiliates, ceases for any reason other than for cause, disability or death, the optionee may exercise the vested portion of any option for three months after the date of such termination. If an optionee's service relationship with us, or any of our affiliates, terminates by reason of disability or death, the optionee or a personal representative may exercise the vested portion of any option for 12 months after the date of such termination. In no event, however, may an option be exercised beyond the expiration of its term.

*Corporate Transactions.* In the event of certain significant corporate transactions, our board of directors has the discretion to take one or more of the following actions: (a) arrange for the assumption or substitution of outstanding awards, (b) accelerate the vesting and termination of outstanding awards in whole or in part, (c) cancel or arrange for the cancellation of awards in exchange for cash payments and (d) arrange for any repurchase rights applicable to award shares to apply to any substituted securities issued in the transaction. Our board of directors need not adopt the same rules for each participant.

*Changes in Control.* In general, the vesting and exercisability of options granted to non-executive employees under the 2003 plan will accelerate with respect to an additional 25% of the option shares if (a) a change in control occurs and (b) the individual's employment is terminated by us without cause within 12 months thereafter. In general, under our employment agreements with our executive officers, the vesting and exercisability of options granted to executive officers under the 2003 plan will accelerate in full (a) if a change in control or significant transaction occurs and the officer's employment is terminated by us without cause or the officer resigns for good reason in connection therewith or within 12 months thereafter or (b) if the employment of the officer (other than Dr. Saks) is terminated by us without cause or the officer (other than Dr. Saks) resigns for good reason within one year of a significant transaction where the employment of 50% or more of the members of our executive management team, including the employment of Dr. Saks, are terminated in connection with such significant transaction. See Executive Employment Agreements Severance and Change of Control Benefits.

*2007 Equity Incentive Plan*

Our board of directors adopted the 2007 Equity Incentive Plan, or 2007 incentive plan, in 2007, and our stockholders approved the 2007 incentive plan in 2007. The 2007 incentive plan will become effective immediately upon the signing of the underwriting agreement for this offering. The 2007 incentive plan will terminate on 2017, unless sooner terminated by our board of directors.

*Stock Awards.* The 2007 incentive plan provides for the grant of incentive stock options, nonstatutory stock options, restricted stock awards, restricted stock unit awards, stock appreciation rights, performance stock awards and other forms of equity compensation, which may be granted to employees, including officers, non-employee directors, and consultants.

*Share Reserve.* Following this offering, the aggregate number of shares of our common stock that may be issued initially pursuant to stock awards under the 2007 incentive plan is \_\_\_\_\_ shares. The number of shares of our common stock reserved for issuance will automatically increase on January 1st, from January 1, 2008 through January 1, 2017, by the lesser of (a) \_\_\_\_\_ % of the total number of shares of our common stock outstanding on December 31st of the preceding calendar year and (b) \_\_\_\_\_ shares. The maximum number of shares that may be issued pursuant to the exercise of incentive stock options under the 2007 incentive plan is equal to the total share reserve, as increased from time to time pursuant to annual increases and shares subject to options granted under the 2003 plan that expire without being exercised in full.

No person may be granted awards covering more than \_\_\_\_\_ shares of our common stock under the 2007 incentive plan during any calendar year pursuant to an appreciation-only stock award. An appreciation-only stock award is a stock award whose value is determined by

reference to an increase over an exercise or strike

## Table of Contents

price of at least 100% of the fair market value of our common stock on the date of grant. A stock option with an exercise price equal to the value of the stock on the date of grant is an example of an appreciation-only award. Such limitation is designed to help assure that any deductions to which we would otherwise be entitled upon the exercise of an appreciation-only stock award or upon the subsequent sale of shares purchased under such an award, will not be subject to the \$1,000,000 limitation on the income tax deductibility of compensation paid per covered executive officer imposed by Section 162(m) of the Internal Revenue Code.

If a stock award granted under the 2007 incentive plan expires or otherwise terminates without being exercised in full, the shares of our common stock not acquired pursuant to the stock award again become available for subsequent issuance under the 2007 incentive plan. In addition, the following types of shares under the 2007 incentive plan may become available for the grant of new stock awards under the 2007 incentive plan: (a) shares that are forfeited to or repurchased by us prior to becoming fully vested, (b) shares withheld to satisfy income and employment withholding taxes, (c) shares used to pay the exercise price of an option in a net exercise arrangement, (d) shares tendered to us to pay the exercise price of an option and (e) shares that are cancelled pursuant to an exchange or repricing program. Shares issued under the 2007 incentive plan may be previously unissued shares or reacquired shares bought on the open market. As of the date hereof, no shares of our common stock have been issued under the 2007 incentive plan.

*Administration.* Our board of directors has delegated its authority to administer the 2007 incentive plan to our compensation committee. Subject to the terms of the 2007 incentive plan, our board of directors or an authorized committee, referred to as the plan administrator, determines recipients, dates of grant, the numbers and types of stock awards to be granted, and the terms and conditions of the stock awards, including the period of their exercisability and vesting. Subject to the limitations set forth below, the plan administrator will also determine the exercise price of options granted, the consideration to be paid for restricted stock awards, and the strike price of stock appreciation rights.

The plan administrator has the authority to:

reduce the exercise price of any outstanding option or the strike price of any outstanding stock appreciation right;

cancel any outstanding option or stock appreciation right and to grant in exchange one or more of the following:

new options or stock appreciation rights covering the same or a different number of shares of common stock,

new stock awards,

cash, and/or

other valuable consideration; or

engage in any action that is treated as a repricing under generally accepted accounting principles.

*Stock Options.* Incentive and nonstatutory stock options are granted pursuant to incentive and nonstatutory stock option agreements adopted by the plan administrator. The plan administrator determines the exercise price for a stock option, within the terms and conditions of the 2007 incentive plan, provided that the exercise price of an incentive stock option and nonstatutory stock option cannot be less than 100% of the fair



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

market value of our common stock on the date of grant. Options granted under the 2007 incentive plan vest at the rate specified by the plan administrator.

Generally, the plan administrator determines the term of stock options granted under the 2007 incentive plan, up to a maximum of ten years (except in the case of certain incentive stock options, as described below). Unless the terms of an optionee's stock option agreement provide otherwise, if an optionee's relationship with us,

## **Table of Contents**

or any of our affiliates, ceases for any reason other than disability or death, the optionee may exercise any vested options for a period of three months following the cessation of service. If an optionee's service relationship with us, or any of our affiliates, ceases due to disability or death (or an optionee dies within a certain period following cessation of service), the optionee or a beneficiary may exercise any vested options for a period of 12 months in the event of disability, and 18 months in the event of death. The option term may be extended in the event that exercise of the option following termination of service is prohibited by applicable securities laws. In no event, however, may an option be exercised beyond the expiration of its term.

Acceptable consideration for the purchase of common stock issued upon the exercise of a stock option will be determined by the plan administrator and may include (a) cash or check, (b) a broker-assisted cashless exercise, (c) the tender of common stock previously owned by the optionee, (d) a net exercise of the option and (e) other legal consideration approved by the plan administrator.

Unless the plan administrator provides otherwise, options generally are not transferable except by will, the laws of descent and distribution, or pursuant to a domestic relations order. An optionee may designate a beneficiary, however, who may exercise the option following the optionee's death.

*Tax Limitations on Incentive Stock Options.* Incentive stock options may be granted only to our employees. The aggregate fair market value, determined at the time of grant, of shares of our common stock with respect to incentive stock options that are exercisable for the first time by an optionee during any calendar year under all of our stock plans may not exceed \$100,000. No incentive stock option may be granted to any person who, at the time of the grant, owns or is deemed to own stock possessing more than 10% of our total combined voting power or that of any of our affiliates unless (a) the option exercise price is at least 110% of the fair market value of the stock subject to the option on the date of grant and (b) the term of the incentive stock option does not exceed five years from the date of grant.

*Restricted Stock Awards.* Restricted stock awards are granted pursuant to restricted stock award agreements adopted by the plan administrator. Restricted stock awards may be granted in consideration for (a) cash or check, (b) past or future services rendered to us or our affiliates or (c) any other form of legal consideration. Shares of common stock acquired under a restricted stock award may, but need not, be subject to a share repurchase option in our favor in accordance with a vesting schedule to be determined by the plan administrator. Rights to acquire shares under a restricted stock award may be transferred only upon such terms and conditions as set by the plan administrator.

*Restricted Stock Unit Awards.* Restricted stock unit awards are granted pursuant to restricted stock unit award agreements adopted by the plan administrator. Restricted stock unit awards may be granted in consideration for any form of legal consideration. A restricted stock unit award may be settled by cash, delivery of stock, a combination of cash and stock as deemed appropriate by the plan administrator, or in any other form of consideration set forth in the restricted stock unit award agreement. Additionally, dividend equivalents may be credited in respect to shares covered by a restricted stock unit award. Except as otherwise provided in the applicable award agreement, restricted stock units that have not vested will be forfeited upon the participant's cessation of continuous service for any reason.

*Stock Appreciation Rights.* Stock appreciation rights are granted pursuant to stock appreciation rights agreements adopted by the plan administrator. The plan administrator determines the strike price for a stock appreciation right which cannot be less than 100% of the fair market value of our common stock on the date of grant. Upon the exercise of a stock appreciation right, we will pay the participant an amount equal to the product of (a) the excess of the per share fair market value of our common stock on the date of exercise over the strike price, multiplied by (b) the number of shares of common stock with respect to which the stock appreciation right is exercised. A stock appreciation right granted under the 2007 incentive plan vests at the rate specified in the stock appreciation right agreement as determined by the plan administrator.



## **Table of Contents**

The plan administrator determines the term of stock appreciation rights granted under the 2007 incentive plan, up to a maximum of ten years. If a participant's service relationship with us, or any of our affiliates, ceases, then the participant, or the participant's beneficiary, may exercise any vested stock appreciation right for three months (or such longer or shorter period specified in the stock appreciation right agreement) after the date such service relationship ends. In no event, however, may a stock appreciation right be exercised beyond the expiration of its term.

*Performance Stock Awards.* The 2007 incentive plan permits the grant of performance stock awards that may qualify as performance-based compensation that is not subject to the \$1,000,000 limitation on the income tax deductibility of compensation paid per covered executive officer imposed by Section 162(m) of the Internal Revenue Code. To assure that the compensation attributable to one or more performance stock awards will so qualify, our compensation committee can structure one or more such awards so that stock will be issued or paid pursuant to such award only upon the achievement of certain pre-established performance goals during a designated performance period. The maximum benefit to be received by a participant in any calendar year attributable to performance stock awards may not exceed \_\_\_\_\_ shares of our common stock.

*Other Stock Awards.* The plan administrator may grant other awards based in whole or in part by reference to our common stock. The plan administrator will set the number of shares under the award and all other terms and conditions of such awards.

*Changes to Capital Structure.* In the event that there is a specified type of change in our capital structure, such as a stock split, appropriate adjustments will be made to (a) the number of shares reserved under the 2007 incentive plan, (b) the maximum number of shares by which the share reserve may increase automatically each year, (c) the maximum number of appreciation-only stock awards and performance stock awards that can be granted in a calendar year and (d) the number of shares and exercise price or strike price, if applicable, of all outstanding stock awards.

*Corporate Transactions.* In the event of certain significant corporate transactions, all outstanding stock awards under the 2007 incentive plan may be assumed, continued or substituted for by any surviving or acquiring entity (or its parent company). If the surviving or acquiring entity (or its parent company) elects not to assume, continue or substitute for such stock awards, then (a) with respect to any such stock awards that are held by individuals whose service with us or our affiliates has not terminated prior to the effective date of the corporate transaction, the vesting and exercisability provisions of such stock awards will be accelerated in full and such awards will be terminated if not exercised prior to the effective date of the corporate transaction and (b) all other outstanding stock awards will terminate if not exercised prior to the effective date of the corporate transaction. Our board of directors may also provide that the holder of an outstanding stock award not assumed in the corporate transaction will surrender such stock award in exchange for a payment equal to the excess of (a) the value of the property that the optionee would have received upon exercise of the stock award, over (b) the exercise price otherwise payable in connection with the stock award.

*Changes in Control.* In the event a participant's service relationship with us or a successor entity is terminated, actually without cause or constructively, within 12 months following, or one month prior to, the effective date of certain specified change in control transactions, the vesting and exercisability of all outstanding stock awards held by such participants will accelerate in full. Our board of directors has the discretion to provide additional acceleration of vesting and exercisability upon or after a change in control transaction as may be provided in the stock award agreement or any other written agreement between us or any of our affiliates and the participant.

### *2007 Non-Employee Directors Stock Option Plan*

Our board of directors adopted our 2007 Non-Employee Directors Stock Option Plan, or 2007 directors plan, in \_\_\_\_\_ 2007 and our stockholders approved the 2007 directors plan in \_\_\_\_\_ 2007. The 2007



## **Table of Contents**

directors plan will become effective immediately upon the signing of the underwriting agreement for this offering. The 2007 directors plan provides for the automatic grant of nonstatutory stock options to purchase shares of common stock to our non-employee directors over their period of service on our board.

*Share Reserve.* Following this offering, the aggregate number of shares of common stock that may be issued initially pursuant to options granted under the 2007 directors plan is \_\_\_\_\_ shares. The number of shares of common stock reserved for issuance will automatically increase on January 1st, from January 1, 2008 through January 1, 2017, by the excess of (a) the number of shares of common stock subject to options granted during the preceding calendar year, over (b) the number of shares added back to the share reserve during the preceding calendar year. If any option expires or terminates for any reason, in whole or in part, without having been exercised in full, the shares of common stock not acquired under such option will become available for future issuance under the 2007 directors plan. As of the date hereof, no shares of common stock have been issued under the 2007 directors plan. The following types of shares issued under the 2007 directors plan may again become available for the grant of new options: (a) any shares withheld to satisfy withholding taxes, (b) any shares used to pay the exercise price of an option in a net exercise arrangement and (c) shares tendered to us to pay the exercise price of an option.

*Administration.* All options granted under the 2007 directors plan are made in strict compliance with its express provisions. Subject to the provisions of the 2007 directors plan, our board of directors has the authority to construe and interpret the 2007 directors plan and the stock options granted under it, and to establish rules for its administration.

*Initial Option.* Pursuant to the terms of the 2007 directors plan, any individual who first becomes a non-employee director after this offering will automatically be granted an option to purchase \_\_\_\_\_ shares of our common stock. The shares subject to each such initial option vest 25% on the first anniversary of the date of grant and the remainder in a series of 36 successive equal monthly installments thereafter.

*Annual Option.* Pursuant to the terms of the 2007 directors plan, each individual who is serving as a non-employee director on the date of an annual meeting of our stockholders, commencing with the annual meeting in 2008, will automatically be granted an option to purchase \_\_\_\_\_ shares of our common stock on such date. The shares subject to each such annual option vest in a series of 12 successive equal monthly installments measured from the date of grant.

*Terms of All Options.* The exercise price of each option granted under the 2007 directors plan is equal to 100% of the fair market value of our common stock on the date of grant. The maximum term of options granted under the 2007 directors plan is ten years. If a non-employee director's service relationship with us, or any of our affiliates, whether as a non-employee director or subsequently as an employee, director or consultant of ours or an affiliate, ceases for any reason other than disability, death, or following a change in control, the optionee may exercise any vested options for a period of three months following the cessation of service. If such an optionee's service relationship with us, or any of our affiliates, ceases due to disability or death (or an optionee dies within a certain period following cessation of service), the option will accelerate in full and the optionee or a beneficiary may exercise the option for a period of 12 months in the event of disability, and 18 months in the event of death. If such an optionee's service terminates within 12 months following a specified change in control transaction, the option will accelerate in full and the optionee may exercise the option for a period of 12 months following the effective date of such a transaction. The option term may be extended in the event that exercise of the option following termination of service is prohibited by applicable securities laws. In no event, however, may an option be exercised beyond the expiration of its term.

*Transferability of Options.* Options granted under the 2007 directors plan are generally not transferable except by will, the laws of descent and distribution, or pursuant to a domestic relations order. However, an option may be transferred for no consideration upon written consent of our board of directors if (a) at the time of transfer, a Form S-8 registration statement under the Securities Act is available for the issuance of shares upon



## Table of Contents

the exercise of such transferred option or (b) the transfer is to the optionee's employer or its affiliate at the time of transfer.

*Changes to Capital Structure.* In the event that there is a specified type of change in our capital structure, such as a stock split, appropriate adjustments will be made to (a) the number of shares reserved under the 2007 directors plan, (b) the number of shares for which options are to be subsequently made to new and continuing non-employee directors and (c) the number of shares and exercise price of all outstanding options.

*Corporate Transactions.* In the event of certain significant corporate transactions, all outstanding options under the 2007 directors plan may be assumed, continued or substituted for by any surviving or acquiring entity (or its parent company). If the surviving or acquiring entity (or its parent company) elects not to assume, continue or substitute for such options, then (a) with respect to any such options that are held by optionees then performing services for us or our affiliates, the vesting and exercisability of such options will be accelerated in full and such options will be terminated if not exercised prior to the effective date of the corporate transaction and (b) all other outstanding options will terminate if not exercised prior to the effective date of the corporate transaction. Our board of directors may also provide that the holder of an outstanding option not assumed in the corporate transaction will surrender such option in exchange for a payment equal to the excess of (a) the value of the property that the optionee would have received upon exercise of the option, over (b) the exercise price otherwise payable in connection with the option.

*Changes in Control.* The vesting and exercisability of options held by non-employee directors who are either (a) required to resign their position in connection with a specified change in control transaction or (b) removed from their position in connection with such a change in control will be accelerated in full.

### *2007 Employee Stock Purchase Plan*

Our board of directors adopted our 2007 Employee Stock Purchase Plan, or 2007 purchase plan, in \_\_\_\_\_ 2007 and our stockholders approved the 2007 purchase plan in \_\_\_\_\_ 2007. The 2007 purchase plan will become effective immediately upon the signing of the underwriting agreement for this offering.

*Share Reserve.* Following this offering, the 2007 purchase plan authorizes the issuance of \_\_\_\_\_ shares of our common stock pursuant to purchase rights granted to our employees or to employees of any of our designated affiliates. The number of shares of our common stock reserved for issuance will automatically increase on January 1st, from January 1, 2008 through January 1, 2017, by the lesser of (a) \_\_\_\_\_ % of the total number of shares of our common stock outstanding on December 31st of the preceding calendar year or (b) \_\_\_\_\_ shares. The 2007 purchase plan is intended to qualify as an employee stock purchase plan within the meaning of Section 423 of the Internal Revenue Code. As of the date hereof, no shares of our common stock have been purchased under the 2007 purchase plan.

*Administration.* Our board of directors has delegated its authority to administer the 2007 purchase plan to our compensation committee. The 2007 purchase plan is implemented through a series of offerings of purchase rights to eligible employees. Under the 2007 purchase plan, we may specify offerings with a duration of not more than 27 months, and may specify shorter purchase periods within each offering. Each offering will have one or more purchase dates on which shares of our common stock will be purchased for employees participating in the offering. An offering may be terminated under certain circumstances, including following a determination that the accounting consequence of operating the 2007 purchase plan is not in our best interest.



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

*Payroll Deductions.* Generally, all regular employees, including executive officers, employed by us or by any of our affiliates may participate in the 2007 purchase plan and may contribute, normally through payroll deductions, up to 15% of their earnings for the purchase of our common stock under the 2007 purchase plan. Unless otherwise determined by our board of directors, common stock will be purchased for accounts of

## Table of Contents

employees participating in the 2007 purchase plan at a price per share equal to the lower of (a) 85% of the fair market value of a share of our common stock on the first date of an offering or (b) 85% of the fair market value of a share of our common stock on the date of purchase.

*Reset Feature.* Our board of directors may specify that if the fair market value of a share of our common stock on any purchase date within a particular offering period is less than the fair market value on the start date of that offering period, then the employees in that offering period will automatically be transferred and enrolled in a new offering period which will begin on the next day following such a purchase date.

*Limitations.* Employees may have to satisfy one or more of the following service requirements before participating in the 2007 purchase plan, as determined by our board of directors: (a) customarily employed for more than 20 hours per week, (b) customarily employed for more than five months per calendar year or (c) continuous employment with us or one of our affiliates for a period of time not to exceed two years. No employee may purchase shares under the 2007 purchase plan at a rate in excess of \$25,000 worth of our common stock valued based on the fair market value per share of our common stock at the beginning of an offering for each year such a purchase right is outstanding. Finally, no employee will be eligible for the grant of any purchase rights under the 2007 purchase plan if immediately after such rights are granted, such employee has voting power over 5% or more of our outstanding capital stock measured by vote or value.

*Changes to Capital Structure.* In the event that there is a specified type of change in our capital structure, such as a stock split, appropriate adjustments will be made to (a) the number of shares reserved under the 2007 purchase plan, (b) the maximum number of shares by which the share reserve may increase automatically each year, and (c) the number of shares and purchase price of all outstanding purchase rights.

*Corporate Transactions.* In the event of certain significant corporate transactions, any then-outstanding rights to purchase our stock under the 2007 purchase plan will be assumed, continued or substituted for by any surviving or acquiring entity (or its parent company). If the surviving or acquiring entity (or its parent company) elects not to assume, continue or substitute for such purchase rights, then the participants' accumulated contributions will be used to purchase shares of our common stock within ten business days prior to such corporate transaction, and such purchase rights will terminate immediately thereafter.

### *Cash Bonus Plan*

We maintain an annual cash bonus plan to reward executive officers and other employees for successful achievement of company-wide and individual performance objectives. For more information regarding our annual cash bonus plan, please see Compensation Discussion and Analysis Executive Compensation Program Cash Bonuses.

### *401(k) Plan*

Our employees are eligible to participate in our 401(k) plan. Our 401(k) plan is intended to qualify as a tax qualified plan under Section 401 of the Code. Our 401(k) plan provides that each participant may contribute a portion of his or her pretax compensation, up to a statutory limit, which for most employees is \$15,500 in 2007 (with a larger catch up limit for older employees). Employee contributions are held and invested by the plan's trustee. Our 401(k) plan also permits us to make discretionary contributions and matching contributions, subject to established limits and a vesting schedule. To date, we have not made any contributions to the plan on behalf of participating employees.



**Table of Contents****Outstanding Equity Awards at Fiscal Year-End**

The following table shows, for the fiscal year ended December 31, 2006, certain information regarding outstanding equity awards at fiscal year end for our named executive officers.

**2006 Outstanding Equity Awards at Fiscal Year-End Table**

Name	Option Awards(1)			Stock Awards(2)		
	Number of Securities Underlying Unexercised Options (#)	Number of Securities Underlying Unexercised Options (#)	Option Exercise Price (\$)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested (\$)(3)
Bruce C. Cozadd	1,286,561	529,760	1.36	02/18/14	165,000	
	428,854	176,586	2.73	02/18/14		
	428,854	176,586	4.09	02/18/14		
Samuel R. Saks, M.D.	1,286,561	529,760	1.36	02/18/14	220,000	
	428,854	176,586	2.73	02/18/14		
	428,854	176,586	4.09	02/18/14		
Robert M. Myers	1,286,561	529,760	1.36	02/18/14	126,042	
	428,854	176,586	2.73	02/18/14		
	428,854	176,586	4.09	02/18/14		
Matthew K. Fust	491,134	202,232	1.36	02/18/14	27,500	
	163,713	67,411	2.73	02/18/14		
	163,713	67,411	4.09	02/18/14		
Carol A. Gamble	491,134	202,232	1.36	02/18/14	25,000	
	163,713	67,411	2.73	02/18/14		
	163,713	67,411	4.09	02/18/14		
Janne L.T. Wissel	491,134	202,232	1.36	02/18/14	61,875	
	163,713	67,411	2.73	02/18/14		
	163,713	67,411	4.09	02/18/14		

(1) For each named executive officer, the shares listed in the table above under "Option Awards" are subject to a single stock option award carrying the varying exercise prices as set forth in the table above. The shares subject to each stock option vest over a four year period, with 25% of the shares subject to the option

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

vesting after one year, an additional 12.5% vesting six months thereafter, and the remaining shares subject to the stock option vesting on an equal monthly basis over the following 30 months. On each vesting date, the number of shares subject to each stock option award vest proportionately based on the exercise price associated with the shares, such that 60% of the shares vesting on each vesting date carry an exercise price equal to \$1.36 per share, 20% carry an exercise price equal to \$2.73 per share, and 20% carry an exercise price equal to \$4.09 per share. All shares of common stock that are issued to a named executive officer pursuant to the exercise of his or her stock option award are subject to a right of repurchase, on the same terms as vested shares as described under Executive Employment Agreements.

- (2) For each named executive officer, our right to repurchase the unvested shares listed in the table above under Stock Awards lapses on a monthly basis at the rate of 2.08% per month.
- (3) The market value of the unvested shares has been calculated assuming a price per share of \$ , which is the mid-point of the range reflected on the cover page of this prospectus, multiplied by the number of unvested shares.

**Table of Contents*****Option Exercises and Stock Vested***

Our named executive officers did not exercise any stock options during the year ended December 31, 2006. The following table shows certain information regarding stock vested during the year ended December 31, 2006 for our named executive officers.

**2006 Option Exercises and Stock Vested Table**

Name	Stock Awards	
	Number of Shares	Value Realized
	Acquired on Vesting	on Vesting
	(#)	(\$)(1)
Bruce C. Cozadd	495,000	
Samuel R. Saks, M.D.	660,000	
Robert M. Myers	261,875	
Matthew K. Fust	82,500	
Carol A. Gamble	75,000	
Janne L.T. Wissel	82,500	

(1) The value realized on vesting has been calculated assuming a price per share of \$ \_\_\_\_\_, which is the mid-point of the range reflected on the cover page of this prospectus, multiplied by the number of shares vested.

***Pension Benefits***

Our named executive officers did not participate in, or otherwise receive any benefits under, any pension or retirement plan sponsored by us during the year ended December 31, 2006.

***Nonqualified Deferred Compensation***

During the year ended December 31, 2006, our named executive officers did not contribute to, or earn any amounts with respect to, any defined contribution or other plan sponsored by us that provides for the deferral of compensation on a basis that is not tax-qualified.

***Non-Employee Director Compensation***

The non-employee members of our board of directors are reimbursed for travel and other reasonable expenses incurred in attending board or committee meetings. Other than respect to Mr. Sebulsky, members of our board of directors do not currently receive cash compensation for attending board or committee meetings. Mr. Sebulsky currently receives \$1,500 for each board meeting he attends and \$500 for each committee meeting he attends.

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

After this offering, we will continue to reimburse our non-employee directors for their travel and other reasonable expenses incurred in attending board or committee meetings. In addition, each non-employee director will receive an annual retainer of \$ . The chair of the audit committee will receive a supplemental annual retainer of \$ , the chair of the compensation committee will receive a supplemental annual retainer of \$ , and the chair of the nominating and corporate governance committee will receive a supplemental annual retainer of \$ . Additionally, our non-employee directors will receive nonstatutory stock options under our 2007 directors plan, which will become effective immediately upon the signing of the underwriting agreement for this offering. The terms of these nonstatutory stock options are described under Executive Compensation Employee Benefit Plans 2007 Non-Employee Directors Stock Option Plan above.

**Table of Contents**

The following table shows for the fiscal year ended December 31, 2006 certain information with respect to the compensation of all of our non-employee directors.

**2006 Director Compensation Table**

Name	Fees Earned or	Option Awards	Total
	Paid in Cash (\$)	(\$)(2)(3)	(\$)
Adam H. Clammer			
Samuel D. Colella			
Bryan C. Cressey(1)			
David Mayer(1)			
Michael W. Michelson			
James C. Momtazee			
Kenneth W. O Keefe			
Alan M. Sebulsky.	9,500(4)	22,475	31,975
James B. Tananbaum, M.D.			

- (1) Mr. Cressey joined our board of directors in October 2006 following the resignation of Mr. Mayer.
- (2) We did not grant any stock option awards to our directors in 2006. The dollar amount in this column represents the compensation cost for the year ended December 31, 2006 of a stock option award granted in 2004. This amount has been calculated in accordance with SFAS No. 123R using the Black-Scholes option-pricing model. Pursuant to SEC rules, the amount shown excludes the impact of estimated forfeiture related to service-based vesting conditions. For a discussion of valuation assumptions, see Note 14 to our consolidated financial statements included elsewhere in this prospectus.
- (3) At December 31, 2006, Mr. Sebulsky held a stock option exercisable for 100,000 shares of our common stock carrying an exercise price of \$1.36 per share, 50,000 shares of which were vested and exercisable at December 31, 2006. None of the other directors listed in the table above held any outstanding stock options at December 31, 2006.
- (4) Consists of fees earned for board and committee meeting attendance.

**Limitation of Liability and Indemnification**

Our third amended and restated certificate of incorporation and amended and restated bylaws to be in effect upon the closing of this offering limit the liability of our directors, officers, employees and other agents to the fullest extent permitted by Delaware law; provided, however, that we indemnify any such person in connection with a proceeding initiated by such person only if such indemnification is expressly required by law, the proceeding was authorized by our board of directors, the indemnification is provided by us, in our sole discretion, pursuant to the Delaware General Corporation Law or other applicable law or is otherwise expressly required by our amended and restated bylaws. Section 145 of the Delaware General Corporation Law permits indemnification of officers, directors and other agents under certain circumstances and subject to certain limitations. Delaware law also permits a corporation to not hold its directors personally liable for monetary damages for breach of their fiduciary duties as directors, except for liability for: (1) breach of their duty of loyalty to the corporation or its stockholders, (2) acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (3) unlawful payments of dividends or unlawful stock repurchases or redemptions and (4) any transaction from which the director derived an improper personal benefit. This limitation of liability does not apply to liabilities arising under the federal or state securities laws and does not affect the availability of equitable remedies such as injunctive relief or rescission.

Our amended and restated bylaws also permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in this capacity. We have obtained directors and officers liability insurance to cover certain liabilities described above. Messrs. Clammer, Michelson and Momtazee are further insured by liability insurance that has been purchased by Kohlberg Kravis Roberts & Co. L.P. on their behalf for any excess liabilities that are not covered by our liability insurance. Mr. Colella is insured by liability insurance purchased on his behalf by, and indemnified pursuant to the governing agreements of, Versant Ventures for his service on our board of



directors.

**Table of Contents**

We have entered into indemnity agreements with each of our directors and executive officers, 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. We believe that these provisions and agreements are necessary to attract and retain qualified persons as officers and directors of our company.

At present, there is no pending litigation or proceeding involving a director or officer of our company for which indemnification is required or permitted, and we are not aware of any threatened litigation or proceeding that may result in a claim for indemnification.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted by directors, executive officers or persons controlling us, we have been informed that in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

**Table of Contents**

**CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS**

The following is a summary of transactions since our inception to which we have been a party in which the amount involved exceeded \$120,000 and in which any of our executive officers, directors or beneficial holders of more than 5% of our capital stock had or will have a direct or indirect material interest, other than compensation arrangements which are described under the section of this prospectus entitled Management Executive Compensation.

**Sales of Securities**

The shares of common stock set forth in the table below were purchased by our executive officers and directors in March 2003 at a per share price of \$.0023, in April 2003 at per share prices of \$.005 and \$.01, in October 2003 at a per share price of \$.10, in January 2004 at a per share price of \$.10 and in September 2004 at a per share price of \$1.3636, for aggregate consideration of \$338,033.

During the period from April 2003 through January 2004, we issued and sold an aggregate of 15,000,000 shares of our Series A preferred stock at a per share price of \$1.00 for aggregate consideration of \$15.0 million. During the period from February 2004 through December 2006, we issued and sold an aggregate of 88,002,330 shares of our Series B preferred stock at a per share price of \$1.3636 for aggregate consideration of approximately \$120.0 million. During the period from February 2004 through December 2006, we also issued and sold an aggregate of 95,335,875 shares of our Series B Prime preferred stock at a per share price of \$1.3636 for aggregate consideration of approximately \$130.0 million.

In June 2005, we issued warrants to purchase an aggregate of 8,695,652 shares of our Series BB preferred stock in connection with the issuance of senior secured notes in the aggregate principal amount of \$80.0 million. The warrants have an exercise price of \$1.84 per share. In connection with the conversion of all our outstanding shares of preferred stock into common stock immediately prior to the closing of this offering, the warrants will automatically become exercisable for shares of common stock. These warrants will terminate on June 24, 2012, unless exercised earlier.

**Table of Contents**

We believe that the terms obtained or consideration that we paid or received, as applicable, in connection with the transactions described were comparable to terms available or the amounts that would be paid or received, as applicable, in arm s-length transactions.

Purchaser	Series A		Series B	Series B	Series BB
	Common	Preferred	Preferred	Prime	Preferred
	Stock	Stock	Stock	Stock	Stock
<b>Executive Officers and Directors</b>					
Bruce C. Cozadd(1)	1,980,000		733,352		
Samuel R. Saks, M.D.(2)	2,640,000	150,000	733,352		
Robert M. Myers(3)	1,047,500		513,347		
Matthew K. Fust(4)	330,000		220,005		
Carol A. Gamble(5)	300,000				
Janne L.T. Wissel(6)	330,000		733,352		
Alan M. Sebulsky(7)	146,671				
<b>Principal Stockholders(8)</b>					
Entities affiliated with Kohlberg Kravis Roberts & Co. L.P.(9)				95,335,875	2,717,391
Entities affiliated with Thoma Cressey Bravo, Inc.(10)			22,000,585		
Entities affiliated with Beecken Petty O Keefe & Company(11)			14,667,057		
Entities affiliated with Prospect Venture Partners(12)		7,425,000	6,233,499		
Entities affiliated with Versant Ventures(13)		7,425,000	6,233,499		
Entities affiliated with Golden Gate Capital(14)			11,000,287		
Entities affiliated with Lehman Brothers Holdings Inc.(15)			7,333,528		3,369,566

- (1) Includes 165,000 shares of common stock that are subject to our right of repurchase as of December 31, 2006, which such right of repurchase lapses in full on April 1, 2007.
- (2) Includes 220,000 shares of common stock that are subject to our right of repurchase as of December 31, 2006, which such right of repurchase lapses in full on April 1, 2007.
- (3) Includes 126,042 shares of common stock that are subject to our right of repurchase as of December 31, 2006, which such right of repurchase lapses in full on December 18, 2007.
- (4) Includes 27,500 shares of common stock that are subject to our right of repurchase as of December 31, 2006, which such right of repurchase lapses in full on April 30, 2007.
- (5) Includes 25,000 shares of common stock that are subject to our right of repurchase as of December 31, 2006, which such right of repurchase lapses in full on April 18, 2007.
- (6) Includes 61,875 shares of common stock that are subject to our right of repurchase as of December 31, 2006, which such right of repurchase lapses in full on September 3, 2007.
- (7) Includes 58,058 shares of common stock that are subject to our right of repurchase as of December 31, 2006, which such right of repurchase lapses in full on July 13, 2008.
- (8) Certain of our directors are associated with our principal stockholders as indicated in the table below:

**Director**

Adam H. Clammer  
Samuel D. Colella  
Bryan C. Cressey  
Michael W. Michelson  
James C. Momtazee  
Kenneth W. O Keefe  
James B. Tananbaum, M.D.

**Principal Stockholder**

Entities affiliated with Kohlberg Kravis Roberts & Co. L.P.  
Entities affiliated with Versant Ventures  
Entities affiliated with Thoma Cressey Bravo  
Entities affiliated with Kohlberg Kravis Roberts & Co. L.P.  
Entities affiliated with Kohlberg Kravis Roberts & Co. L.P.  
Entities affiliated with Beecken Petty O Keefe & Company  
Entities affiliated with Prospect Venture Partners

- (9) Consists of 94,932,531 shares of Series B Prime preferred stock held by KKR JP LLC, 403,344 shares of Series B Prime preferred stock held by KKR JP III LLC and warrants to purchase 2,717,391 shares of Series BB preferred stock held by KKR TRS Holdings, Inc.



---

## **Table of Contents**

- (10) Consists of 21,662,348 shares of Series B preferred stock held by Thoma Cressey Fund VII, LP and 338,237 shares of Series B preferred stock held by Thoma Cressey Friends Fund VII, LP.
- (11) Consists of 14,667,057 shares of Series B preferred stock held by Jazz Investors LLC.
- (12) Consists of 7,313,625 shares of Series A preferred stock and 6,139,997 shares of Series B preferred stock held by Prospect Venture Partners II, L.P. and 111,375 shares of Series A preferred stock and 93,502 shares of Series B preferred stock held by Prospect Associates II, L.P.
- (13) Consists of 7,223,361 shares of Series A preferred stock and 6,064,216 shares of Series B preferred stock held by Versant Venture Capital II, L.P., 137,080 shares of Series A preferred stock and 115,083 shares of Series B preferred stock held by Versant Affiliates Fund II-A, L.P., and 64,559 shares of Series A preferred stock and 54,200 shares of Series B preferred stock held by Versant Side Fund II, L.P.
- (14) Consists of 9,521,349 shares of Series B preferred stock held by CCG Investment Fund, LP, 480,987 shares of Series B preferred stock held by CCG AV, LLC-Series C, 523,132 shares of Series B preferred stock held by CCG Associates-QP, LLC, 127,260 shares of Series B preferred stock held by CCG AV, LLC-Series A, 127,553 shares of Series B preferred stock held by CCG Investment Fund-AI, LP, and 220,006 shares of Series B preferred stock held by CCG CI, LLC.
- (15) Consists of 1,833,382 shares of Series B preferred stock held by Lehman Brothers HealthCare Venture Capital LP, 3,509,093 shares of Series B preferred stock held by Lehman Brothers PA LLC, 1,581,017 shares of Series B preferred stock held by Lehman Brothers Partnership Account 2000/2001, LP, 410,036 shares of Series B preferred stock held by Lehman Brothers Offshore Partnership Account 2000/2001 LP, and warrants to purchase 3,369,566 shares of Series BB Preferred Stock held by LB I Group Inc. Lehman Brothers Holdings Inc. is affiliated with Lehman Brothers Inc., which is acting as a representative of the underwriters of this offering.

## **Senior Secured Notes**

In June 2005, we issued senior secured notes in the aggregate principal amount of \$80.0 million with interest payable on the notes at the rate of 15% per year, payable quarterly in arrears. The notes are due and payable on June 24, 2011. As of December 31, 2006, KKR TRS Holdings, Inc., an entity affiliated with Kohlberg Kravis Roberts & Co. L.P., and LB I Group, an entity affiliated with Lehman Brothers Holdings Inc., both of which are significant stockholders, held \$25.0 million and \$31.0 million, respectively, in principal amount of these senior secured notes which represented the largest aggregate amount of principal balance outstanding to date for each of these note holders. The interest payments made to KKR TRS Holdings, Inc. during the fiscal years ended December 31, 2006 and 2005 were approximately \$3.8 million and \$1.9 million, respectively. The interest payments made to LB I Group during the fiscal years ended December 31, 2006 and 2005 were approximately \$4.6 million and \$2.3 million, respectively. There were no payments of principal made in either of these periods. Lehman Brothers Inc., one of the representatives of the underwriters of this offering, is affiliated with Lehman Brothers Holdings Inc. In connection with the issuance of the senior secured notes, we issued warrants to purchase 2,717,391 and 3,369,566 shares of our Series BB preferred stock to KKR TRS Holdings, Inc. and LB I Group, respectively.

## **Second Amended and Restated Investor Rights Agreement**

We entered into an investor rights agreement with certain purchasers of our common stock, preferred stock and warrants to purchase our Series BB preferred stock, including our principal stockholders with which certain of our directors are affiliated. As of January 31, 2007, the holders of 213,661,357 shares of our common stock, including the shares of common stock issuable upon the conversion of our preferred stock and exercise of outstanding warrants, are entitled to rights with respect to the registration of their shares under the Securities Act. In addition, upon exercise of outstanding options by our executive officers, our executive officers will be entitled to rights with respect to registration of the shares of common stock acquired upon exercise. For a description of these registration rights, see [Description of Capital Stock](#) [Registration Rights](#).

## **Second Amended and Restated Voting Agreement**

The election of the members of our board of directors is governed by a voting agreement with certain of the purchasers of our outstanding common stock, preferred stock and warrants to purchase our Series BB preferred stock, including our principal stockholders with which certain of our directors are affiliated, and by related provisions of our second amended and restated certificate of incorporation. The parties to the voting agreement have agreed, subject to certain conditions, to vote their shares so as to elect as directors the nominees designated



## **Table of Contents**

by certain of our investors, including KKR JP LLC and its affiliated funds, Thoma Cressey Fund VII, L.P. and its affiliated funds, Jazz Investors LLC, Versant Venture Capital II, L.P. and its affiliated funds, and Prospect Venture Partners II, L.P. and its affiliated funds. In addition, so long as Mr. Cozadd and Dr. Saks are employed by us, the parties to the voting agreement have agreed to vote their shares so as to elect each of Mr. Cozadd and Dr. Saks to our board of directors. The parties further agreed to vote their shares so as to elect up to three persons who are not affiliates of us or any of our stockholders, and which nominees are nominated by at least two-thirds of our board of directors. Upon the closing of this offering, the obligations of the parties to the voting agreement to vote their shares so as to elect as these nominees will terminate and none of our stockholders will have any special rights regarding the nomination, election or designation of members of our board of directors.

## **Other Transactions**

We have entered into employment agreements with our executive officers that, among other things, provide for certain severance and change of control benefits. For a description of these agreements, see [Management Executive Compensation Executive Employment Agreements](#).

We have granted stock options to our executive officers and to one of our directors. For a description of these options, see [Management Non-Employee Director Compensation](#) and [Executive Compensation](#).

We have entered into indemnity agreements with our directors and executive officers. For a description of these agreements, see [Management Limitation of Liability and Indemnification](#).



**Table of Contents**

**PRINCIPAL STOCKHOLDERS**

The following table sets forth the beneficial ownership of our common stock as of January 31, 2007 by:

each person, or group of affiliated persons, who is known by us to beneficially own more than 5% of our common stock;

each of the named executive officers;

each of our directors; and

all of our executive officers and directors as a group.

The percentage ownership information shown in the table is based upon 205,246,300 shares outstanding as of January 31, 2007, assuming the conversion of all outstanding shares of our preferred stock as of January 31, 2007, and the issuance of \_\_\_\_\_ shares of common stock in this offering. The percentage ownership information assumes no exercise of the underwriters' overallotment option.

Information with respect to beneficial ownership has been furnished by each director, officer or beneficial owner of more than 5% of our common stock. We have determined beneficial ownership in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. In addition, the rules include shares of common stock issuable pursuant to the exercise of stock options or warrants that are either immediately exercisable or exercisable on or before April 1, 2007, which is 60 days after January 31, 2007. These shares are deemed to be outstanding and beneficially owned by the person holding those options or a warrant for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to applicable community property laws.

**Table of Contents**

Except as otherwise noted below, the address for person or entity listed in the table is c/o Jazz Pharmaceuticals, Inc., 3180 Porter Drive, Palo Alto, California 94304.

Name of Beneficial Owner	Number of	Percentage of Shares	
	Shares	Beneficially Owned	
	Beneficially Owned	Before Offering	After Offering
<b>5% Stockholders</b>			
Entities affiliated with Kohlberg Kravis Roberts & Co. L.P.			
KKR JP, LLC(1)	94,932,531	46.25%	
KKR JP III LLC(1)	403,344	*	*
KKR TRS Holdings, Inc.(2)	2,717,391	1.31	
Entities affiliated with Thoma Cressey Bravo, Inc.(3)	22,000,585	10.72	
Entities affiliated with Beecken Petty O Keefe & Company(4)	14,667,057	7.15	
Entities affiliated with Prospect Venture Partners(5)	13,658,499	6.65	
Entities affiliated with Versant Ventures(6)	13,658,499	6.65	
Entities affiliated with Golden Gate Capital(7)	11,000,287	5.36	
Entities affiliated with Lehman Brothers Holdings Inc.(8)	10,703,094	5.13	
<b>Named Executive Officers and Directors</b>			
Bruce C. Cozadd(9)	5,046,818	2.43	
Samuel R. Saks, M.D.(10)	5,856,818	2.82	
Robert M. Myers(11)	3,894,313	1.88	
Matthew K. Fust(12)	1,440,788	*	*
Janne L.T. Wissel(13)	1,954,135	*	*
Carol A. Gamble(14)	1,190,783	*	*
Adam H. Clammer(15)	98,053,266	47.15	
Samuel D. Colella(16)	13,658,499	6.65	
Bryan C. Cressey(17)	22,000,585	10.72	
Michael W. Michelson(18)	98,053,266	47.15	
James C. Momtazee(19)	98,053,266	47.15	
Kenneth W. O Keefe(20)	14,667,057	7.15	
Alan M. Sebulsky(21)	196,671	*	*
James B. Tananbaum, M.D.(22)	13,658,499	6.65	
All directors and executive officers as a group (14 persons)(23)	181,618,232	83.43%	

\* Represents beneficial ownership of less than 1%.

- (1) All of the outstanding equity interests of KKR JP LLC are owned directly by KKR Millennium Fund L.P. KKR Millennium GP LLC is the general partner of KKR Associates Millennium L.P., which is the general partner of KKR Millennium Fund L.P. All of the outstanding equity interests of KKR JP III LLC are owned directly by KKR Partners III, L.P. KKR III GP LLC is the general partner of KKR Partners III, L.P. The entities named in this footnote (1) are sometimes referred to as the KKR Funds. KKR Millennium GP LLC and KKR III GP LLC are limited liability companies, the managing members of which are Messrs. Henry R. Kravis and George R. Roberts, and the other members of which are James H. Greene, Jr., Paul E. Raether, Mr. Michelson, Perry Golkin, Johannes P. Huth, Todd A. Fisher, Alexander Navab, Marc Lipschultz, Jacques Garaialde, Reinhard Gorenflos, Michael M. Calbert and Scott C. Nuttall. Mr. Michelson is a member of our board of directors. Each of such individuals may be deemed to share beneficial ownership of any shares beneficially owned by KKR Millennium GP LLC and KKR III GP LLC, but disclaim beneficial ownership of such shares. Mr. Clammer is a member of our board of directors and is a member of KKR & Co. L.L.C. which is the general partner of Kohlberg Kravis Roberts & Co. L.P., which is an affiliate of the KKR Funds. Mr. Momtazee is a member of our board of directors and is an executive of Kohlberg Kravis Roberts & Co. L.P. Each of Messrs. Clammer and Momtazee disclaim beneficial ownership of any shares beneficially owned by the KKR Funds. The address of the KKR Funds and Messrs. Kravis, Raether, Golkin, Navab, Lipschultz and Nuttall is c/o Kohlberg Kravis Roberts & Co. L.P., 9 West 57th Street, New York, NY 10019. The address of Messrs. Roberts, Michelson, Greene, Calbert, Clammer and Momtazee is 2800 Sand Hill Road, Suite 200, Menlo Park, CA 94025. The address of Messrs. Fisher, Huth, Gorenflos and Garaialde is c/o Kohlberg Kravis Roberts & Co. Ltd., Stirling Square, 7 Carlton Garden, London SW1Y 5AD, England.
- (2) Consists of 2,717,391 shares that KKR TRS Holdings, Inc. has the right to acquire within 60 days of January 31, 2007 through the exercise of a warrant. All of the outstanding equity interests of KKR TRS Holdings, Inc. are owned by KKR Financial Corp. KKR Financial Advisors LLC is the manager of KKR Financial Corp. KKR Financial LLC is the sole member of KKR Financial Advisors LLC. Kohlberg Kravis Roberts & Co. L.P. owns a majority of the

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

outstanding equity interests of KKR Financial LLC. KKR & Co. L.L.C. is the general partner of Kohlberg Kravis Roberts & Co. L.P. The investment committee of KKR Financial Advisors LLC

**Table of Contents**

- reviews the investments held by KKR Financial Corp. Mr. Nuttall is one of four members of the investment committee, and Messrs. Kravis and Roberts are ad hoc members of the investment committee. The members of KKR & Co. L.L.C. consist of the individuals named in footnote (1) above (other than Mr. Momtazee) and other executives of Kohlberg Kravis Roberts & Co. L.P., and in such capacity may be deemed to share beneficial ownership of any shares beneficially owned by KKR & Co. L.L.C., but disclaim beneficial ownership of such shares. The address of KKR TRS Holdings, Inc., KKR Financial Corp. and KKR Financial LLC is 555 California Street, 50th Floor, San Francisco, CA 94104.
- (3) Consists of 21,662,348 shares held by Thoma Cressey Fund VII, LP and 338,237 shares held by Thoma Cressey Friends Fund VII, LP. Mr. Cressey, Orlando Bravo, Lee Mitchell and Carl Thoma are partners of Thoma Cressey Bravo, Inc., which is the general partner of each of Thoma Cressey Fund VII, LP and Thoma Cressey Friends Fund VII, LP., or the Thoma Cressey Funds, and are deemed to have shared voting and investment power over the shares held by the Thoma Cressey Funds. Each of Messrs. Cressey, Bravo, Mitchell and Thoma disclaim beneficial ownership of the shares held by the Thoma Cressey Funds, except to the extent of each of their pecuniary interest therein. The address for all entities and individuals affiliated with Thoma Cressey Bravo is Sears Tower, 92nd Floor, 22 South Wacker Drive, Chicago, IL 60606.
  - (4) Consists of 14,667,057 shares held by Jazz Investors LLC. Mr. O Keefe, David K. Beecken, William G. Petty, Jr., Thomas A. Schlesinger, David J. Cooney, Gregory A. Moerschel and John W. Kneen are partners of Beecken Petty O Keefe & Company, which is the general partner of Jazz Investors LLC, and are deemed to have shared voting and investment power over the shares held by Jazz Investors LLC. Each of Messrs. O Keefe, Beecken, Petty, Schlesinger, Cooney, Moerschel and Kneen disclaim beneficial ownership of the shares held by Jazz Investors LLC, except to the extent of each of their pecuniary interest therein. The address for all entities and individuals affiliated with Beecken Petty O Keefe & Company is 131 South Dearborn Street, Ste. 2800, Chicago, IL 60603.
  - (5) Consists of 13,453,622 shares held by Prospect Venture Partners II, L.P. and 204,877 shares held by Prospect Associates II, L.P. Dr. Tananbaum is a managing member of Prospect Management Co. II, L.L.C., which is the general partner of each of Prospect Venture Partners II, L.P. and Prospect Associates II, L.P., or the Prospect Funds. The managing members of Prospect Management Co. II, L.L.C. are deemed to have shared voting and investment power over the shares held by the Prospect Funds. Dr. Tananbaum disclaims beneficial ownership of the shares held by the Prospect Funds, except to the extent of his pecuniary interest therein. The address for all entities and individuals affiliated with Prospect Venture Partners is 435 Tasso Street, Suite 200, Palo Alto, CA 94301.
  - (6) Consists of 13,287,577 shares held by Versant Venture Capital II, L.P., 252,163 shares held by Versant Affiliates Fund II-A, L.P. and 118,759 shares held by Versant Side Fund II, L.P. Mr. Colella is a managing member of Versant Ventures II, LLC, which is the general partner of each of Versant Venture Capital II, L.P., Versant Affiliates Fund II-A, L.P. and Versant Side Fund II, L.P., or the Versant Funds, and is deemed to have shared voting and investment power over the shares held by the Versant Funds. Mr. Colella disclaims beneficial ownership of the shares held by the Versant Funds, except to the extent of his pecuniary interest therein. The address for all entities and individuals affiliated with Versant Ventures II LLC is 3000 Sand Hill Road, Building 4, Ste. 210, Menlo Park, CA 94025.
  - (7) Consists of 523,132 shares held by CCG Associates-QP, LLC, 127,260 shares held by CCG AV, LLC-Series A, 480,987 shares held by CCG AV, LLC-Series C, 220,006 shares held by CCG CI, LLC, 9,521,349 shares held by CCG Investment Fund, LP and 127,553 shares held by CCG Investment Fund-AI, LP. Golden Gate Capital Management, L.L.C. is the general partner or managing member of CCG Associates-QP, LLC, CCG AV, LLC-Series A, CCG AV, LLC-Series C, CCG CI, LLC, CCG Investment Fund, LP and CCG Investment Fund AI, LP, or the CCG Funds. Messrs. David C. Dominik and Jesse T. Rogers, as principal managing members of Golden Gate Capital Management, L.L.C., are deemed to have shared voting and investment power over the shares held by the CCG Funds. Each of Messrs. Dominik and Rogers disclaim beneficial ownership of the shares held by the CCG Funds, except to the extent of each of their pecuniary interest therein. The address for all entities and individuals affiliated with Golden Gate Capital is One Embarcadero Center, 33<sup>rd</sup> Floor, San Francisco, CA 94111.
  - (8) Consists of 1,833,382 shares held by Lehman Brothers HealthCare Venture Capital LP, 3,509,093 shares held by Lehman Brothers PA LLC, 1,581,017 shares held by Lehman Brothers Partnership Account 2000/2001, LP, 410,036 shares held by Lehman Brothers Offshore Partnership Account 2000/2001 LP, and warrants to purchase 3,369,566 shares held by LB I Group Inc. Each of the foregoing entities is managed by a subsidiary of Lehman Brothers Holdings Inc. The address for all entities and individuals affiliated with Lehman Brothers Holdings Inc. is 399 Park Avenue, New York, NY 10022. Lehman Brothers Holdings Inc. is affiliated with Lehman Brothers Inc., which is acting as a representative of the underwriters of this offering.
  - (9) Includes 2,333,466 shares Mr. Cozadd has the right to acquire within 60 days of January 31, 2007 through the exercise of options.
  - (10) Includes 2,333,466 shares Dr. Saks has the right to acquire within 60 days of January 31, 2007 through the exercise of options.
  - (11) Includes 2,333,466 shares Mr. Myers has the right to acquire within 60 days of January 31, 2007 through the exercise of options, and 43,594 shares subject to our unvested share repurchase right within 60 days of January 31, 2007.
  - (12) Includes 890,783 shares Mr. Fust has the right to acquire within 60 days of January 31, 2007 through the exercise of options, and 6,875 shares subject to our unvested share repurchase right within 60 days of January 31, 2007.
  - (13) Includes 890,783 shares Ms. Wissel has the right to acquire within 60 days of January 31, 2007 through the exercise of options, and 41,250 shares subject to our unvested share repurchase right within 60 days of January 31, 2007.
  - (14) Includes 890,783 shares Ms. Gamble has the right to acquire within 60 days of January 31, 2007 through the exercise of options, and 6,250 shares subject to our unvested share repurchase right within 60 days of January 31, 2007.
  - (15) Consists solely of the shares described in Notes (1) and (2) above. Mr. Clammer disclaims beneficial ownership of these shares.
  - (16) Consists solely of the shares described in Note (6) above. Mr. Colella disclaims beneficial ownership of these shares, except to the extent of his pecuniary interest therein.
  - (17) Consists solely of the shares described in Note (3) above. Mr. Cressey disclaims beneficial ownership of these shares, except to the extent of his pecuniary interest therein.
  - (18) Consists solely of the shares described in Notes (1) and (2) above. Mr. Michelson disclaims beneficial ownership of these shares.

**Table of Contents**

- (19) Consists solely of the shares described in Notes (1) and (2) above. Mr. Momtazee disclaims beneficial ownership of these shares.
- (20) Consists solely of the shares described in Note (4) above. Mr. O Keefe disclaims beneficial ownership of these shares, except to the extent of his pecuniary interest therein.
- (21) Includes 50,000 shares Mr. Sebulsky has the right to acquire within 60 days of January 31, 2007 through the exercise of options, and 48,891 shares subject to our unvested share repurchase right within 60 days of January 31, 2007.
- (22) Consists solely of the shares described in Note (5) above. Dr. Tananbaum disclaims beneficial ownership of these shares, except to the extent of his pecuniary interest therein.
- (23) Includes 162,037,906 shares held by entities affiliated with certain of our directors, 9,722,747 shares that certain of our executive officers and directors have the right to acquire within 60 days of January 31, 2007 through the exercise of options and 146,860 shares subject to our unvested share repurchase right within 60 days of January 31, 2007.

**Table of Contents**

**DESCRIPTION OF CAPITAL STOCK**

Upon the closing of this offering and the filing of our third amended and restated certificate of incorporation, our authorized capital stock will consist of \_\_\_\_\_ shares of common stock, par value \$.0001 per share, and shares of preferred stock, par value \$.0001 per share.

The following is a summary of the rights of our common stock and preferred stock. This summary is not complete. For more detailed information, please see our third amended and restated certificate of incorporation and amended and restated bylaws, which are filed as exhibits to the registration statement of which this prospectus is a part.

**Common Stock**

*Outstanding Shares*

Based on 6,908,095 shares of common stock outstanding as of January 31, 2007, the conversion of outstanding preferred stock as of January 31, 2007 into 198,338,205 shares of common stock upon the completion of this offering, the issuance of \_\_\_\_\_ shares of common stock in this offering, and no exercise of options or warrants, there will be \_\_\_\_\_ shares of common stock outstanding upon the closing of this offering. As of January 31, 2007, assuming the conversion of all outstanding preferred stock into common stock upon the closing of this offering, we had approximately 44 record holders of our common stock.

As of January 31, 2007, there were 8,695,652 shares of common stock subject to outstanding warrants, assuming the conversion of all outstanding preferred stock into common stock upon the closing of this offering, and 17,572,774 shares of common stock subject to outstanding options.

*Voting Rights*

Each holder of common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors. Our third amended and restated certificate of incorporation and amended and restated bylaws do not provide for cumulative voting rights. Because of this, the holders of a majority of the shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they should so choose.

*Dividends*

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.

***Liquidation***

In the event of our liquidation, dissolution or winding up, holders of common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities and the satisfaction of any liquidation preference granted to the holders of any then outstanding shares of preferred stock.

***Rights and Preferences***

Holders of common stock have no preemptive, conversion, subscription or other rights, and there are no redemption or sinking fund provisions applicable to the common stock. The rights, preferences and privileges of the holders of common stock are subject to and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that we may designate in the future.

## **Table of Contents**

### ***Fully Paid and Nonassessable***

All of our outstanding shares of common stock are, and the shares of common stock to be issued pursuant to this offering will be, fully paid and nonassessable.

### **Preferred Stock**

Upon the closing of this offering, all outstanding shares of preferred stock will have been converted into shares of common stock. See Note 12 to our consolidated financial statements for a description of the currently outstanding preferred stock. Following this offering, our third amended and restated certificate of incorporation will be amended and restated to delete all references to such shares of preferred stock. Under our third amended and restated certificate of incorporation, our board of directors will have the authority, without further action by the stockholders, to issue up to \_\_\_\_\_ 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 rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon 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).

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 the common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in our control and may adversely affect the market price of the common stock and the voting and other rights of the holders of common stock. We have no current plans to issue any shares of preferred stock.

### **Warrants**

As of January 31, 2007, warrants exercisable for 8,695,652 shares of our Series BB preferred stock at an exercise price of \$1.84 per share were outstanding. These warrants were issued in June 2005 under a senior secured note and warrant purchase agreement entered into in connection with our acquisition of Orphan Medical. In connection with the conversion of all our outstanding shares of preferred stock into common stock immediately prior to the closing of this offering, the warrants will automatically become exercisable for shares of common stock. The warrants have a net exercise provision under which their holders may, in lieu of payment of the exercise price in cash, surrender the warrant and receive a net amount of shares based on the fair market value of our stock at the time of exercise of the warrants after deduction of the aggregate exercise price. The warrants contain provisions for the adjustment of the exercise price and the number of shares issuable upon the exercise of the warrants in the event of certain stock dividends, stock splits, reorganizations, reclassifications and consolidations. The warrants will terminate on June 24, 2012 if not exercised earlier.

### **Registration Rights**

Under our investor rights agreement, following the closing of this offering, the holders of 213,661,357 shares of common stock, including warrants to purchase 8,695,652 shares of common stock, or their transferees, have the right to require us to register their shares with the SEC so that those shares may be publicly resold, or to include their shares in any registration statement we file, in each case as described below. If our executive officers exercise outstanding stock options, the shares of common stock acquired on exercise would have the registration rights



described below.

***Demand Registration Rights***

At any time after six months following the effective date of the registration statement for this offering, the holders of at least 40% of the shares having registration rights (or a lesser number if the anticipated aggregate amount of shares to be sold is expected to not be less than \$25.0 million), and each holder who was an original

## **Table of Contents**

purchaser of at least 50 million shares of our Series B preferred stock and/or Series B Prime preferred stock, each have the right to demand that we file one registration statement. These registration rights are subject to specified conditions and limitations, including the right of the underwriters to limit the number of shares included in any such registration under certain circumstances.

### ***Form S-3 Registration Rights***

At any time after we are qualified to file a registration statement on Form S-3, the holders of at least 20% of the shares having registration rights and each holder who is an original purchaser of \$40.0 million in original issue price of shares having registration rights, each have the right to demand that we file a registration statement on Form S-3 so long as the aggregate amount of shares to be sold under the registration statement on Form S-3 is at least \$25.0 million. A holder who was an original purchaser of \$40.0 million in original issue price of our shares having registration rights has the right to demand one registration statement for each \$40.0 million in original issue price of such shares having registration rights that the holder purchased. We are only obligated to file up to two registration statement on Form S-3 in any 12 month period. These registration rights are subject to specified conditions and limitations, including the right of the underwriters to limit the number of shares included in any such registration under certain circumstances.

### ***Piggyback Registration Rights***

At any time after the closing of this offering, if we propose to register any of our securities under the Securities Act either for our own account or for the account of other stockholders, a stockholder with registration rights will have the right to include their shares of common stock in the registration statement. These registration rights are subject to specified conditions and limitations, including the right of the underwriters to limit the number of shares included in any such registration under certain circumstances, but not below 30% of the total number of shares included in the registration statement.

### ***Expenses of Registration***

We will pay all expenses relating to any demand registrations, Form S-3 registrations and piggyback registrations, other than underwriting discounts and commissions.

### ***Termination***

The registration rights and our obligations terminate upon the earlier of either February 18, 2016, or as to a given holder of registration rights, when such holder of registration rights can sell all of such holder's registrable securities in a three month period pursuant to Rule 144 promulgated under the Securities Act.

### **Delaware Anti-Takeover Law and Certain Provisions of Our Third Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws**

*Delaware Law*

We are subject to Section 203 of the Delaware General Corporation Law. Section 203 generally prohibits a public Delaware corporation 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;

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

**Table of Contents**

outstanding (a) shares owned by persons who are directors and also officers and (b) shares owned by 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<sup>2</sup>/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, transfer, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;

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;

any transaction involving the corporation that has the effect 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 of any loans, advances, guarantees, pledges or other financial benefits 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 the entity or person.

***Third Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws***

Provisions of our third amended and restated certificate of incorporation and amended and restated bylaws, which will become effective upon the closing of this offering, 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 third amended and restated certificate of incorporation and amended and restated bylaws:

permit our board of directors to issue up to \_\_\_\_\_ 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 resolution of the board of directors;

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

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;

**Table of Contents**

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<sup>2</sup>/<sub>3</sub>% 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.

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

**Transfer Agent and Registrar**

The transfer agent and registrar for our common stock is . The transfer agent and registrar's address is .

**NASDAQ Global Market Listing**

We have applied for quotation of our common stock on the NASDAQ Global Market under the trading symbol JAZZ.

**Table of Contents**

**SHARES ELIGIBLE FOR FUTURE SALE**

Immediately prior to this offering, there has been no public market for our common stock. Future sales of substantial amounts of common stock in the public market could adversely affect prevailing market prices. Furthermore, since only a limited number of shares will be available for sale shortly after this offering because of contractual and legal restrictions on resale described below, sales of substantial amounts of common stock in the public market after the restrictions lapse could adversely affect the prevailing market price for our common stock as well as our ability to raise equity capital in the future.

Based on the number of shares of common stock outstanding as of January 31, 2007, upon completion of this offering, \_\_\_\_\_ shares of common stock will be outstanding, assuming no exercise of the underwriters' over-allotment option and no exercise of options or warrants. All of the shares sold in this offering will be freely tradable unless purchased by our affiliates. Except as set forth below, the remaining shares of common stock outstanding after this offering will be restricted as a result of securities laws or lock-up agreements. These remaining shares will generally become available for sale in the public market as follows:

no restricted shares will be eligible for immediate sale upon the closing of this offering;

\_\_\_\_\_ shares, less shares subject to a repurchase option in our favor tied to the holders' continued service to us (which will be eligible for sale upon lapse of the repurchase option), will be eligible for sale upon expiration of lock-up agreements 180 days after the date of this prospectus; and

the remainder of the restricted shares will be eligible for sale from time to time thereafter upon expiration of their respective one-year holding periods, but could be sold earlier if the holders exercise any available registration rights.

**Rule 144**

In general, under Rule 144 under the Securities Act of 1933, as in effect on the date of this prospectus, a person who has beneficially owned shares of our common stock for at least one year would be entitled to sell within any three-month period a number of shares that does not exceed the greater of:

1% of the number of shares of our common stock then outstanding, which will equal approximately \_\_\_\_\_ shares immediately after this offering; or

the average weekly trading volume of our common stock on the NASDAQ Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

Sales under Rule 144 are also subject to manner of sale provisions and notice requirements and to the availability of current public information about us.

**Rule 144(k)**

Under Rule 144(k) of the Securities Act as in effect on the date of this prospectus, a person who is not deemed to have been one of our affiliates at any time during the 90 days preceding a sale, and who has beneficially owned the shares proposed to be sold for at least two years, including the holding period of any prior owner other than an affiliate, is entitled to sell the shares without complying with the manner of sale, public information, volume limitation or notice provisions of Rule 144. shares of our common stock will qualify for resale under Rule 144(k) within 180 days of the date of this prospectus.

**Rule 701**

Rule 701 under the Securities Act, as in effect on the date of this prospectus, permits resales of shares in reliance upon Rule 144 but without compliance with certain restrictions of Rule 144, including the holding period requirement. Most of our employees, executive officers or directors who purchased shares under a written



## **Table of Contents**

compensatory plan or contract may be entitled to rely on the resale provisions of Rule 701, but all holders of Rule 701 shares are required to wait until 90 days after the date of this prospectus before selling their shares. However, substantially all Rule 701 shares are subject to lock-up agreements as described below and under **Underwriters** and will become eligible for sale upon the expiration of the restrictions set forth in those agreements.

### **Lock-up Agreements**

We, along with our directors, executive officers and substantially all of our other stockholders, optionholders and warrant holders have agreed with the underwriters that for a period of 180 days following the date of this prospectus, we or they will not offer, sell, assign, transfer, pledge, contract to sell or otherwise dispose of or hedge any shares of our common stock or any securities convertible into or exchangeable for shares of common stock, subject to specified exceptions. Morgan Stanley & Co. Incorporated and Lehman Brothers Inc. may, in their sole discretion, at any time without prior notice, release all or any portion of the shares from the restrictions in any such agreement.

The 180-day restricted period described in the preceding paragraph will be extended if:

during the last 17 days of the 180-day restricted period we issue an earnings release or material news or a material event relating to us is publicly announced; or

prior to the expiration of the 180-day restricted period, we announce that we will release earnings results during the 16-day period beginning on the last day of the 180-day period,

in which case the restrictions described in the preceding paragraph will continue to apply until the expiration of the 18-day period beginning on the issuance of the release or the occurrence of the material news or material event, except in no event will the restrictions extend past 214 days after the date of this prospectus.

### **Registration Rights**

Upon the closing of this offering, the holders of 213,661,357 shares of our common stock, including warrants exercisable for shares of our common stock will be entitled to rights with respect to the registration of their shares under the Securities Act, subject to the 180-day lock-up arrangement described above. Shares acquired upon exercise of outstanding options by our executive officers would have these registration rights. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act (except for shares held by affiliates) immediately upon the effectiveness of this registration. Any sales of securities by these stockholders could adversely effect on the trading price of our common stock. See **Description of Capital Stock** **Registration Rights**.

### **Equity Incentive Plans**

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

We intend to file with the SEC a registration statement under the Securities Act covering the shares of common stock subject to outstanding stock options granted under our 2003 Equity Incentive Plan, as well as the shares of common stock reserved for issuance under our 2007 Equity Incentive Plan, 2007 Non-Employee Directors Stock Option Plan and 2007 Employee Stock Purchase Plan. The registration statement is expected to be filed and become effective as soon as practicable after the closing of this offering. Accordingly, shares registered under the registration statement will be available for sale in the open market following its effective date, subject to Rule 144 volume limitations applicable to our affiliates and the lock-up agreements described above.

**Table of Contents**

**MATERIAL U.S. TAX CONSEQUENCES FOR  
NON-U.S. HOLDERS OF COMMON STOCK**

The following is a general discussion of the material U.S. federal income and estate tax consequences of the ownership and disposition of our common stock by a non-U.S. holder. For purposes of this discussion, you are a non-U.S. holder if you are a beneficial owner of our common stock and you are not, for U.S. federal income tax purposes:

an individual who is a citizen or resident of the United States;

a corporation created or organized in or under the laws of the United States, or of any political subdivision of the United States;

an estate whose income is subject to U.S. federal income taxation regardless of its source; or

a trust, in general, if a U.S. court is able to exercise primary supervision over the administration of the trust and one or more U.S. persons have authority to control all substantial decisions of the trust or if the trust has made a valid election to be treated as a U.S. person under applicable U.S. Treasury regulations.

If you are an individual, you may be treated as a resident of the United States in any calendar year for U.S. federal income tax purposes, instead of a nonresident, by, among other ways, being present in the United States for at least 31 days in that calendar year and for an aggregate of at least 183 days during a three-year period ending in the current calendar year. For purposes of this calculation, you would count all of the days present in the current year, one-third of the days present in the immediately preceding year and one-sixth of the days present in the second preceding year. Residents are taxed for U.S. federal income tax purposes as if they were U.S. citizens. If a partnership or other flow-through entity is a beneficial owner of our common stock, the tax treatment of a partner in the partnership or owner of the entity will generally depend on the status of the partner or owner and the activities of the partnership or entity. Such holders and their partners or owners should consult their own tax advisors regarding U.S. federal, state, local and non-U.S. income and other tax consequences of acquiring, holding and disposing of shares of our common stock.

This discussion does not purport to address all aspects of U.S. federal income and estate taxes or specific facts and circumstances that may be relevant to a particular non-U.S. holder's tax position, including:

U.S. state or local or any non-U.S. tax consequences;

the tax consequences for the stockholders, partners or beneficiaries of a non-U.S. holder;

special tax rules that may apply to particular non-U.S. holders, such as financial institutions, insurance companies, tax-exempt organizations, U.S. expatriates, broker-dealers and traders in securities; and special tax rules that may apply to a non-U.S. holder that holds our common stock as part of a straddle, hedge, conversion transaction, synthetic security or integrated investment.

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

The following discussion is based on provisions of the U.S. Internal Revenue Code of 1986, as amended, existing and proposed U.S. Treasury regulations and administrative and judicial interpretations, all as of the date of this prospectus, and all of which are subject to change, possibly with retroactive effect. The following summary assumes that you hold our common stock as a capital asset. **Each non-U.S. holder should consult a tax advisor regarding the U.S. federal, state, local and non-U.S. income and other tax consequences of acquiring, holding and disposing of shares of our common stock.**

### Dividends

We do not anticipate paying cash dividends on our common stock in the foreseeable future. See Dividend Policy. In the event, however, that we pay dividends on our common stock, we will have to withhold a

## **Table of Contents**

U.S. federal withholding tax at a rate of 30%, or a lower rate under an applicable income tax treaty, from the gross amount of the dividends paid to you. You should consult your tax advisors regarding your entitlement to benefits under a relevant income tax treaty. Generally, in order for us to withhold tax at a lower treaty rate, you must provide us with a properly executed Form W-8BEN certifying your eligibility for the lower treaty rate. However:

in the case of common stock held by a foreign partnership, the certification requirement will generally be applied to partners and the partnership will be required to provide certain information;

in the case of common stock held by a foreign trust, the certification requirement will generally be applied to the trust or the beneficial owners of the trust, depending on whether the trust is a foreign complex trust, foreign simple trust or foreign grantor trust as defined in the U.S. Treasury regulations; and

look-through rules apply for tiered partnerships, foreign simple trusts and foreign grantor trusts.

A non-U.S. holder that is a foreign partnership or a foreign trust is urged to consult its tax advisor regarding its status under these U.S. Treasury regulations and the certification requirements applicable to it.

If you are eligible for a reduced rate of U.S. federal withholding tax under an income tax treaty, you may obtain a refund or credit of any excess amounts withheld by filing an appropriate claim for a refund with the U.S. Internal Revenue Service.

If the dividend is effectively connected with your conduct of a trade or business in the United States and, if an income tax treaty applies, is attributable to a permanent establishment that you maintain in the United States, the dividend will generally be exempt from the U.S. federal withholding tax, provided that you supply us with a properly executed Form W-8ECI. In this case, the dividend will be taxed on a net income basis at the regular graduated rates and in the manner applicable to U.S. persons and, if you are a foreign corporation, you may be subject to an additional branch profits tax at a rate of 30% or a lower rate as may be specified by an applicable income tax treaty.

## **Gain on Dispositions of Common Stock**

You generally will not be subject to U.S. federal income tax on gain recognized on a disposition of our common stock unless:

the gain is effectively connected with your conduct of a trade or business in the United States and, if an income tax treaty applies, the gain is attributable to a permanent establishment maintained by you in the United States; in this case, the gain will be taxed on a net income basis at the regular graduated rates and in the manner applicable to U.S. persons and, if you are a foreign corporation, you may be subject to an additional branch profits tax at a rate of 30% or a lower rate as may be specified by an applicable income tax treaty;

you are an individual who is present in the United States for 183 days or more in the taxable year of the disposition and meets other requirements; or

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

we are or have been a U.S. real property holding corporation for U.S. federal income tax purposes at any time during the shorter of the five-year period ending on the date of disposition or the period that you held our common stock; in this case, subject to the discussion below, the gain will be taxed on a net income basis in the manner described in the first bullet paragraph above.

Generally, a corporation is a U.S. real property holding corporation if the fair market value of its U.S. real property interests equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. The tax relating to stock in a U.S. real property holding corporation generally will not apply to a non-U.S. holder whose holdings, direct and

## **Table of Contents**

indirect, at all times during the applicable period, constituted 5% or less of our common stock, provided that our common stock was regularly traded on an established securities market. We believe that we are not currently, and we do not anticipate becoming in the future, a U.S. real property holding corporation for U.S. federal income tax purposes.

## **Federal Estate Tax**

Common stock owned or treated as owned by an individual who is a non-U.S. holder (as specially defined for U.S. federal estate tax purposes) at the time of death will be included in the individual's gross estate for U.S. federal estate tax purposes, unless an applicable estate tax or other treaty provides otherwise and, therefore, may be subject to U.S. federal estate tax.

## **Information Reporting and Backup Withholding**

Information returns will be filed with the U.S. Internal Revenue Service in connection with payments of dividends and the proceeds from a sale or other disposition of our common stock. Dividends paid to you may be subject to information reporting and U.S. backup withholding. You generally will be exempt from such backup withholding if you provide a properly executed Form W-8BEN or otherwise meet documentary evidence requirements for establishing that you are a non-U.S. holder or otherwise establish an exemption.

The gross proceeds from the disposition of our common stock may be subject to information reporting and backup withholding. If you sell your shares of our common stock outside of the United States through a non-U.S. office of a non-U.S. broker and the sales proceeds are paid to you outside of the United States, then the U.S. backup withholding and information reporting requirements generally (except as provided in the following sentence) will not apply to that payment. However, information reporting, but not backup withholding, will apply to a payment of sales proceeds, even if that payment is made outside of the United States, if you sell our common stock through a non-U.S. office of a broker that:

is a U.S. person;

derives 50% or more of its gross income in specific periods from the conduct of a trade or business in the United States;

is a controlled foreign corporation for U.S. tax purposes; or

is a foreign partnership, if at any time during its tax year, one or more of its partners are U.S. persons who in the aggregate hold more than 50% of the income or capital interests in the partnership, or the foreign partnership is engaged in a U.S. trade or business,

unless the broker has documentary evidence in its files that you are a non-U.S. person and various other conditions are met or you otherwise establish exemption.

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

If you receive payments of the proceeds of a sale of our common stock to or through a U.S. office of a broker, the payment is subject to both U.S. backup withholding and information reporting unless you provide a properly executed Form W-8BEN certifying that you are a non-U.S. person and various other conditions are met or you otherwise establish an exemption.

You generally may obtain a refund of any amount withheld under the backup withholding rules that exceeds your income tax liability by filing a refund claim with the U.S. Internal Revenue Service.



**Table of Contents**

**UNDERWRITERS**

Under the terms and subject to the conditions contained in an underwriting agreement dated the date of this prospectus, the underwriters named below, for whom Morgan Stanley & Co. Incorporated and Lehman Brothers Inc. are acting as representatives and joint book-running managers, have severally agreed to purchase, and we have agreed to sell to them, severally, the number of shares indicated below:

Name	Number of Shares
Morgan Stanley & Co. Incorporated	
Lehman Brothers Inc.	
Credit Suisse Securities (USA) LLC	
Natexis Bleichroeder Inc.	
<b>Total</b>	

The underwriters are offering the shares of common stock subject to their acceptance of the shares from us and subject to prior sale. The underwriting agreement provides that the obligations of the several underwriters to pay for and accept delivery of the shares of common stock offered by this prospectus are subject to the approval of certain legal matters by their counsel and to certain other conditions. The underwriters are obligated to take and pay for all of the shares of common stock offered by this prospectus if any such shares are taken. However, the underwriters are not required to take or pay for the shares covered by the underwriters' over-allotment option described below.

The underwriters initially propose to offer part of the shares of common stock directly to the public at the public offering price listed on the cover page of this prospectus and part to certain dealers at a price that represents a concession not in excess of \$ \_\_\_\_\_ a share under the public offering price. After the initial offering of the shares of common stock, the offering price and other selling terms may from time to time be varied by the representatives.

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase up to an aggregate of \_\_\_\_\_ additional shares of common stock at the public offering price listed on the cover page of this prospectus, less underwriting discounts and commissions. The underwriters may exercise this option solely for the purpose of covering over-allotments, if any, made in connection with the offering of the shares of common stock offered by this prospectus. To the extent the option is exercised, each underwriter will become obligated, subject to certain conditions, to purchase approximately the same percentage of the additional shares of common stock as the number listed next to the underwriter's name in the preceding table bears to the total number of shares of common stock listed next to the names of all underwriters in the preceding table. If the underwriters' option is exercised in full, the total price to the public would be \$ \_\_\_\_\_, the total underwriters' discounts and commissions would be \$ \_\_\_\_\_ and the total proceeds to us would be \$ \_\_\_\_\_.

The underwriters have informed us that they do not intend sales to discretionary accounts to exceed five percent of the total number of shares of common stock offered by them.

Application has been made to have our common stock listed on the NASDAQ Global Market under the symbol JAZZ .

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

We and our directors, executive officers and certain other stockholders have agreed that, without the prior written consent of Morgan Stanley & Co. Incorporated and Lehman Brothers Inc. on behalf of the underwriters, we and they will not, during the period ending 180 days after the date of this prospectus:

offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of directly or indirectly, any shares of common stock or any securities convertible into or exercisable or exchangeable for common stock;

**Table of Contents**

file any registration statement with the SEC relating to the offering of any shares of common stock or any securities convertible into or exercisable or exchangeable for common stock; or

enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the common stock;

whether any such transaction described above is to be settled by delivery of common stock or such other securities, in cash or otherwise.

The restrictions described in the preceding paragraph do not apply to: the sale of shares by us to the underwriters or the issuance by us of shares of common stock upon the exercise of an option or a warrant or the conversion of a security outstanding on the date of this prospectus of which the underwriters have been advised in writing, and, in the case of our directors, officers and stockholders, (1) transactions relating to shares of common stock or other securities acquired in open market transactions after the completion of this offering, provided that no filing under Section 16(a) of the Securities and Exchange Act of 1934, as amended, shall be required or shall be voluntarily made in connection with subsequent sales of common stock or other securities acquired in such open market transactions, (2) transfers of shares of common stock or any security convertible into common stock as a bona fide gift, or (3) distributions of shares of common stock or any security convertible into common stock to limited partners or stockholders of such persons; *provided* that in the case of any transfer or distribution pursuant to clause (2) or (3), (a) each donee or distributee shall sign and deliver in respect of shares of common stock and any security convertible into common stock so transferred or distributed, a lock-up agreement substantially in the form of the agreement entered into by our directors and officers and (b) no filing under Section 16(a) of the Securities Exchange Act of 1934, as amended, reporting a reduction in beneficial ownership of shares of common stock, shall be required or shall be voluntarily made during the 180-day restricted period referred to in the preceding paragraph. The 180-day restricted period described in the preceding paragraph will be extended if:

during the last 17 days of the 180-day restricted period we issue a release regarding earnings or regarding material news or events relating to us; or

prior to the expiration of the 180-day restricted period, we announce that we will release earnings results during the 16-day period beginning on the last day of the 180-day period,

in which case the restrictions described in the preceding paragraph will continue to apply until the expiration of the 18-day period beginning on the issuance of the release or the occurrence of the material news or material event; provided, however, that the restrictions described in the preceding paragraph will not extend beyond 214 days after the date of this prospectus.

In order to facilitate the offering of the common stock, the underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of the common stock. Specifically, the underwriters may sell more shares than they are obligated to purchase under the underwriting agreement, creating a short position. A short sale is covered if the short position is no greater than the number of shares available for purchase by the underwriters under the over-allotment option. The underwriters can close out a covered short sale by exercising the over-allotment option or purchasing shares in the open market. In determining the source of shares to close out a covered short sale, the underwriters will consider, among other things, the open market price of shares compared to the price available under the over-allotment option. The underwriters may also sell shares in excess of the over-allotment option, creating a naked short position. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market after pricing that could adversely affect investors who purchase in the offering. As an additional means of facilitating the offering, the underwriters may bid for, and purchase, shares of common stock in the open market to stabilize the price of the common stock. The underwriting syndicate may also reclaim selling concessions allowed to an underwriter or a dealer for distributing the common stock in the offering, if the syndicate repurchases previously distributed common stock to cover syndicate short positions or to stabilize the price of the



## **Table of Contents**

common stock. These activities may raise or maintain the market price of the common stock above independent market levels or prevent or retard a decline in the market price of the common stock. The underwriters are not required to engage in these activities, and may end any of these activities at any time.

The underwriters may in the future provide investment banking services to us for which they would receive customary compensation. In addition, entities affiliated with Lehman Brothers Inc. have entered into certain transactions with us, including the acquisition of shares of our capital stock and warrants to purchase shares of our capital stock, as described under Certain Relationships and Related Party Transactions.

We and the underwriters have agreed to indemnify each other against certain liabilities, including liabilities under the Securities Act.

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive, each underwriter has represented and agreed that with effect from and including the date on which the Prospectus Directive is implemented in that Member State it has not made and will not make an offer of shares of common stock to the public in that Member State, except that it may, with effect from and including such date, make an offer of shares of common stock to the public in that Member State:

at any time to legal entities which are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities;

at any time to any legal entity which has two or more of (1) an average of at least 250 employees during the last financial year; (2) a total balance sheet of more than 43,000,000 and (3) an annual net turnover of more than 50,000,000, as shown in its last annual or consolidated accounts; or

at any time in any other circumstances which do not require the publication by us of a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of the above, the expression an offer of shares of common stock to the public in relation to any shares of common stock in any Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the shares of common stock to be offered so as to enable an investor to decide to purchase or subscribe the shares of common stock, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State and the expression Prospectus Directive means Directive 2003/71/EC and includes any relevant implementing measure in that Member State.

Each underwriter has represented and agreed that it has only communicated or caused to be communicated and will only communicate or cause to be communicated an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the Financial Services and Markets Act 2000) in connection with the issue or sale of the common stock in circumstances in which Section 21(1) of such Act does not apply to us and it has complied and will comply with all applicable provisions of such Act with respect to anything done by it in relation to any shares of common stock in, from or otherwise involving the United Kingdom.

## **Pricing of the Offering**

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

Prior to this offering, there has been no public market for the shares of common stock. The initial public offering price will be determined by negotiations between us and the representatives of the underwriters. Among the factors to be considered in determining the initial public offering price will be our future prospects and our industry in general, our sales, earnings and certain other financial operating information in recent periods, and the price-earnings ratios, price-sales ratios, market prices of securities and certain financial and operating information of companies engaged in activities similar to ours. The estimated initial public offering price range set forth on the cover page of this preliminary prospectus is subject to change as a result of market conditions and other factors.

**Table of Contents**

**LEGAL MATTERS**

The validity of the shares of common stock being offered by this prospectus will be passed upon for us by Cooley Godward Kronish LLP, Palo Alto, California. The underwriters are being represented by Davis Polk & Wardwell, Menlo Park, California.

**EXPERTS**

Ernst & Young LLP, independent registered public accounting firm, has audited our consolidated financial statements and schedule at December 31, 2005 and 2006, and for each of the three years in the period ended December 31, 2006, 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). We have included our consolidated financial statements and schedule in the prospectus and elsewhere in the registration statement in reliance on Ernst & Young LLP's report, given on their authority as experts in accounting and auditing.

Ernst & Young LLP, independent auditors, has audited the financial statements of Orphan Medical, Inc. for the period from January 1, 2005 to June 24, 2005, as set forth in their report. We have included Orphan Medical, Inc.'s financial statements in the prospectus and elsewhere in the registration statement in reliance on Ernst & Young LLP's report, given on their authority as experts in accounting and auditing.

**WHERE YOU CAN FIND ADDITIONAL INFORMATION**

We have filed with the SEC a registration statement on Form S-1 under the Securities Act of 1933, as amended, with respect to the shares of common stock being offered by this prospectus. This prospectus does not contain all of the information in the registration statement and its exhibits. For further information with respect to Jazz Pharmaceuticals and the common stock offered by this prospectus, we refer you to the registration statement and its exhibits. Statements contained in this prospectus as to the contents of any contract or any other document referred to are not necessarily complete, and in each instance, we refer you to the copy of the contract or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference.

You can read our SEC filings, including the registration statement, over the Internet at the SEC's website at <http://www.sec.gov>. You may also read and copy any document we file with the SEC at its public reference facilities at 100 F Street, N.E., Washington, D.C. 20549. You may also obtain copies of these documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference facilities.

Upon completion of this offering, we will be subject to the information reporting requirements of the Securities Exchange Act of 1934, as amended, and we will file reports, proxy statements and other information with the SEC. These reports, proxy statements and other information will be available for inspection and copying at the public reference room and web site of the SEC referred to above. We also maintain a website at <http://www.jazzpharmaceuticals.com>, at which you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. The information contained in, or that can be accessed through, our website is not part of this prospectus.





**Table of Contents**

**JAZZ PHARMACEUTICALS, INC.**

**Index to Consolidated Financial Statements**

	<b>Page</b>
<b>Jazz Pharmaceuticals, Inc.</b>	
<u>Report of Independent Registered Public Accounting Firm</u>	F-2
<u>Consolidated Balance Sheets</u>	F-3
<u>Consolidated Statements of Operations</u>	F-4
<u>Consolidated Statements of Convertible Preferred Stock and Stockholders' Deficit</u>	F-5
<u>Consolidated Statements of Cash Flows</u>	F-7
<u>Notes to Consolidated Financial Statements</u>	F-8
<b>Orphan Medical, Inc.</b>	
<u>Report of Independent Auditors</u>	F-35
<u>Statement of Operations</u>	F-36
<u>Statement of Cash Flows</u>	F-37
<u>Notes to Financial Statements</u>	F-38

**Table of Contents**

**Report of Independent Registered Public Accounting Firm**

The Board of Directors and Stockholders

Jazz Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of Jazz Pharmaceuticals, Inc. as of December 31, 2005 and 2006, and the related consolidated statements of operations, convertible preferred stock and stockholders' deficit, and cash flows for each of the three years in the period ended December 31, 2006. Our audits also included the financial statement schedule listed in Item 16(b) of this Registration Statement. These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Jazz Pharmaceuticals, Inc. at December 31, 2005 and 2006, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2006, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

As discussed in Note 2 to the consolidated financial statements, Jazz Pharmaceuticals Inc.'s recurring losses from operations and cash used in operating activities raise substantial doubt about its ability to continue as a going concern. Management's plans as to these matters also are described in Note 2. The 2006 financial statements do not include any adjustments that might result from the outcome of this uncertainty.

As discussed in Note 2 to the consolidated financial statements, Jazz Pharmaceuticals, Inc. changed its method of accounting for stock-based compensation in accordance with guidance provided in Statement of Financial Accounting Standards No. 123(R), "Share-Based Payment", on January 1, 2006.

/s/ Ernst & Young LLP

Edgar Filing: JAZZ PHARMACEUTICALS INC - Form S-1

Palo Alto, California

March 6, 2007

F-2

**Table of Contents****JAZZ PHARMACEUTICALS, INC.****CONSOLIDATED BALANCE SHEETS****(In thousands, except share and per share amounts)**

	<b>December 31,</b>	
	<b>2005</b>	<b>2006</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 20,614	\$ 78,948
Restricted cash	300	275
Accounts receivable, net of allowances of \$122 and \$198 at December 31, 2005 and 2006, respectively	3,597	5,380
Inventories	3,262	3,026
Prepaid expenses	3,240	3,447
Other current assets	371	487
<b>Total current assets</b>	<b>31,384</b>	<b>91,563</b>
Property and equipment, net	1,941	2,107
Intangible assets, net purchased developed technology	71,023	63,130
Intangible assets, net other	7,717	6,010
Goodwill	38,883	38,213
Long-term restricted cash and available-for-sale securities	12,000	12,000
Other long-term assets	1,833	1,548
<b>Total assets</b>	<b>\$ 164,781</b>	<b>\$ 214,571</b>
<b>LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS DEFICIT</b>		
Current liabilities:		
Line of credit	\$	\$ 2,191
Accounts payable	4,786	5,443
Accrued liabilities	11,121	12,943
Deferred revenue		1,422
Preferred stock warrant liability (including \$5,107 and \$5,965 as of December 31, 2005 and 2006, respectively, held by related parties)	7,429	8,521
<b>Total current liabilities</b>	<b>23,336</b>	<b>30,520</b>
Liability for early exercise of options and restricted common stock	184	98
Deferred rent	649	436
Non-current portion of deferred revenue		13,495
Senior secured notes (including \$50,620 and \$51,998 as of December 31, 2005 and 2006, respectively, held by related parties)	73,629	74,283
Development financing obligation	15,445	
Commitments and contingencies (Note 8)		
Convertible preferred stock, \$.0001 par value; 308,236,575 authorized at December 31, 2005 and 2006; 125,002,932 and 198,338,205 shares issued and outstanding at December 31, 2005 and 2006, respectively; aggregate liquidation preference of \$165,000 and \$265,000 at December 31, 2005 and 2006, respectively	163,862	263,852
Common stock subject to repurchase	5,924	8,183
Stockholders deficit:		

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

Common stock, \$.0001 par value; 252,716,057 shares authorized at December 31, 2005 and 2006; 6,839,171 and 6,905,733 shares issued and outstanding at December 31, 2005 and 2006, respectively; 4,345,209 and 6,002,085 of which are vested and included in common stock subject to repurchase above at December 31, 2005 and 2006, respectively

Additional paid-in capital		1,335
Accumulated other comprehensive income	4	12
Accumulated deficit	(118,252)	(177,643)
 Total stockholders' deficit	 (118,248)	 (176,296)
 Total liabilities, convertible preferred stock and stockholders' deficit	 \$ 164,781	 \$ 214,571

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

F-3

**Table of Contents****JAZZ PHARMACEUTICALS, INC.****CONSOLIDATED STATEMENTS OF OPERATIONS****(In thousands, except per share amounts)**

	Year Ended December 31,		
	2004	2005	2006
<b>Revenues:</b>			
Product sales, net	\$	\$ 18,796	\$ 43,299
Royalties, net		146	594
Contract revenue		2,500	963
<b>Total revenues</b>		<b>21,442</b>	<b>44,856</b>
<b>Operating expenses:</b>			
Cost of product sales		4,292	6,968
Research and development	17,988	45,783	54,956
Selling, general and administrative	7,459	23,551	51,384
Amortization of intangible assets		4,960	9,600
Purchased in-process research and development		21,300	
<b>Total operating expenses</b>	<b>25,447</b>	<b>99,886</b>	<b>122,908</b>
<b>Loss from operations</b>	<b>(25,447)</b>	<b>(78,444)</b>	<b>(78,052)</b>
Interest income	643	1,318	2,307
Interest expense (including \$4,595 and \$9,024 for the years ended December 31, 2005 and 2006, respectively, pertaining to related parties)		(7,129)	(14,129)
Other expense		(901)	(1,109)
Gain on extinguishment of development financing obligation			31,592
<b>Net loss</b>	<b>(24,804)</b>	<b>(85,156)</b>	<b>(59,391)</b>
Beneficial conversion feature			(21,920)
<b>Loss attributable to common stockholders</b>	<b>\$ (24,804)</b>	<b>\$ (85,156)</b>	<b>\$ (81,311)</b>
<b>Loss per share attributable to common stockholders, basic and diluted</b>	<b>\$ (137.80)</b>	<b>\$ (1,216.51)</b>	<b>\$ (572.61)</b>
<b>Weighted-average common shares used in computing loss per share attributable to common stockholders, basic and diluted</b>	<b>180</b>	<b>70</b>	<b>142</b>

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

Table of Contents

## JAZZ PHARMACEUTICALS, INC.

## CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS DEFICIT

(In thousands, except share and per share amounts)

	Convertible Preferred Stock				Series B Prime Shares	Series B Prime Amount	Common Stock Subject to Repurchase Amount	Common Stock		Stockholders Deficit		Total Stockholders Deficit	
	Series A		Series B					Shares	Amount	Capital	Income		Accum- ulated Deficit
	Shares	Amount	Shares	Amount									
<b>Balance at January 1, 2004</b>	7,150,000	\$ 7,076			\$	\$	6,395,000	\$ 16	\$	\$	(2,528)	\$ (2,512)	
Reincorporation in Delaware and reissuance of common stock with \$.0001 par value								(16)	16				
Issuance of common stock subject to repurchase rights for cash							444,171		230			230	
Transfer of common stock subject to repurchase to temporary equity						1,773			(21)		(1,752)	(1,773)	
Vesting of common stock subject to repurchase						1,892			(24)		(1,839)	(1,863)	
Repurchase rights to shares issued under restricted stock purchase agreements									(201)			(201)	
Issuance of Series A convertible preferred stock net of issuance costs of \$0	7,850,000	7,850											
Issuance of Series B convertible preferred stock, net of issuance costs of \$441			17,600,469	23,560									
Issuance of Series B Prime convertible preferred stock, net of issuance costs of \$477					19,067,175	25,523							
Net loss and comprehensive loss											(24,804)	(24,804)	

Edgar Filing: JAZZ PHARMACEUTICALS INC - Form S-1

<b>Balance at December 31, 2004</b>	15,000,000	14,926	17,600,469	23,560	19,067,175	25,523	3,665	6,839,171	(30,923)	(30,923)
Lapse of repurchase rights to shares issued under restricted stock purchase agreements									53	53
Vesting of common stock subject to repurchase							2,259		(53)	(2,173)
Issuance of Series B convertible preferred stock, net of issuance costs of \$11			35,200,937	47,989						
Issuance of Series B Prime convertible preferred stock, net of issuance costs of \$136					38,134,351	51,864				
Comprehensive loss:										
Net loss									(85,156)	(85,156)
Gain on available-for-sale securities									4	4
Comprehensive loss										(85,152)
<b>Balance at December 31, 2005</b>	15,000,000	14,926	52,801,406	71,549	57,201,526	77,387	5,924	6,839,171	4	(118,252)

F-5



Table of Contents

## JAZZ PHARMACEUTICALS, INC.

## CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS DEFICIT (Continued)

(In thousands, except share and per share amounts)

	Convertible Preferred Stock						Common Stock Subject to Repurchase Amount	Common Stock		Stockholders Deficit			Total Stockholders Deficit
	Series A		Series B		Series B Prime			Shares	Amount	Additional Paid-in Capital	Compre- hensive Income	Accum- ulated Deficit	
	Shares	Amount	Shares	Amount	Shares	Amount	Amount	Shares	Amount	Capital	Income	Deficit	Deficit
<b>Balance at December 31, 2005</b>	15,000,000	\$ 14,926	52,801,406	\$ 71,549	57,201,526	\$ 77,387	\$ 5,924	6,839,171	\$	\$	\$ 4	\$ (118,252)	\$ (118,248)
Lapse of repurchase rights to shares issued under restricted stock purchase agreements										53			53
Vesting of common stock subject to repurchase							2,259			(2,226)			(2,226)
Issuance of Series B convertible preferred stock, net of issuance costs of \$5			35,200,924	47,995									
Issuance of Series B Prime convertible preferred stock, net of issuance costs of \$5					38,134,349	51,995							
Issuance of Common stock for cash upon exercise of stock options								66,562		10			10
Stock-based compensation										3,498			3,498
Beneficial conversion feature deemed dividend on issuance of Series B preferred stock										21,920			21,920
Beneficial conversion feature										(21,920)			(21,920)
Comprehensive loss:													
Net loss												(59,391)	(59,391)
Gain on available-for-sale securities											8		8

Edgar Filing: JAZZ PHARMACEUTICALS INC - Form S-1

Comprehensive loss	(59,383)
--------------------	----------

<b>Balance at December 31, 2006</b>	15,000,000	\$ 14,926	88,002,330	\$ 119,544	95,335,875	\$ 129,382	\$ 8,183	6,905,733	\$	\$	1,335	\$ 12	\$ (177,643)	\$ (176,296)
-------------------------------------	------------	-----------	------------	------------	------------	------------	----------	-----------	----	----	-------	-------	--------------	--------------

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

F-6

**Table of Contents****JAZZ PHARMACEUTICALS, INC.****CONSOLIDATED STATEMENTS OF CASH FLOWS****(In thousands)**

	<b>Year Ended December 31,</b>		
	<b>2004</b>	<b>2005</b>	<b>2006</b>
<b>Operating activities</b>			
Net loss	\$ (24,804)	\$ (85,156)	\$ (59,391)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	122	479	710
Amortization of intangible assets		4,960	9,600
Loss on disposal of property and equipment			481
Fair value adjustment to acquired finished goods		1,584	775
Purchased in-process research and development		21,300	
Amortization of debt discount and debt issuance costs		476	949
Revaluation of preferred stock warrant liability		901	1,092
Stock-based compensation expense			3,480
Interest on development financing obligation		445	1,147
Gain on extinguishment of development financing obligation			(31,592)
Changes in assets and liabilities:			
Restricted cash	150	(175)	25
Accounts receivable		(249)	(1,783)
Inventories		(219)	(521)
Prepaid expenses and other current assets	(1,915)	1,158	(473)
Other assets	(151)		323
Accounts payable	1,564	2,408	657
Accrued liabilities	3,340	(210)	2,492
Deferred revenue			14,917
Deferred rent	688	(39)	(213)
Net cash used in operating activities	(21,006)	(52,337)	(57,325)
<b>Investing activities</b>			
Purchases of property and equipment	(992)	(1,413)	(1,682)
Proceeds from sale of property and equipment			150
Purchases of available-for-sale securities	(45,946)		(1,705)
Proceeds from sales of available-for-sale securities	40,000	3,450	
Proceeds from maturities of available-for-sale securities		2,500	
Cash paid for shares of Orphan Medical, Inc., net of cash acquired		(146,116)	
Proceeds from maturities of long-term restricted cash equivalents			1,705
Increase in long-term restricted cash and investments		(12,000)	
Net cash used in investing activities	(6,938)	(153,579)	(1,532)
<b>Financing activities</b>			
Proceeds from issuances of convertible preferred stock, net of issuance costs	56,933	99,853	99,990
Proceeds from issuances of common stock, net of issuance costs	58		10
Proceeds from issuances of common stock with repurchase rights and the early exercise of stock options	171		
Proceeds from line of credit			3,283
Repayments under line of credit			(1,092)
Proceeds from sale of senior secured notes, net of issuance costs		77,999	
Proceeds from development financing		15,000	15,000
Net cash provided by financing activities	57,162	192,852	117,191
Net increase (decrease) in cash and cash equivalents	29,218	(13,064)	58,334
Cash and cash equivalents, at beginning of period	4,460	33,678	20,614

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

Cash and cash equivalents, at end of period	\$ 33,678	\$ 20,614	\$ 78,948
Supplemental disclosure of cash flow information:			
Cash paid for interest	\$	\$ 6,200	\$ 12,000
Supplemental disclosure of non-cash financing and investing activities:			
Warrants to purchase Series BB convertible preferred stock issued in conjunction with senior secured notes	\$	\$ 6,696	\$
Beneficial conversion feature	\$	\$	\$ 21,920

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

F-7

**Table of Contents**

**JAZZ PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**1. Organization and Description of Business**

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

Since its inception, the Company has built a commercial operation and assembled a portfolio that currently includes two marketed products, two product candidates for which new drug applications ( NDAs ) have been submitted to the U.S. Food and Drug Administration ( FDA ) and five product candidates in various stages of clinical development. The Company also has additional product candidates in early-stage development and feasibility activities. In March 2007, the Company sold its rights to a third marketed product.

**2. Summary of Significant Accounting Policies**

***Basis of Presentation***

The consolidated financial statements include the accounts of Jazz Pharmaceuticals, Inc. and its wholly-owned subsidiary, Orphan Medical, Inc. ( Orphan Medical ), after elimination of intercompany transactions and balances.

***Significant Risks and Uncertainties***

The Company has incurred significant losses from operations since its inception and expects losses to continue for the next several years. To achieve profitable operations, the Company must successfully identify, develop and commercialize its products. Products developed by the Company will require approval of the FDA or a foreign regulatory authority prior to commercial sales. The regulatory approval process is expensive, time consuming and uncertain, and any denial or delay of approval could have a material adverse effect on the Company. Even if approved, the Company's products may not achieve market acceptance and will face competition from both generic and branded pharmaceutical products. The Company will need to raise additional funds to support its operations, and such funding may not be available to it on acceptable terms, or at all. The Company's board of directors has approved the filing of a registration statement on Form S-1 with respect to a proposed initial public offering of its common stock. The Company may seek additional sources of financing through development financings, collaborations or public or private debt or equity financings, and may also seek to reduce expenses related to its operations.

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

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The 2006 financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from uncertainty related to the Company's ability to continue as a going concern.

### *Use of Estimates*

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

**Table of Contents**

**JAZZ PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

***Concentration of Credit Risks and Fair Value of Financial Instruments***

Financial instruments that potentially subject the Company to concentrations of credit risk consist of cash equivalents, restricted cash, marketable securities and accounts receivable. The Company's investment policy limits investments to certain types of debt securities issued by the U.S. government, its agencies and institutions with investment-grade credit ratings and places restrictions on maturities and concentration by type and issuer. The Company is exposed to credit risk in the event of a default by the financial institutions holding its cash, cash equivalents and marketable securities and issuers of investments to the extent recorded on the balance sheet.

The Company monitors its exposure within accounts receivable and records a reserve against uncollectible accounts receivable as necessary. The Company extends credit to pharmaceutical companies, pharmaceutical wholesale distributors and a specialty pharmaceutical distribution company primarily in the U.S. in the normal course of business. Customer creditworthiness is monitored and collateral is not normally required. Historically, the Company has not experienced significant credit losses on its accounts receivable. The Company's five largest customers accounted for an aggregate of approximately 88% and 90% of gross accounts receivable as of December 31, 2005 and 2006, respectively.

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

***Cash Equivalents, Restricted Cash and Available-for-Sale Securities***

The Company considers all highly liquid investments, readily convertible to cash, that mature within three months or less from date of purchase to be cash equivalents. Restricted cash and available-for-sale securities consist of cash equivalents and available-for-sale securities, the use of which is restricted either by contract or agreement. At December 31, 2006 the Company held a money market account in the amount of \$275,000 as collateral securing a letter of credit. The Company has a \$12.0 million investment account which is restricted under the agreement governing the Company's senior secured notes. Available-for-sale securities are investments in debt securities with maturities of less than one year from the balance sheet date, or securities with maturities of greater than one year that are specifically identified to fund current operations. Collectively, cash equivalents, restricted cash and available-for-sale securities are classified as available-for-sale and are recorded at fair value, based on quoted market prices. Unrealized gains and losses, net of tax, are recorded in other comprehensive income and included as a separate component of stockholders' deficit. The Company uses the specific-identification method for calculating realized gains and losses on securities sold. Realized gains and losses and declines in value judged to be other than temporary on available-for-sale securities are included in interest income in the statement of operations. Realized gains and losses on sales of available-for-sale securities have not been material.

***Inventories***

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

Inventories are valued at the lower of cost or market. Cost is determined using the first-in, first-out method for all inventories. The Company's policy is to write down inventory that has become obsolete, inventory that has a cost basis in excess of its expected net realizable value and inventory in excess of expected requirements.

### *Property and Equipment*

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

F-9



**Table of Contents**

**JAZZ PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

***Goodwill and Intangible and Long-Lived Assets***

Goodwill represents the excess of the purchase price over the fair value of assets acquired and liabilities assumed. The Company has determined that it operates in a single segment and has a single reporting unit associated with the development and commercialization of pharmaceutical products. The annual test for goodwill impairment is a two-step process. The first step is a comparison of the fair value of the reporting unit with its carrying amount, including goodwill. If this step indicates an impairment, then the loss is measured as the excess of recorded goodwill over its implied fair value. Implied fair value is the excess of the fair value of the reporting unit over the fair value of all identified assets and liabilities. Management tests goodwill for impairment annually in October and concluded that no impairment existed as of October 1, 2006. Management will also test for impairment whenever events or changes in circumstances indicate that the carrying value may not be recoverable. There have been no changes since October 1, 2006 that would cause management to reevaluate its conclusion.

Intangible assets consist primarily of purchased developed technology, agreements not to compete and trademarks. Intangible assets are amortized on a straight-line basis over their estimated useful lives, which range from three to ten years. The estimated useful lives associated with intangible assets are consistent with underlying agreements, or the estimated lives of the products. Once an intangible asset is fully amortized, the gross costs and accumulated amortization are removed from the consolidated balance sheet. The Company evaluates purchased intangibles and other long-lived assets, other than goodwill, for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. The amount of any impairment is measured as the difference between the carrying value and the fair value of the impaired asset. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount. The impairment loss, if recognized, would be based on the excess of the carrying value of the impaired asset over its respective fair value, calculated using discounted cash flows. Since the Company's inception, there has been no such impairment loss recognized.

***Preferred Stock Warrant Liability***

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

Upon adoption of FSP 150-5, the Company reclassified the fair value of its warrants to purchase shares of convertible preferred stock from equity to a liability. There was no cumulative effect on adoption. The Company recorded other expense of \$901,000 and \$1.1 million during the years ended December 31, 2005 and 2006, respectively, to reflect the increase in the fair value of the warrants. The Company will continue to adjust the preferred stock warrant liability for changes in the fair value of the warrants until the earlier of the exercise of the warrants, at which time the liability will be reclassified to temporary equity, or the conversion of the underlying convertible preferred stock issuable into common stock, at which time the liability will be reclassified to stockholders' deficit.



**Table of Contents**

**JAZZ PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

***Deferred Rent***

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

***Revenue Recognition***

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

***Product Sales, Net***

Revenues from sales of Xyrem within the U.S. are recognized upon transfer of title, which occurs when the Company's specialty pharmaceutical distributor removes product from the Company's consigned inventory location at its facility for shipment to a patient. Antizol is, and prior to our sale of the Company's rights Cystadane was, shipped to the Company's wholesaler customers in the U.S. with free on board destination shipping terms, and the Company recognizes revenues when delivery occurs. The Company's international sales often have customer acceptance clauses and therefore the Company recognizes revenues when it is notified of acceptance or the time to inspect and reject the shipment has lapsed. When sales to international customers do not have acceptance clauses, the Company recognizes revenues when title transfers, which is generally when the product leaves the Company's logistics provider's facilities.

Revenues from sales of products within the U.S. are recorded net of estimated allowances for prompt payment discounts, wholesaler and specialty distributor fees, government chargebacks and rebates. Significant judgment is inherent in the selection of assumptions and in the interpretation of historical experience, as well as the identification of external and internal factors affecting the estimates. Because Xyrem is sold to one distributor in the United States, allowances and adjustments to estimates for allowances have not historically been material.

*Royalties, Net*

The Company receives royalties from third parties based on sales of its products under out-licensing and distributor arrangements. For those arrangements where royalties are reasonably estimable, the Company recognizes revenues based on estimates of royalties earned during the applicable period, and adjusts for differences between the estimated and actual royalties in the following quarter. Historically, these adjustments have not been material. For those arrangements where royalties are not reasonably estimable, the Company recognizes revenues upon receipt of royalty statements from the licensee or distributor.

F-11

**Table of Contents**

**JAZZ PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

*Contract Revenues*

Nonrefundable fees where the Company has no continuing performance obligations are recognized as revenues when collection is reasonably assured. In situations where the Company has continuing performance obligations, nonrefundable fees are deferred and recognized ratably over the performance period. The Company recognizes at-risk milestone payments, which are typically related to regulatory, commercial or other achievements by the Company or its licensees and distributors, as revenues when the milestone is accomplished and collection is reasonably assured. Refundable fees are deferred and recognized as revenues upon the later of when they become nonrefundable or when performance obligations are completed.

*Cost of Product Sales and Concentrations of Supply Risk*

Cost of product sales includes third party manufacturing and distribution costs, the cost of drug substance, royalties due to third parties on product sales, product liability insurance, FDA user fees, freight, shipping, handling and storage costs, and salaries and related costs of employees involved with production. The Company's product exchange policy for Antizol allows and, prior to our sale of our rights to Cystadane, our product exchange policy for Cystadane allowed, customers to return expired product for exchange up to six months before or after the product's expiration date. These expiration date returns are exchanged for replacement product, and the estimated cost of such exchanges is included in cost of product sales. Amounts accrued for replacement product have not been material to date. In addition, as part of the acquisition of Orphan Medical, the Company recorded finished goods on-hand at the acquisition date at fair value, which is defined as inventory valued at estimated selling prices less the sum of (a) costs of disposal and (b) reasonable profit allowance for the selling effort of the acquiring entity. The fair value of inventory acquired is recorded as cost of product sales when the related product revenues are recorded.

The Company relies on certain sole suppliers for drug substance and certain sole manufacturing partners for each of its marketed products and certain of its product candidates. The Company attempts to mitigate this risk by establishing contractual relationships where appropriate.

*Research and Development*

The Company's research and development expenses consist of expenses incurred in identifying, developing and testing its product candidates. These expenses consist primarily of fees paid to contract research organizations and other third parties to assist us in managing, monitoring and analyzing our clinical trials, clinical trial costs paid to sites and investigators' salaries, costs of non-clinical studies, including toxicity studies in animals, costs of contract manufacturing services, costs of materials used in clinical trials and non-clinical studies, fees paid to third parties for development candidates or drug delivery or formulation technologies that the Company has licensed, allocated expenses, such as facilities and information technology that support the Company's research and development activities, and related personnel expenses, including stock-based compensation. Research and development costs are expensed as incurred, including payments made under the Company's license agreements. For products that have not been approved by the FDA, inventory used in clinical trials is expensed at the time of production and recorded as research and development expense. For products that have been approved by the FDA, inventory used in clinical trials is expensed at the time the inventory is packaged for the trial and therefore is not included in inventory.

*In-Process Research and Development*

In connection with the acquisition of Orphan Medical, the Company recorded a charge of \$21.3 million for acquired in-process research and development during the year ended December 31, 2005. This amount

F-12

**Table of Contents**

**JAZZ PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

represented the estimated fair value related to three incomplete product candidate development projects for which, at the time of the acquisition, technological feasibility had not been established and there was no alternative future use.

***Advertising Expenses***

The Company expenses the costs of advertising, including promotional expenses, as incurred. Advertising expenses for the years ended December 31, 2004, 2005 and 2006 were zero, \$551,000, and \$2.3 million, respectively.

***Income Taxes***

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

***Comprehensive Loss***

Comprehensive loss includes net loss and all changes in stockholders' deficit during a period, except for those changes resulting from investments by stockholders or distributions to stockholders. For the years ended December 31, 2005 and 2006, the difference between comprehensive loss and net loss represented unrealized gains on available-for-sale securities. For the year ended December 31, 2004, comprehensive loss was equal to the net loss.

***Loss Per Common Share***

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

Edgar Filing: JAZZ PHARMACEUTICALS INC - Form S-1

	Year Ended December 31,		
	2004	2005	2006
	(In thousands, except per share data)		
<b>Numerator:</b>			
Loss attributable to common stockholders	\$ (24,804)	\$ (85,156)	\$ (81,311)
<b>Denominator:</b>			
Weighted-average common shares outstanding	6,724	6,839	6,857
Less: weighted-average common shares outstanding subject to repurchase	(6,544)	(6,769)	(6,715)
Weighted-average common shares used in computing loss per share attributable to common stockholders, basic and diluted	180	70	142
Loss per share attributable to common stockholders, basic and diluted	\$ (137.80)	\$ (1,216.51)	\$ (572.61)

F-13



**Table of Contents****JAZZ PHARMACEUTICALS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The following convertible preferred stock, stock options, common stock subject to repurchase and warrants were excluded from the computation of diluted loss per share attributable to common stockholders for the periods presented because including them would have an antidilutive effect (in thousands):

	Year Ended December 31,		
	2004	2005	2006
Series A convertible preferred stock (as if converted)	15,000	15,000	15,000
Series B convertible preferred stock (as if converted)	17,600	52,801	88,002
Series B Prime convertible preferred stock (as if converted)	19,067	57,202	95,336
Warrants to purchase Series BB convertible preferred stock (as if exercised and converted)		8,696	8,696
Options to purchase common stock	14,133	16,128	17,678
Common stock subject to repurchase	4,107	2,397	688

**Stock-Based Compensation**

Prior to January 1, 2006, the Company accounted for stock-based employee compensation arrangements using the intrinsic value method of Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* ( APB 25 ) and related interpretations, and complied with the disclosure-only provisions of SFAS No. 123, *Accounting for Stock-Based Compensation*, ( SFAS 123 ) as amended by SFAS No. 148, *Accounting for Stock-Based Compensation, Transition and Disclosure, an amendment to SFAS Statement No. 123* ( SFAS 148 ). Under APB 25 compensation expense for employees is based on the excess, if any, of the fair value of the Company's common stock over the exercise price of the option on the date of grant. No stock-based compensation expense was recorded under APB 25 during the years ended December 31, 2004 and 2005.

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

The Company is using the straight-line method to allocate compensation cost to reporting periods under SFAS 123 and SFAS 123R for stock options granted during each of the three years ended December 31, 2006.

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

The Company accounts for potentially beneficial conversion features under EITF Issue No. 98-5, *Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios* ( EITF 98-5 ) and EITF Issue No. 00-27, *Application of Issue No. 98-5 to Certain Convertible Instruments*. Issuances of convertible preferred stock during the year ended December 31, 2006 were deemed to result in a beneficial conversion feature calculated in accordance with EITF 98-5. For additional information regarding this beneficial conversion feature, see Note 12.

**Table of Contents**

**JAZZ PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Reclassifications**

Certain reclassifications have been made to the prior year amounts in order to conform to the current year presentation. Convertible preferred stock, which in prior year financial statements had been classified as part of stockholders' deficit, is now classified as temporary equity in accordance with EITF Topic D-98, *Classification and Measurement of Redeemable Securities*. Previously the Company had recorded the original purchase price of unvested shares of common stock subject to a right of repurchase by the Company as a liability and reclassified amounts to stockholders' deficit at the original purchase price as these shares vested. In the financial statements as reclassified, all vested shares of common stock subject to repurchase held by the Company's executive officers have been classified as temporary equity at fair value as of the date the Company entered into certain executive employment agreements. Certain payments to a customer for services performed, which had previously been classified as part of selling, general and administrative expense, have been reclassified as a reduction of revenue. These reclassifications did not impact previously reported net loss.

**Recent Accounting Pronouncements**

In July 2006, the FASB issued Interpretation No. 48, *Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement No. 109* (FIN 48). FIN 48 clarifies the accounting for uncertainty in income taxes by prescribing the recognition threshold a tax position is required to meet before being recognized in the financial statements. It also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. FIN 48 is effective for fiscal years beginning after December 15, 2006 and is required to be adopted by the Company effective January 1, 2007. The cumulative effects, if any, of applying FIN 48 will be recorded as an adjustment to accumulated deficit as of the beginning of the period of adoption. The Company is currently evaluating the effect that the adoption of FIN 48 will have on its results of operations and financial position.

In September 2006, the Securities and Exchange Commission issued Staff Accounting Bulletin No. 108, *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements* (SAB 108). SAB 108 provides guidance on the consideration of the effects of prior year misstatements in quantifying current year misstatements for the purpose of a materiality assessment. SAB 108 establishes an approach that requires quantification of financial statement errors based on the effects on each of the Company's balance sheets and statement of operations and the related financial statement disclosures. SAB 108 will be adopted by the Company in the first quarter of 2007. The Company is currently evaluating the effect that the adoption of SAB 108 will have on its results of operations and financial position.

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



**Table of Contents****JAZZ PHARMACEUTICALS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****3. Cash, Cash Equivalents, Restricted Cash and Available-For-Sale Securities**

Cash, cash equivalents, restricted cash and available-for-sale securities, all of which are classified as available-for-sale securities, consisted of the following as of December 31, 2005 and 2006 (in thousands):

	December 31, 2005			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Cash	\$ 5,189	\$	\$	\$ 5,189
Obligations of U.S. government agencies	15,484	2		15,486
Corporate debt securities	7,578	2		7,580
Other debt securities, primarily money market funds	4,659			4,659
<b>Total available-for-sale securities</b>	<b>\$ 32,910</b>	<b>\$ 4</b>	<b>\$</b>	<b>\$ 32,914</b>
Amounts classified as cash and cash equivalents				\$ 20,614
Amounts classified as restricted cash				300
Amounts classified as long-term restricted cash and available-for-sale securities				12,000
<b>Total</b>				<b>\$ 32,914</b>

	December 31, 2006			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Cash	\$ 11,799	\$	\$	\$ 11,799
Obligations of U.S. government agencies	35,106	10		35,116
Corporate debt securities	17,180	2		17,182
Other debt securities, primarily money market funds	27,126			27,126
<b>Total available-for-sale securities</b>	<b>\$ 91,211</b>	<b>\$ 12</b>	<b>\$</b>	<b>\$ 91,223</b>
Amounts classified as cash and cash equivalents				\$ 78,948
Amounts classified as restricted cash				275
Amounts classified as long-term restricted cash and available-for-sale securities				12,000
<b>Total</b>				<b>\$ 91,223</b>

All available-for-sale securities held as of December 31, 2005 and 2006 had contractual maturities of less than one year.

Since inception, there have been no material realized gains or losses on available-for-sale securities. No available-for-sale securities held as of December 31, 2005 or 2006 had been in a continuous unrealized loss position for more than 12 months. The aggregate fair value of available-for-sale securities held at December 31, 2005 and 2006 which had unrealized losses was \$1.5 million and \$1.6 million, respectively. The amount of the unrealized loss at December 31, 2005 and 2006 was immaterial and the Company does not believe that the impairment is other than temporary.

F-16

**Table of Contents****JAZZ PHARMACEUTICALS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****4. Certain Balance Sheet Items**

Inventories consist of the following (in thousands):

	<b>December 31,</b>	
	<b>2005</b>	<b>2006</b>
Raw materials	\$ 1,109	\$ 541
Finished goods	2,153	2,485
<b>Total inventories</b>	<b>\$ 3,262</b>	<b>\$ 3,026</b>

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

	<b>December 31,</b>	
	<b>2005</b>	<b>2006</b>
Leasehold improvements	\$ 616	\$ 700
Computer equipment	707	873
Computer software	558	1,271
Furniture and fixtures	160	182
Construction-in-progress	506	316
<b>Total</b>	<b>2,547</b>	<b>3,342</b>
<b>Less accumulated depreciation and amortization</b>	<b>(606)</b>	<b>(1,235)</b>
<b>Property and equipment, net</b>	<b>\$ 1,941</b>	<b>\$ 2,107</b>

Accrued liabilities consists of the following (in thousands):

	<b>December 31,</b>	
	<b>2005</b>	<b>2006</b>
Accrued research and development expense	\$ 4,166	\$ 5,119
Accrued compensation	3,329	4,322
Accrued sales and marketing expense	2,231	783
Accrued general and administrative expense	365	1,440
Other	1,030	1,279

Total accrued liabilities

\$ 11,121    \$ 12,943

### **5. Acquisition of Orphan Medical**

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

F-17



**Table of Contents****JAZZ PHARMACEUTICALS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

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

Liabilities of \$8.0 million as shown above included \$4.0 million of restructuring charges related primarily to employee severance payments and the closure of facilities, of which no amounts remained unpaid as of December 31, 2006.

The Company retained an independent appraisal firm to assist in the valuation of identifiable intangible assets acquired in the transaction. The estimated fair value of intangible assets identified and the useful lives assigned at the time of acquisition are as follows (in thousands):

	<b>Gross Carrying Amount</b>	<b>Weighted- Average Estimated Useful Life (Years)</b>
Developed technology	\$ 75,100	9.5
Agreements not to compete	5,600	4.4
Trademarks	2,600	9.5
Other	400	4.5
<b>Amortized intangible assets</b>	<b>\$ 83,700</b>	<b>9.1</b>

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

risks associated with the cash flows being discounted.

In January 2005, Orphan Medical submitted a supplemental New Drug Application, or sNDA, to the FDA seeking an expanded label indication for Xyrem. At the time of acquisition, the FDA had not yet approved the sNDA. As a result, the Company charged the value associated with the additional label indication to in-process research and development, which accounted for 71% of the total in-process research and development expense recorded in connection with the acquisition. The discount rate used to calculate the fair value of Xyrem for the new indication, excessive daytime sleepiness in patients with narcolepsy, was 26%. At the time of acquisition,

**Table of Contents****JAZZ PHARMACEUTICALS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Orphan Medical was also conducting a Phase II clinical trial to evaluate the use of sodium oxybate, the active pharmaceutical ingredient ( API ) in Xyrem, to treat fibromyalgia syndrome ( FMS ). The discount rate used to calculate the fair value of this development project was 50%. Positive results for the Phase II trial were determined when the trial was unblinded in August 2005. In August 2006 the Company initiated a Phase III clinical trial to evaluate the use of sodium oxybate for the treatment of FMS.

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

In March 2007, the Company sold its rights to Cystadane, a product acquired in connection with the acquisition of Orphan Medical. See Note 19 for a further discussion of this transaction.

The following unaudited pro forma information presents the results of continuing operations and net income of Jazz Pharmaceuticals and Orphan Medical for the years ended December 31, 2004 and 2005 as if the acquisition of Orphan Medical had been consummated as of January 1, 2004 and 2005, respectively. The pro forma results exclude the nonrecurring charge for purchased in-process research and development that resulted directly from the June 24, 2005 acquisition of Orphan Medical by the Company. The unaudited pro forma condensed combined financial information does not reflect any incremental direct costs, including any restructuring charges to be recorded in connection with the acquisition, or any potential cost savings that may result from the consolidation of certain operations of the Company and Orphan Medical. Accordingly, the unaudited pro forma financial information is presented for illustrative purposes and not necessarily indicative of the results of operations of the combined company that would have occurred had the acquisition occurred at the beginning of each period presented, nor is it necessarily indicative of future operating results. The unaudited pro forma information is as follows (in thousands, except per share data):

	<b>Year Ended December 31,</b>	
	<b>2004</b>	<b>2005</b>
Revenues	\$ 23,768	\$ 37,275
Net loss	(60,318)	(77,643)
Loss per common share	\$ (335.10)	\$ (1,111.13)

**6. Goodwill and Intangible Assets**

The gross carrying amount and net book value of goodwill and intangible assets is as follows (in thousands):

Edgar Filing: JAZZ PHARMACEUTICALS INC - Form S-1

	December 31, 2005			December 31, 2006		
	Gross Carrying Amount	Accumulated Amortization	Net Book Value	Gross Carrying Amount	Accumulated Amortization	Net Book Value
Developed technology	\$ 75,100	\$ 4,077	\$ 71,023	\$ 75,100	\$ 11,970	\$ 63,130
Agreements not to compete	5,600	696	4,904	5,600	2,042	3,558
Trademarks	2,600	141	2,459	2,600	414	2,186
Other	400	46	354	400	134	266
Amortizable intangible assets	83,700	4,960	78,740	83,700	14,560	69,140
Goodwill	38,883			38,213		
<b>Total</b>	<b>\$ 122,583</b>			<b>\$ 121,913</b>		

F-19

**Table of Contents****JAZZ PHARMACEUTICALS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

Year Ended December 31,	Estimated Amortization Expense
2007	\$ 9,600
2008	9,307
2009	9,033
2010	8,542
2011	8,164

**7. Debt and Financing Obligations*****Line of Credit***

In September 2006, the Company entered into a one year line of credit agreement with a financial institution under which the Company may borrow up to 80% of eligible receivables up to a maximum borrowing limit of \$5.0 million. Borrowings under the line of credit bear interest at the lender's prime rate. The Company is subject to certain financial and operating covenants under the credit agreement. The lender has a security interest in all of the Company's assets, with the exception of intellectual property. As of December 31, 2006, \$2.2 million was outstanding under the line of credit with interest accruing at a rate of 8.25% per year.

***Senior Secured Notes***

In order to partially finance the acquisition of Orphan Medical, a wholly-owned subsidiary of the Company issued \$80.0 million aggregate principal amount of senior secured notes (the "notes") and warrants to purchase 8,695,652 shares of the Company's Series BB preferred stock exercisable at \$1.84 per share (the "warrants") to certain third parties, some of whom are affiliated with preferred stock investors in June 2005. The notes accrue interest at a rate of 15% per annum, payable quarterly in arrears. The principal on the notes is due in full on June 24, 2011 and can be repaid by the Company at any time, at certain premiums over the principal amount.

The Company estimated the fair value of the warrants to be \$6.7 million using the Black-Scholes option pricing model with the following assumptions at the time of issuance: risk free interest rate of 3.96%, volatility of 60%, dividend yield of 0.0%, and an expected life of seven years. For additional information on the determination of fair value for the warrants as of December 31, 2005 and 2006, see Note 11. The discount to the notes is being accreted to zero over the life of the notes using the effective interest rate method and is included as a component of interest expense. Total issuance costs of \$2.0 million were allocated to the notes and the warrants based on their relative fair values. Of the total

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

issuance costs, \$1.8 million was allocated to the notes and included in other assets and is being amortized to interest expense using the effective interest method.

The Company and all existing and future domestic subsidiaries fully and unconditionally guarantee repayment of the notes. The notes and each guarantee are secured by a lien and security interest in substantially all of the Company's and each subsidiary's assets. The subsidiary of the Company that issued the notes is required to maintain a minimum cash balance equal to 15% of the outstanding principal amount on the notes. This amount was \$12.0 million at December 31, 2005 and 2006 and is reflected as long-term restricted cash and investments on the Company's consolidated balance sheet. The notes contain customary covenants including limitations on the Company's ability to pay dividends, make investments or other restricted payments, incur debt,

F-20

**Table of Contents**

**JAZZ PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

grant liens, sell assets and enter into sale-leaseback transactions. Upon the occurrence of certain events of default under the notes, including a default by the Company in payment of principal or interest on the notes, a bankruptcy filing by the Company, or a change in control of the Company, the Company may be required to repay the notes at a premium. The repayment premium was 30.0% of the principal amount of the notes as of December 31, 2006 and is reduced to zero ratably over the term of the notes.

***Development Financing Obligation***

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

**8. Commitments and Contingencies**

***Indemnification***

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

The Company has agreed to indemnify its officers and directors and the officers and directors of Orphan Medical for losses and costs incurred in connection with certain events or occurrences, including advancing money to cover certain costs, subject to certain limitations. The maximum potential amount of future payments the Company could be required to make under this indemnification is unlimited; however, the Company maintains insurance policies that may limit its exposure and may enable it to recover a portion of any future amounts paid. Assuming the applicability of coverage, the willingness of the insurer to assume coverage, and subject to certain retention, loss limits and other policy provisions, the Company believes the fair value of these indemnification obligations is not material. Accordingly, the Company has not recognized any liabilities relating to these obligations as of December 31, 2005 and 2006. No assurances can be given that the covering insurers will not attempt to dispute the validity, applicability, or amount of coverage without expensive litigation against these insurers, in which case the Company may incur substantial liabilities as a result of these indemnification obligations.

*Lease and Other Commitments*

In June 2004, the Company entered into a noncancelable operating lease for an office facility in Palo Alto, California which expires in August 2008. The lease is renewable through 2017 at the Company's option. In

F-21



**Table of Contents****JAZZ PHARMACEUTICALS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

In addition to these lease payments, the Company is obligated to pay for operating expenses for the leased property. The Company is also obligated to make payments under noncancelable operating leases for cars used by its sales force. Rent expense under all operating leases was \$435,000, \$930,000 and \$1.3 million for the years ended December 31, 2004, 2005 and 2006, respectively. Future minimum lease payments under the Company's noncancelable operating leases at December 31, 2006, are as follows (in thousands):

Year ended December 31,	Lease Payments
2007	\$ 1,227
2008	929
2009	238
2010	17
<b>Total future minimum lease payments</b>	<b>\$ 2,411</b>

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

**Legal Proceedings**

In April 2006, a physician who was a speaker for Orphan Medical (and for a short time for the Company), was indicted by a federal grand jury in the U.S. District Court for the Eastern District of New York. The indictment alleges that the physician engaged in a scheme with Orphan Medical sales representatives and other Orphan Medical employees to promote and obtain reimbursement for Xyrem for medical uses not approved for marketing by the FDA. Also in April 2006, the Department of Justice, acting through the U.S. Attorney for the Eastern District of New York, issued to the Company and Orphan Medical subpoenas for documents relating to Xyrem. The Company is cooperating with this investigation and has provided documents to the U.S. Attorney's Office. As a result of the Company's acquisition of Orphan Medical, the Government may seek to hold the Company responsible for Orphan Medical's conduct. The Company has been in discussions with the U.S. Attorney's Office regarding the possible settlement of any potential government claims against Orphan Medical and/or the Company. It is currently unknown if any such settlement will be reached on reasonable terms, or at all. The Company cannot predict or determine the outcome of this matter or reasonably estimate the amount of any fines or penalties that might result from an adverse outcome. Therefore, in accordance with Statement of Financial Accounting Standard No. 5, *Accounting for Contingencies* (SFAS 5), the Company has not recorded an associated liability. The Company will recognize a liability, if any, when it has an adequate basis to estimate any probable exposure, if any.

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

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

fees and other disbursements, as well as unspecified other and further relief. On October 25, 2006, the defendants filed a motion to dismiss the complaint and oral argument on the motion was heard by the U.S. District Court for the District of Minnesota. On February 16, 2007, the U.S. District Court for the District of Minnesota granted the defendants

F-22

**Table of Contents**

**JAZZ PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

motion to dismiss the complaint, but granted the plaintiff a one-month leave to amend the plaintiff's complaint. The Company cannot predict or determine the outcome of this matter or reasonably estimate the amount of any judgments or payments that might result from an adverse outcome. Therefore, in accordance with SFAS 5 the Company has not recorded an associated liability. The Company will recognize a liability, if any, when it has an adequate basis to estimate any probable exposure, if any.

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

**9. Collaboration and License Agreements**

In October 2004, the Company entered into an agreement with GlaxoSmithKline to purchase worldwide rights to the API in JZP-4. The Company paid and recorded research and development expense of \$2.0 million upon execution of the agreement and \$3.0 million in July 2006 upon achievement of a developmental milestone. The Company also agreed to pay up to \$113.5 million upon the achievement of future developmental and commercial milestones and royalties at specified rates based on net sales.

The Company paid and expensed as research and development \$3.0 million and \$10.4 million during the years ended December 31, 2004 and 2005, respectively, upon achievement of developmental milestones under the terms of three agreements which have since been terminated and under which no future obligations existed at December 31, 2006. In connection with its product development activities, the Company may enter into agreements with third party technology providers, patent holders and others. Patent licenses may require upfront payments, patent prosecution and maintenance fees and royalties on sales of products covered by the patents. Agreements with technology providers often provide for upfront payments and milestone payments based upon the achievement of specified developmental and commercial milestones and royalties based on sales of the products the Company develops with the technology provider. The Company currently has two such agreements pursuant to which it has agreed to pay up to \$8.2 million upon achievement of developmental and commercial milestones.

**10. Product License**

In June 2006, the Company entered into an agreement with UCB Pharma Limited (UCB) that amended and restated a prior agreement between Orphan Medical and UCB. Under the terms of the amended agreement, UCB has the right to market Xyrem for the treatment of narcolepsy and JZP-6 for the treatment of FMS in 54 countries outside of the U.S. Under the prior agreement UCB made a nonrefundable development milestone payment of \$2.5 million in November 2005 and a nonrefundable commercial milestone payment of \$500,000 in June 2006 which the Company recognized upon achievement of the milestones. UCB also made upfront payments of \$5.0 million upon execution of the amended agreement in June 2006 and \$10.0 million in August 2006 upon exercise of its rights to develop and commercialize JZP-6 for the treatment of FMS. The Company recognized revenues of \$463,000 related to these upfront payments during the year ended December 31, 2006. The remaining \$14.5 million was recorded as deferred revenues as of December 31, 2006 and is being recognized ratably through 2019, the expected performance period under the agreement. The amended agreement requires UCB to make additional milestone payments of up to \$148.0 million,

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

of which up to \$8.0 million relate specifically to Xyrem for the treatment of narcolepsy, up to \$40.0 million relate to the development and approval of JZP-6 for the treatment of FMS and up to \$100.0 million relate primarily to the commercialization of JZP-6 for the treatment of FMS as well as additional sales of Xyrem for the treatment of narcolepsy.

F-23

**Table of Contents****JAZZ PHARMACEUTICALS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****11. Convertible Preferred Stock Warrant Liability**

In June 2005 in connection with the issuance of the notes referenced in Note 7, the Company issued warrants to purchase 8,695,652 shares of Series BB preferred stock at an exercise price of \$1.84 per share. The warrants are exercisable, at the option of the holders, at any time until June 24, 2012, and are recorded as preferred stock warrant liability. The warrants may be exercised using the net exercise method. Under this method, the number of shares issued upon exercise is reduced by an amount equal to the product of the number of shares subject to the exercise and the exercise price per share, divided by the fair value of the Series BB preferred stock on the date of the exercise. The number of shares issuable upon exercise of the warrants, and the exercise price per share, are adjustable in the event of stock splits, dividends and similar fundamental changes. The preferred stock warrant liability is revalued at the end of each reporting period to fair value using the Black-Scholes option pricing model to determine the fair value of the warrants. The fair value of the warrants was estimated to be \$7.4 million and \$8.5 million as of December 31, 2005 and 2006, respectively, using the following assumptions:

	December 31,	
	2005	2006
Series BB preferred stock fair value	\$ 1.50	\$ 1.75
Volatility	60%	59%
Contractual term	6.5	5.5
Risk-free rate	4.3%	4.7%
Expected dividend yield	0.0%	0.0%

The Company recorded other expense of \$901,000 and \$1.1 million during the years ended December 31, 2005 and 2006, respectively, to reflect increases in the fair value of the preferred stock warrant liability. The Company will continue to adjust the preferred stock warrant liability for changes in the fair value of the warrants until the earlier of the exercise of the warrants to purchase Series BB preferred stock, at which time the liability will be reclassified to temporary equity, or the conversion of the underlying Series BB preferred stock into common stock, at which time the liability will be reclassified to stockholders' deficit.

**12. Convertible Preferred Stock**

The Company's Second Amended and Restated Certificate of Incorporation authorizes the Company to issue shares of Series A preferred stock, Series B preferred stock, Series B Prime preferred stock and Series BB preferred stock, which hereinafter are collectively referred to as preferred stock.

As of December 31, 2005, the preferred stock is comprised of the following (in thousands, except share amounts):

Edgar Filing: JAZZ PHARMACEUTICALS INC - Form S-1

	<b>Shares Authorized</b>	<b>Shares Issued and Outstanding</b>	<b>Carrying Amount</b>	<b>Aggregate Liquidation Preference</b>
Series A	15,000,000	15,000,000	\$ 14,926	\$ 15,000
Series B	189,205,047	52,801,406	71,549	72,000
Series B Prime	95,335,876	57,201,526	77,387	78,000
Series BB	8,695,652			
<b>Total</b>	<b>308,236,575</b>	<b>125,002,932</b>	<b>\$ 163,862</b>	<b>\$ 165,000</b>

F-24

**Table of Contents****JAZZ PHARMACEUTICALS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

As of December 31, 2006, the preferred stock is comprised of the following (in thousands, except share amounts):

	Shares Authorized	Shares Issued and Outstanding	Carrying Amount	Aggregate Liquidation Preference
Series A	15,000,000	15,000,000	\$ 14,926	\$ 15,000
Series B	189,205,047	88,002,330	119,544	120,000
Series B Prime	95,335,876	95,335,875	129,382	130,000
Series BB	8,695,652			
<b>Total</b>	<b>308,236,575</b>	<b>198,338,205</b>	<b>\$ 263,852</b>	<b>\$ 265,000</b>

The Company initially recorded the preferred stock at their fair values on the dates of issuance, net of issuance costs. A redemption event will only occur upon a liquidation or winding up of the Company or a change of control as defined in the Company's Second Amended and Restated Certificate of Incorporation. All shares of preferred stock have been presented outside of permanent equity in accordance with EITF Topic D-98, *Classification and Measurement of Redeemable Securities*. The Company has elected not to adjust the carrying values of the preferred stock to their redemption value since it is uncertain whether or when a redemption event will occur. Subsequent adjustments to increase the carrying values to the redemption values will be made when it becomes probable that such redemption will occur.

As of December 31, 2006, the Company has reserved 95,335,876 shares of Series B preferred stock for conversion of the Series B Prime preferred stock.

In January and December 2006, the Company issued 35,200,924 and 38,134,349 shares, respectively, of Series B preferred stock and Series B Prime preferred stock at a purchase price of \$1.3636 per share. At the time of each of these issuances, the value of the common stock into which the Series B preferred stock and Series B Prime preferred stock is convertible had a fair value greater than the proceeds for such issuances. Accordingly, the Company recorded a deemed dividend on the Series B preferred stock and Series B Prime preferred stock of \$3.5 million in January 2006 and \$18.4 million in December 2006, which equals the amount by which the estimated fair value of the common stock issuable upon conversion of the issued Series B preferred stock and Series B Prime preferred stock exceeded the proceeds from such issuances.

The significant rights, privileges and preferences of the preferred stock are as follows:

***Election of Directors***

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

The Company has two classes of directors on the Company's board of directors, designated as standard directors and Series B Prime directors. The holders of Series A preferred stock, Series B preferred stock, Series B Prime preferred stock, Series BB preferred stock and common stock, voting together as a single class on an as-if-converted to common stock basis, are entitled to elect the standard directors. The holders of Series B Prime preferred stock, voting as a single class on an as-if-converted-to-common-stock basis, are entitled to elect Series B Prime directors. The number of Series B Prime directors which the holders of Series B Prime preferred stock are entitled to elect and the number of votes which each Series B Prime director is entitled to cast with respect to any action of the Board of Directors is dependent upon (i) the total number of authorized directors; (ii) the ratio of outstanding Series B Prime preferred stock to the total outstanding shares of Series B preferred stock and Series B Prime preferred stock collectively, including common stock issued on conversion thereof; and (iii) the ratio of total capital committed by holders of Series B Prime preferred stock to the total capital commitments of all holders of Series B preferred stock and Series B Prime preferred stock.

F-25



**Table of Contents**

**JAZZ PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

***Conversion***

Each share of Series B Prime preferred stock is convertible into one share of Series B preferred stock at the option of the holder or automatically at any time that the holder, together with its affiliates, owns less than 8.7% of the aggregate total shares of Series B preferred stock and Series B Prime preferred stock, including common stock issued upon conversion thereof. Each share of Series A preferred stock, Series B preferred stock, Series B Prime preferred stock, and Series BB preferred stock is convertible into one share of common stock, subject to adjustment upon the occurrence of certain events. Each share of preferred stock will automatically be converted into common stock at the conversion price then in effect upon the earlier of (i) the closing of a firm commitment underwritten public offering with aggregate proceeds to the Company in excess of \$60 million and a per share price not less than \$4.09; or (ii) the consent of the holders of at least 55% of the total outstanding shares of preferred stock, voting together as a single class on an as-if-converted to common stock basis.

***Voting Rights***

The holder of each share of preferred stock is entitled to the number of votes equal to the number of shares of common stock into which the share of preferred stock could be converted. Other than as stated in the Second Amended and Restated Certificate of Incorporation or as required by law, holders of preferred stock vote together with holders of common stock and not as a separate class or series.

***Dividends***

Holders of the preferred stock are entitled to receive on a pari passu basis, prior and in preference to any declaration or payment of any dividend on the common stock, noncumulative dividends out of any assets legally available at an annual rate of 8% of the respective original purchase prices for the shares of preferred stock, when and if declared by the board of directors. No dividends on preferred stock have been declared through December 31, 2006.

***Liquidation***

In the event of any liquidation, dissolution or winding up of the Company, whether voluntary or involuntary, or any change of control of the Company, the holders of Series A preferred stock, Series B preferred stock, Series B Prime preferred stock and Series BB preferred stock are entitled to receive, in preference to distributions to holders of common stock, an amount per share equal to \$1.00, \$1.3636, \$1.3636 and \$1.84, respectively, plus any declared but unpaid dividends with respect to such shares of preferred stock. If the assets of the Company are insufficient to permit payment of the liquidation amount in full to all holders of preferred stock, the assets of the Company will be distributed ratably to holders of all series of preferred stock in proportion to the preferential amount each such holder would otherwise be entitled to receive. A change of control of the Company is defined in the Company's Second Amended and Restated Certificate of Incorporation as (i) a sale of all or

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

substantially all the Company's assets other than to certain holders of Series B Prime preferred stock, their affiliates, a group including such holders or affiliates, or entities controlled by the existing stockholders of the Company; (ii) a transaction or series of transactions resulting in more than 50% of the Company's voting power being led by certain holders of Series B Prime preferred stock, their affiliates or a group including such holders or affiliates; or (iii) a merger or consolidation with an entity other than certain holders of Series B Prime preferred stockholders, their affiliates, or a group including such holder or affiliates if after such merger or consolidation the directors immediately prior to such merger or consolidation do not constitute a majority of the directors of the surviving entity or its parent.

F-26

**Table of Contents****JAZZ PHARMACEUTICALS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****13. Common Stock**

The Company's Second Amended and Restated Certificate of Incorporation authorizes the Company to issue 252,716,057 shares of common stock. The Company has issued certain shares of its common stock under restricted stock purchase agreements with its executives and a non-employee director and upon the early exercise of stock options. Under the terms of these restricted stock purchase agreements and exercised stock options, the Company has the option to repurchase unvested shares of common stock at the initial purchase price upon the termination of a holder's services to the Company. The number of shares subject to repurchase is reduced ratably over 48 months from the date of purchase or, in the case of stock options early exercised, the date of grant of the stock option.

Unvested shares are subject to a right of repurchase at cost upon termination of employment. The original purchase price paid for these shares are recorded as a liability. Prior to 2004 these amounts were reclassified to permanent equity as these shares vested. In February 2004, each of the Company's executive officers entered into an employment agreement which permits the executive officer or the officer's estate to require the Company to repurchase vested shares at fair market value upon termination of the executive officer's employment due to death or disability. The fair value of vested shares held by the Company's executive officers as of the date of such agreements (the Agreement Date Fair Value) was recorded as temporary equity and following the date of such agreements, the Agreement Date Fair Value of shares held by the Company's executive officers is recorded as temporary equity as such shares vest. The excess of the Agreement Date Fair Value over the original purchase price paid for such shares is charged against additional paid-in capital or, to the extent additional paid-in capital is insufficient, as an increase to stockholders' deficit. As of December 31, 2005 and 2006, the Company had recorded liability of \$184,000 and \$98,000 respectively, associated with 2,397,324 and 687,545 unvested shares, respectively. As of December 31, 2005 and 2006, the Company had recorded \$5.9 million and \$8.2 million as temporary equity, respectively, associated with 4,345,209 and 6,002,085 vested shares held by executive officers, respectively.

The Company has reserved the following shares of authorized but unissued Common Stock as of December 31, 2006:

	<b>Shares</b>
Reserved for conversion of Series A preferred stock	15,000,000
Reserved for conversion of Series B, Series B Prime and Series BB preferred stock	197,900,699
Reserved for the Company's equity incentive plan	23,056,296
 Total reserved shares of common stock	 235,956,995

**14. Stock-Based Compensation***2003 Equity Incentive Plan*

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

In March 2003, the board of directors adopted and the stockholders approved the 2003 Equity Incentive Plan (the 2003 Plan ). The 2003 Plan provides for the grant of incentive and nonstatutory stock options, stock issuances, cash awards and certain other equity-related awards to employees, directors and consultants of the Company. An aggregate of 23,517,858 shares of common stock is reserved under the 2003 plan. Incentive stock options may be granted by the board of directors or a committee of the board of directors to employees with an exercise price not less than 100% of the fair value of the common stock on the date of grant. Nonstatutory stock options may be granted to employees, directors and consultants with an exercise price not less than 85% of the fair market value of the common stock on the date of grant. Option grants to employees generally vest 25% upon the first anniversary of the date of hire and ratably each month thereafter for the next three years. The only

F-27

**Table of Contents****JAZZ PHARMACEUTICALS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

activity under the 2003 Plan since adoption has related to the grant of stock options to employees and a non-employee director, all of which expire ten years from the date of grant if not exercised.

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

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

For each of the three years ended December 31, 2004, 2005, 2006, under both SFAS 123 and SFAS 123R the Company elected to use the Black-Scholes valuation model to calculate the fair value of stock options. The fair value of stock options was estimated at the grant date with using the following assumptions:

	Year Ended December 31,		
	2004	2005	2006
Weighted-average volatility	80%	60%	61%
Weighted-average expected term	5	5	6
Range of risk-free rates	3.0-4.0%	3.9-4.4%	4.6-5.1%
Expected dividend yield	0.0%	0.0%	0.0%

The weighted-average grant date fair value per share of employee stock options granted during the years ended December 31, 2004, 2005 and 2006 was \$.81, \$.78 and \$.97, respectively.

***Volatility***

As the Company does not have any trading history for its common stock, the expected stock price volatility for the Company's common stock was estimated by taking the median historic stock price volatility for industry peers based on daily price observations over a period equivalent to the expected term of the stock option grants. Industry peers consist of several public companies in the biopharmaceutical industry similar in size, stage of life cycle and financial leverage. The Company did not rely on the implied volatilities of traded options in its industry peers' common stock, because either the term of those traded options was much shorter than the expected term of the Company's stock option grants, or the volume of activity was relatively low.

***Expected Term***

The Company has very little historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior for its stock option grants. As a result, for stock option grants made during the year ended December 31, 2006, the expected term was estimated using the short-cut method allowed under Securities and Exchange Commission SAB No. 107 *Share-Based Payment*. For stock options granted during the years ended December 31, 2004 and 2005 the Company estimated the expected term of stock options based on the expected terms of options granted by publicly traded industry peers.

*Risk-Free Rate*

The risk-free interest rate assumption was based on zero coupon U.S. Treasury instruments whose term was consistent with the expected term of the Company's stock option grants.

*Expected Dividend Yield*

The Company has never declared or paid any cash dividends and does not presently plan to pay cash dividends in the foreseeable future. Consequently, the Company used an expected dividend yield of zero.

---

**Table of Contents**

**JAZZ PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

*Common Stock Fair Value*

The fair value of the Company's common stock during the years ended December 31, 2004 and 2005 was determined by its board of directors with assistance from management. In May 2006, the Company engaged an independent valuation specialist to perform a valuation of the Company's common stock. The valuation used a two-step methodology that first estimated the fair value of the Company as a whole, and then allocated a portion of the enterprise value to the Company's common stock. This approach is consistent with the methods outlined in the AICPA Practice Aid Valuation of Privately-Held-Company Equity Securities Issued as Compensation. The valuation methodology utilized both the income approach and the market approach to estimate enterprise value. The income approach estimates the fair value of the enterprise based upon a projection of future cash flows while the market approach is based upon comparisons to publicly-held companies in the Company's industry at a similar stage of development. In order to allocate the enterprise value to the various securities that comprise the Company's capital structure the option-pricing method was used. A discount was applied to account for a lack of marketability. After considering this valuation and other factors, the board of directors determined the fair value of the Company's common stock to be \$1.50 as of June 28, 2006.

In December 2006, the Company engaged the independent valuation specialist to perform another valuation effective as of December 31, 2006. This valuation was completed in February 2007 and used the same methodology as the previous valuation except that the Company also considered the probability-weighted expected return method for allocating enterprise value to the common stock. After considering the valuation and other factors, including valuation estimates prepared by the Company's proposed underwriters, the board of directors determined the fair value of the Company's common stock to be \$1.75 as of February 13, 2007. The board of directors also reviewed the developments of the Company from June 28, 2006 to February 13, 2007 and noted that while there were a number of development milestones reached during the period from June 28, 2006 to December 31, 2006 no such developments occurred in the period from December 31, 2006 to February 13, 2007. Accordingly, the Company increased the estimated fair value of the common stock ratably from \$1.50 to \$1.75 over the period from June 28, 2006 to December 31, 2006 for purposes of calculating stock-based compensation expense associated with the Company's stock option grants under SFAS 123R.

*Forfeitures*

SFAS 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. In determining the Company's historic forfeiture rate, the Company has excluded stock option grants totaling 12,548,445 shares issued to executives of the Company in February 2004. The Company believes these stock option grants will not be cancelled due to termination, and therefore has applied a forfeiture rate of 0% for those stock option grants. The annualized forfeiture rate used for the remaining stock option grants was 7%. The forfeiture rate selected did not have a material impact on stock-based compensation expense in the year ended December 31, 2006. Prior to adoption of SFAS 123R, the Company accounted for forfeitures of stock option grants as they occurred.

As a result of the Company's Black-Scholes option fair value calculations and the allocation of value to the vesting periods using the straight-line vesting attribution method, the Company recognized \$3.5 million of stock-based compensation expense during the year ended December 31, 2006, of which \$8,000, \$661,000, and \$2.8 million were charged to cost of product sales, research and development and selling, general and administrative expense, respectively. The adoption of SFAS 123R caused basic and diluted net loss per common share to increase by \$24.51 in 2006. No income tax benefit was recognized in the statement of operations for the year ended December 31, 2006. Compensation cost

capitalized as a component of inventory during 2006 was \$18,000.

The total compensation cost related to unvested stock option grants not yet recognized as of December 31, 2006 was \$5.5 million and the weighted-average period over which these grants are expected to vest is 1.9 years.



**Table of Contents****JAZZ PHARMACEUTICALS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The following table summarizes activity under the Company's stock option plans from January 1, 2004 through December 31, 2006:

	Shares Available for Grant	Shares Subject to Outstanding Options	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (\$000)
Outstanding at December 31, 2003		372,500	\$ .10		
Shares authorized through Plan amendment	22,815,358				
Options granted at fair value on date of grant	(8,806,067)	8,806,067	1.36		
Options granted in excess of fair value on date of grant	(5,019,378)	5,019,378	3.41		
Options exercised		(65,000)	.10		
Outstanding at December 31, 2004	8,989,913	14,132,945	2.06		
Options granted at fair value on date of grant	(2,318,500)	2,318,500	1.43		
Options forfeited	303,500	(303,500)	1.22		
Options expired	20,000	(20,000)	.10		
Outstanding at December 31, 2005	6,994,913	16,127,945	1.99		
Options granted at fair value on date of grant	(1,963,600)	1,963,600	1.50		
Options exercised		(66,562)	.15		
Options forfeited	337,239	(337,239)	1.38		
Options expired	10,180	(10,180)	1.43		
Outstanding at December 31, 2006	5,378,732	17,677,564	1.95	7.5	\$ 4,722
Vested and expected to vest at December 31, 2006		17,182,590	1.97	7.5	\$ 4,577
Exercisable at December 31, 2006		10,581,005	2.04	7.2	\$ 2,580

The aggregate intrinsic value shown in the table above is equal to the difference between the exercise price of the underlying stock options and \$1.75, the fair value of the Company's common stock as of December 31, 2006, for stock options that were in-the-money as of December 31, 2006.

During 2004, stock options exercised had no intrinsic value. No options were exercised during 2005. The aggregate intrinsic value of options exercised during 2006 was \$99,000.

The following table summarizes information about stock options outstanding as of December 31, 2006:

**Options Outstanding**

Exercise Price	Number of Shares	Weighted-Average Remaining Contractual Life (Years)	Options Exercisable  Number of Shares
\$ .10	172,500	6.5	172,500
1.36	9,645,726	7.3	6,479,341
1.50	2,839,954	9.3	373,762
2.73	2,509,692	7.1	1,777,701
4.09	2,509,692	7.1	1,777,701
	17,677,564	7.6	10,581,005

F-30

**Table of Contents****JAZZ PHARMACEUTICALS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

***Accounting and Disclosures Under APB 25 and SFAS 123***

Prior to January 1, 2006, the Company accounted for stock-based employee compensation arrangements using the intrinsic value method of APB 25 and related interpretations in accounting for its employee stock options and complied with the disclosure-only provisions of SFAS 123, as amended by SFAS 148. No stock-based compensation expense was recorded under APB 25 during the years ended December 31, 2004 and 2005.

The pro forma information required to be disclosed under SFAS 123 for the years ended December 31, 2004 and 2005 is as follows:

	<b>Year Ended December 31,</b>	
	<b>2004</b>	<b>2005</b>
	<b>(In thousands except per share data)</b>	
Loss attributable to common stockholders, as reported	\$ (24,804)	\$ (85,156)
Add: Employee stock-based compensation using the intrinsic value method		
Deduct: Total employee stock compensation calculated using the fair-value method	(2,325)	(2,934)
Pro forma loss attributable to common stockholders	\$ (27,129)	\$ (88,090)
Loss per share attributable to common stockholders, basic and diluted		
As reported	\$ (137.80)	\$ (1,216.51)
Pro forma	\$ (150.72)	\$ (1,258.43)

The Company estimated fair value of stock options at the grant date using the assumptions set forth above. The Company granted options with exercise prices equal to fair value per share with weighted-average exercise price per share and fair value per share of \$1.36, \$1.43 and \$1.50 during the years ended December 31, 2004, 2005 and 2006, respectively. The Company granted options with exercise prices greater than fair value per share with a weighted-average exercise price per share of \$3.41 and weighted-average fair value per share of \$1.36 during the year ended December 31, 2004.

**15. Income Taxes**

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

The Company has a history of losses and therefore has made no provision for income taxes. All of the Company's losses result from domestic operations.

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

F-31

**Table of Contents****JAZZ PHARMACEUTICALS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Significant components of the Company's deferred tax assets and liabilities are as follows (in thousands):

	December 31,	
	2005	2006
Deferred tax assets:		
Federal and state net operating loss carryforwards	\$ 48,552	\$ 58,474
Federal and state tax credit carryforwards	8,420	9,876
Deferred contract revenues		5,453
Acquired capitalized research and development	4,256	3,889
Other	1,996	2,631
<b>Total deferred tax assets</b>	<b>63,224</b>	<b>80,323</b>
Deferred tax liabilities:		
Acquired intangible assets	(27,559)	(24,328)
Other		(457)
<b>Total deferred tax liabilities</b>	<b>(27,559)</b>	<b>(24,785)</b>
Valuation allowance	(35,665)	(55,538)
<b>Net deferred tax assets</b>	<b>\$</b>	<b>\$</b>

Realization of the deferred tax assets is dependent upon the generation of future taxable income, if any, the amount and timing of which are uncertain. Based on available objective evidence, management believes it more likely than not that the Company's deferred tax assets are not recognizable. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by \$10.0 million, \$24.6 million and \$19.9 million for the years ended December 31, 2004, 2005 and 2006, respectively.

At December 31, 2006, the Company had net operating loss carryforwards for federal income tax purposes of approximately \$161.0 million which expire in the period from 2008 to 2026, and federal tax credits of approximately \$8.0 million which expire in the period from 2008 to 2026. The Company also has state net operating loss carryforwards of approximately \$73.0 million which expire beginning in 2013 and state tax credits of approximately \$2.0 million which have no expiration date. Utilization of the Company's net operating loss carryforwards and tax credit carryforwards are subject to annual limitation due to the ownership change limitations provided by the Internal Revenue Code and similar state provisions. Such an annual limitation may result in the expiration of the net operating loss before utilization. Because our acquisition of Orphan Medical triggered an ownership change, approximately \$37.0 million of the net operating loss carryforward is only available ratably through 2018 based upon the annual limitation under Section 382 of the Internal Revenue Code. Similarly, approximately \$5.0 million of tax credits are only available from 2019 to 2024.

**16. Related Party Transactions**

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

In June 2005, the Company issued senior secured notes in the aggregate principal amount of \$80.0 million with interest payable on the notes at the rate of 15% per year, payable quarterly in arrears. The notes are due and payable on June 24, 2011. As of December 31, 2006, KKR TRS Holdings, Inc., an entity affiliated with Kohlberg Kravis Roberts & Co. L.P., and LB I Group, an entity affiliated with Lehman Brothers Holdings Inc., both of which are significant stockholders, held \$25.0 million and \$31.0 million, respectively, in principal amount of these senior secured notes. The interest expense recognized with respect to notes held by KKR TRS Holdings, Inc. during the fiscal years ended December 31, 2005 and 2006 was \$2.1 million and \$4.0 million, respectively. The interest expense recognized with respect to notes held by LB I Group during the fiscal years ended

F-32

**Table of Contents****JAZZ PHARMACEUTICALS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

December 31, 2005 and 2006 was \$2.5 million and \$5.0 million, respectively. No payments of principal were made in either of these periods. In connection with the issuance of the senior secured notes, we issued warrants to purchase 2,717,391 and 3,369,566 shares of our Series BB preferred stock to KKR TRS Holdings, Inc. and LB I Group, respectively.

**17. 401(k) Plan**

The Company provides a qualified 401(k) savings plan for its employees. All employees are eligible to participate, provided they meet the requirements of the plan. While the Company may elect to match employee contributions, no such matching contributions have been made through December 31, 2006.

**18. Segment and Other Information**

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

The following table presents a summary of product sales (in thousands):

	<b>Year Ended December 31,</b>	
	<b>2005</b>	<b>2006</b>
Xyrem	\$ 11,200	\$ 29,049
Antizol	6,782	12,813
Cystadane	814	1,437
Total	\$ 18,796	\$ 43,299

The Company had no product sales or other revenues prior to the acquisition of Orphan Medical in June 2005. In March 2007, the Company sold its rights to Cystadane. See Note 19 for a further discussion of this transaction.

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

Edgar Filing: JAZZ PHARMACEUTICALS INC - Form S-1

	Year Ended December 31,	
	2005	2006
United States	\$ 18,305	\$ 42,326
Europe	3,020	1,757
All other	117	773
Total	\$ 21,442	\$ 44,856

F-33



**Table of Contents****JAZZ PHARMACEUTICALS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

	<b>Year Ended December 31,</b>	
	<b>2005</b>	<b>2006</b>
Express Scripts	51%	65%
Cardinal Health	*	12%
Amerisource Bergen	15%	*
UCB	12%	*

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

**19. Subsequent Events*****Product License Agreement***

In January 2007, the Company entered into a product license agreement with Solvay Pharmaceuticals, Inc. (Solvay) for the rights to market Luvox CR and Luvox in the United States. The Company made a \$2.0 million payment upon execution of the agreement, and agreed to make additional payments of up to \$138.0 million upon achievement of developmental and commercial milestones. Up to \$41.0 million of these milestone payments are payable at or prior to commercial launch of Luvox CR and \$2.0 million of these milestone payments are payable if the Company commercially launches Luvox. In addition, the Company is required to pay Solvay royalties at specified rates on commercial sales.

***Facilities Lease***

In March 2007, the Company entered into a lease agreement for approximately 13,000 square feet of office space in Palo Alto, California. The annual lease payments for this space are approximately \$460,000. The fixed term expires in August 2008, after which the Company may extend the term for up to six months subject to certain conditions.

***Divestiture of Cystadane***

In March 2007, the Company signed a Product Acquisition Agreement with an unrelated third party under which that third party purchased the Company's rights to Cystadane for cash consideration of \$9.0 million, along with its associated product registrations, commercial inventory and trademarks. The unrelated third party was also assigned certain contracts related to Cystadane, and assumed substantially all liabilities associated

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

with Cystadane arising subsequent to March 1, 2007. The Company and the third party concurrently entered into a Transition Services Agreement under which the Company has agreed to perform substantially all of the ongoing services necessary for the sale and promotion of Cystadane on behalf of the third party for up to 90 days following the date of the transaction, subject to certain conditions. The Company expects to record a gain of approximately \$5.1 million on the sale of the rights to Cystadane in the first quarter of 2007.

F-34

**Table of Contents**

**Report of Independent Auditors**

The Board of Directors and Stockholders

Jazz Pharmaceuticals, Inc.

We have audited the accompanying statements of operations and cash flows of Orphan Medical, Inc. for the period from January 1, 2005 to June 24, 2005. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the results of operations and cash flows of Orphan Medical, Inc. for the period January 1, 2005 to June 24, 2005, in conformity with accounting principles generally accepted in the United States.

/s/ Ernst & Young LLP

Palo Alto, California

March 6, 2007

F-35

**Table of Contents****ORPHAN MEDICAL, INC.****STATEMENT OF OPERATIONS****(In thousands, except per share amounts)**

	<b>Period from January 1, 2005 to June 24, 2005</b>
<b>Revenues:</b>	
Product sales, net	\$ 12,966
Royalties, net	71
Contract revenues	1,806
<b>Total revenues</b>	<b>14,843</b>
<b>Operating expenses:</b>	
Cost of product sales	1,975
Research and development	4,212
Selling, general and administrative	12,155
<b>Total operating expenses</b>	<b>18,342</b>
<b>Loss from operations</b>	<b>(3,499)</b>
Interest income	111
Interest expense	(13)
<b>Net loss</b>	<b>(3,401)</b>
Less: Preferred stock dividends	491
<b>Loss attributable to common stockholders</b>	<b>\$ (3,892)</b>

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

**Table of Contents****ORPHAN MEDICAL, INC.****STATEMENT OF CASH FLOWS****(In thousands)**

	<b>Period from January 1, 2005 to June 24, 2005</b>
<b>Operating activities</b>	
Net loss	\$ (3,401)
Adjustments to reconcile net loss to net cash used in operating activities:	
Depreciation	196
Stock compensation expense for non-employee	25
Loss on disposal of property and equipment	37
Changes in assets and liabilities:	
Restricted cash	(1)
Prepaid expenses and other current assets	(2,074)
Accounts receivable	(1,045)
Inventories	115
Accounts payable	(1,241)
Accrued liabilities	(510)
Deferred revenue	(806)
Net cash used in operating activities	(8,705)
<b>Investing activities</b>	
Purchases of property and equipment	(5)
Net cash used in investing activities	(5)
<b>Financing activities</b>	
Proceeds from employee stock purchase plan	16
Proceeds from exercise of stock options	164
Payments on capital lease obligations	(9)
Payments on premium finance note	(683)
Preferred stock dividend payments	(388)
Net cash used in financing activities	(900)
Net decrease in cash and cash equivalents	(9,610)
Cash and cash equivalents, at beginning of period	12,709
Cash and cash equivalents, at end of period	\$ 3,099
Schedule of non-cash financing activities:	
Issuance of preferred stock dividends	\$ 491
Supplemental disclosure of cash flow information:	
Cash paid for interest	\$ 4

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

F-37

**Table of Contents**

**ORPHAN MEDICAL, INC.**

**NOTES TO FINANCIAL STATEMENTS**

**1. Description of Business**

Orphan Medical, Inc. (the Company) acquires, develops, and markets products of high medical value intended to treat sleep disorders, pain and other central nervous system disorders that are addressed by physician specialists. On June 24, 2005, Jazz Pharmaceuticals, Inc. acquired the Company for cash consideration (net of cash acquired) of \$145.4 million plus direct acquisition costs of \$750,000. At the time of acquisition, the Company had three pharmaceutical products approved for marketing by the U.S. Food and Drug Administration (FDA).

**2. Summary of Significant Accounting Policies**

*Basis of Presentation*

The Statement of Operations and Statement of Cash Flows have been prepared in accordance with U.S. generally accepted accounting principles. These statements were prepared for the purpose of complying with Regulation S-X, Rule 3.05 of the Securities and Exchange Commission and are being included in the Form S-1 of Jazz Pharmaceuticals, Inc.

*Use of Estimates*

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

*Revenue Recognition*

Revenues are recognized when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed and determinable and collection is reasonably assured. In evaluating arrangements with multiple elements the Company considers whether components of the arrangement represent separate units of accounting based upon whether certain criteria are met, including whether the delivered element has stand-alone value to the customer and whether there is objective and reliable evidence of the fair value of the undelivered items. This evaluation requires subjective determinations and requires management to make judgments about the fair value of individual elements and whether such elements are separable from other aspects of the contractual relationship. The consideration received in such arrangements is allocated among the separate units of accounting based on their respective fair values when there is reliable evidence of fair value for all elements of the

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

arrangement. If there is no evidence of fair value for all the elements of the arrangement consideration is allocated based on the residual value method for the delivered elements. Under the residual method, the amount of revenues allocated to the delivered elements equals the total arrangement consideration less the aggregate fair value of any undelivered elements. The applicable revenue recognition criteria are applied to each of the separate units. Payments received in advance of work performed are recorded as deferred revenues and recognized when earned.

### *Product Sales, Net*

Revenues from sales of Xyrem within the United States are recognized upon transfer of title, which occurs when the Company's specialty pharmaceutical distributor removes product from the Company's consigned inventory location at its facility for shipment to a patient. Antizol is and, prior to our sale of the Company's

F-38



**Table of Contents**

**ORPHAN MEDICAL, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

rights, and Cystadane was shipped to the Company's wholesaler customers in the United States with free on board destination shipping terms, and the Company recognizes revenues when delivery occurs. The Company's international sales often have customer acceptance clauses and therefore the Company recognizes revenues when it is notified of acceptance or the time to inspect and reject the shipment has lapsed. When sales to international customers do not have acceptance clauses, the Company recognizes revenues when title transfers, which is generally when the product leaves the Company's logistics provider's facilities.

Revenues from sales of products within the United States are recorded net of estimated allowances for prompt payment discounts, wholesaler and speciality distributor fees, government chargebacks and rebates. Significant judgment is inherent in the selection of assumptions and in the interpretation of historical experience, as well as the identification of external and internal factors affecting the estimates. Because Xyrem is sold to one distributor in the United States, allowances and adjustments to estimates for allowances have not historically been material.

*Royalties, Net*

The Company receives royalties from third parties based on sales of its products under out-licensing and distributor arrangements. For those arrangements where royalties are reasonably estimable, the Company recognizes revenues based on estimates of royalties earned during the applicable period, and adjusts for differences between the estimated and actual royalties in the following quarter. Historically, these adjustments have not been material. For those arrangements where royalties are not reasonably estimable, the Company recognizes revenues upon receipt of royalty statements from the licensee or distributor.

*Contract Revenues*

Nonrefundable fees where the Company has no continuing performance obligations are recognized as revenues when collection is reasonably assured. In situations where the Company has continuing performance obligations, nonrefundable fees are deferred and recognized ratably over the performance period. The Company recognizes at-risk milestone payments, which are typically related to regulatory, commercial or other achievements by the Company or its licensees and distributors, as revenues when the milestone is accomplished and collection is reasonably assured. Refundable fees are deferred and recognized as revenues upon the later of when they become nonrefundable or when performance obligations are completed.

*Cost of Product Sales*

Cost of product sales includes third party manufacturing and distribution costs, the cost of drug substance, royalties due to third parties on product sales, product liability insurance, FDA user fees, freight, shipping, handling and storage costs. The Company's product exchange policy for Antizol and Cystadane allows customers to return expired product for exchange up to six months before or after the product's expiration date.

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

These expiration date returns are exchanged for replacement product, and the estimated cost of such exchanges is included in cost of product sales. Amounts accrued for replacement product have not been material.

### ***Research and Development***

The Company's research and development expenses consist of expenses incurred in identifying, developing and testing its product candidates. These expenses consist primarily of fees paid to contract research organizations and other third parties to assist us in managing, monitoring and analyzing our clinical trials, clinical trial costs paid to sites and investigators' salaries, costs of non-clinical studies, including toxicity studies in animals, costs of contract manufacturing services, costs of materials used in clinical trials and non-clinical studies, fees paid to third parties for development candidates, allocated expenses, such as facilities and

F-39

**Table of Contents****ORPHAN MEDICAL, INC.****NOTES TO FINANCIAL STATEMENTS (Continued)**

information technology that support the Company's research and development activities and related personnel expenses. For products that have not been approved by the FDA, inventory used in clinical trials is expensed at the time of production and recorded as research and development expense. Research and development costs are expensed as incurred, including payments made under the Company's license agreements. For products that have been approved by the FDA, inventory used in clinical trials is expensed at the time the inventory is packaged for the trial and therefore not included in inventory.

***Income Taxes***

The Company utilizes the liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and the tax basis of assets and liabilities and are measured using enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized. The Company has a history of losses and therefore has made no provision for income taxes.

***Stock-Based Compensation***

The Company accounts for stock-based employee compensation arrangements using the intrinsic value method of Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees*, ( APB 25 ) and complies with the disclosure-only provisions of Statement of Financial Accounting Standards No. 123, *Accounting for Stock-Based Compensation*, ( SFAS 123 ) as amended by Statement of Financial Accounting Standards No. 148, *Accounting for Stock-Based Compensation, Transition and Disclosure, an amendment to SFAS Statement No. 123* ( SFAS 148 ). Under APB 25 compensation expense for employees is based on the excess, if any, of the fair value of the Company's common stock over the exercise price of the option on the date of grant. No stock-based compensation expense was recorded under APB 25 during the period January 1, 2005 to June 24, 2005. The following table illustrates the effect on net loss and loss per common share if the Company had applied the fair value recognition provisions of SFAS 123 as amended by SFAS 148 to stock-based employee compensation.

	<b>Period from January 1, 2005 to June 24, 2005</b>
Loss attributable to common stockholders, as reported	\$ (3,892)
Add: Employee stock-based compensation using the intrinsic value method	
Deduct: Total employee stock compensation calculated using the fair-value method	(1,240)
Pro forma loss attributable to common stockholders	\$ (5,132)
Loss per share attributable to common stockholders, basic and diluted	
As reported	\$ (.35)
Pro forma	\$ (.46)



**Table of Contents****ORPHAN MEDICAL, INC.****NOTES TO FINANCIAL STATEMENTS (Continued)**

The Company estimated the fair value of the stock options using the Black-Scholes method in accordance with SFAS No. 123 as amended by SFAS 148. The fair value of the stock options was estimated at the grant date with the following assumptions:

	<b>Period from January 1, 2005 to June 24, 2005</b>
Expected dividend yield	0%
Expected stock price volatility	65%
Risk-free interest rate	4%
Expected life of option (in years)	8

The weighted average grant date fair value per share of employee stock options granted during the period January 1, 2005 to June 24, 2005 was \$6.16.

**3. Product License**

In October 2003, the Company entered into an agreement with Celltech Pharmaceuticals, Inc., which was subsequently acquired by UCB Pharma Limited ( UCB ), pursuant to which the Company has licensed to UCB all European sales and marketing rights for Xyrem for the treatment of narcolepsy. The Company received \$2.5 million upon execution of the agreement which is being amortized on a straight-line basis as contract revenues through September 2005, the expected regulatory approval period. The Company recognized \$806,000 of contract revenues in the period from January 1, 2005 to June 24, 2005 related to the upfront payment. UCB also made two \$1.0 million milestone payments related to the filing of an application for marketing approval for

**Table of Contents****ORPHAN MEDICAL, INC.****NOTES TO FINANCIAL STATEMENTS (Continued)**

Xyrem for the treatment of cataplexy in patients with narcolepsy with the European Agency for the Evaluation of Medicinal Products and to the Company's delivery to UCB of a supplemental new drug application package for Xyrem for the treatment the excessive daytime sleepiness in patients with narcolepsy. These payments were recognized as revenues upon the achievement of the milestones in March 2004 and January 2005, respectively.

**4. Segment and Other Information**

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

The following table presents a summary of product sales (in thousands):

	<b>Period from January 1, 2005 to June 24, 2005</b>
Xyrem	\$ 8,034
Antizol	4,267
Cystadane	665
Total	\$ 12,966

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

	<b>Period from January 1, 2005 to June 24, 2005</b>
United States	\$ 12,464
Europe	2,107
All other	272
Total	\$ 14,843

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

	<b>Period from January 1, 2005 to June 24, 2005</b>
ExpressScripts	54%
UCB	12%
Cardinal Health	11%
Amerisource Bergen	10%

**5. Subsequent Events**

*Legal Proceedings*

In April 2006, a physician who was a speaker for the Company was indicted by a federal grand jury in the U.S. District Court for the Eastern District of New York. The indictment alleges that the physician engaged in a scheme with the Company's sales representatives and other Company employees to promote and obtain reimbursement for Xyrem for medical uses not approved for marketing by the FDA. Also in April 2006, the

**Table of Contents**

**ORPHAN MEDICAL, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

Department of Justice, acting through the U.S. Attorney for the Eastern District of New York, issued to the Company and Jazz Pharmaceuticals subpoenas for documents relating to Xyrem. The Company is cooperating with this investigation and has provided documents to the U.S. Attorney's Office. There have been discussions with the U.S. Attorney's Office regarding the possible settlement of any potential government claims. It is currently unknown if any such settlement will be reached on reasonable terms, or at all. The Company cannot predict or determine the outcome of this matter or reasonably estimate the amount of any fines or penalties that might result from an adverse outcome. Therefore, in accordance with Statement of Financial Accounting Standard No. 5, *Accounting for Contingencies* ( SFAS 5 ), the Company has not recorded an associated liability. The Company will recognize a liability, if any, when it has an adequate basis to estimate any probable exposure, if any.

On April 10, 2006, Little Gem Life Sciences LLC, individually and purportedly on behalf of a class of persons similarly situated, filed a complaint against the Company and former officers of the Company in the U.S. District Court for the District of Minnesota. The complaint alleges that the defendants made false and misleading statements in the proxy statement prepared by the Company in connection with the solicitation of proxies to be voted at the special meeting of Company stockholders held on June 22, 2005 for the purpose of considering and voting upon a proposal to adopt the definitive merger agreement pursuant to which the Company was acquired by Jazz Pharmaceuticals. The plaintiff seeks damages for itself and the putative class, in an unspecified amount, together with interest, litigation costs and expenses, and its attorneys' fees and other disbursements, as well as unspecified other and further relief. On October 25, 2006, the defendants filed a motion to dismiss the complaint and oral argument on the motion was heard by the U.S. District Court for the District of Minnesota. On February 16, 2007, the U.S. District Court for the District of Minnesota granted the defendants' motion to dismiss the complaint, but granted the plaintiff a one-month leave to amend the plaintiff's complaint. The Company cannot predict or determine the outcome of this matter or reasonably estimate the amount of any judgments or payments that might result from an adverse outcome. Therefore, in accordance with SFAS 5 the Company has not recorded an associated liability. The Company will recognize a liability, if any, when it has an adequate basis to estimate any probable exposure, if any.



**Table of Contents**

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

The following table sets forth all costs and expenses, other than underwriting discounts and commissions, payable by us in connection with the sale of the common stock being registered. All amounts shown are estimates except for the SEC registration fee, the NASD filing fee and the NASDAQ Global Market filing fee.

	<b>Amount to be</b>
	<b>Paid</b>
SEC registration fee	\$ 5,296
NASD filing fee	17,750
NASDAQ Global Market initial listing fee	150,000
Blue sky qualification fees and expenses	15,000
Printing and engraving expenses	*
Legal fees and expenses	*
Accounting fees and expenses	*
Transfer agent and registrar fees and expenses	20,000
Miscellaneous expenses	*
 Total	 \$ *

\* To be filed by amendment.

**Item 14. Indemnification of Directors and Officers.**

We are incorporated under the laws of the State of Delaware. Section 145 of the Delaware General Corporation Law provides that a Delaware corporation may indemnify any persons who are, or are threatened to be made, parties to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of such corporation), by reason of the fact that such person was an officer, director, employee or agent of such corporation, or is or was serving at the request of such person as an officer, director, employee or agent of another corporation or enterprise. The indemnity may include expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding, provided that such person acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the corporation's best interests and, with respect to any criminal action or proceeding, had no reasonable cause to believe that his or her conduct was illegal. A Delaware corporation may indemnify any persons who are, or are threatened to be made, a party to any threatened, pending or completed action or suit by or in the right of the corporation by reason of the fact that such person was a director, officer, employee or agent of such corporation, or is or was serving at the request of such corporation as a director, officer, employee or agent of another corporation or enterprise. The indemnity may include expenses (including attorneys' fees) actually and reasonably incurred by such person in connection with the defense or settlement of such action or suit provided such person acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the corporation's best interests except that no indemnification is permitted without judicial approval if the officer or director is adjudged to be liable to the corporation. Where an officer or director is successful on the merits or otherwise in the defense of any action referred

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

to above, the corporation must indemnify him or her against the expenses that such officer or director has actually and reasonably incurred. Our third amended and restated certificate of incorporation and our amended and restated bylaws, each of which will become effective upon the closing of this offering, provide for the indemnification of our directors and officers to the fullest extent permitted under the Delaware General Corporation Law.

II-1

## Table of Contents

Section 102(b)(7) of the Delaware General Corporation Law permits a corporation to provide in its certificate of incorporation that a director of the corporation shall not be personally liable to the corporation or its stockholders for monetary damages for breach of fiduciary duties as a director, except for liability for any:

transaction from which the director derives an improper personal benefit;

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

unlawful payment of dividends or redemption of shares; or

breach of a director's duty of loyalty to the corporation or its stockholders.

Our third amended and restated certificate of incorporation and amended and restated bylaws include such a provision. Expenses incurred by any officer or director in defending any such action, suit or proceeding in advance of its final disposition shall be paid by us upon delivery to us of an undertaking, by or on behalf of such director or officer, to repay all amounts so advanced if it shall ultimately be determined that such director or officer is not entitled to be indemnified by us.

Section 174 of the Delaware General Corporation Law provides, among other things, that a director who willfully or negligently approves of an unlawful payment of dividends or an unlawful stock purchase or redemption may be held liable for such actions. A director who was either absent when the unlawful actions were approved, or dissented at the time, may avoid liability by causing his or her dissent to such actions to be entered in the books containing minutes of the meetings of the board of directors at the time such action occurred or immediately after such absent director receives notice of the unlawful acts.

As permitted by the Delaware General Corporation Law, we have entered into indemnity agreements with each of our directors and officers 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 Jazz Pharmaceuticals 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 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.

At present, there is no pending litigation or proceeding involving any of our directors or officers as to which indemnification is required or permitted, and we are not aware of any threatened litigation or proceeding that may result in a claim for indemnification.

We have an insurance policy covering our officers and directors with respect to certain liabilities, including liabilities arising under the Securities Act or otherwise. Messrs. Clammer, Michelson and Momtazee are further insured by liability insurance that has been purchased by Kohlberg Kravis Roberts & Co. L.P. on their behalf for any excess liabilities that are not covered by our liability insurance. Mr. Colella is insured by liability insurance purchased on his behalf by, and indemnified pursuant to the governing agreements of, Versant Ventures for his service on our board of directors.

We plan to enter into an underwriting agreement that provides that the underwriters are obligated, under some circumstances, to indemnify our directors, officers and controlling persons against specified liabilities, including liabilities under the Securities Act.

II-2

**Table of Contents**

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

The following list sets forth information regarding all unregistered securities sold by us since our inception through January 31, 2007.

- (1) Since our inception through January 31, 2007, we have granted options under our 2003 Stock Equity Incentive Plan, to purchase 18,810,045 shares of common stock to employees and directors, having exercise prices ranging from \$.10 to \$4.09 per share. Of these, options to purchase 463,924 shares of common stock have been exercised for aggregate consideration of \$52,536.02, at exercise prices ranging from \$.10 to \$1.36 per share. As of January 31, 2007, we have cancelled options to purchase 773,347 shares of common stock.
- (2) On March 20, 2003, we issued and sold an aggregate of 3,960,000 shares of common stock to two of our executive officers for aggregate consideration of \$9,108.
- (3) On March 31, 2003, we issued and sold 815,000 shares of common stock to one of our executive officers for aggregate consideration of \$1,874.50.
- (4) On April 18, 2003, we issued and sold 300,000 shares of common stock to one of our executive officers for aggregate consideration of \$1,500.
- (5) On April 23, 2003, we issued and sold 330,000 shares of common stock to one of our executive officers for aggregate consideration of \$3,300.
- (6) On April 30, 2003, we issued and sold an aggregate of 2,150,000 shares of Series A preferred stock to a total of six accredited investors for aggregate consideration of \$2,150,000.
- (7) On August 29, 2003, we issued and sold an aggregate of 5,000,000 shares of Series A preferred stock to a total of five accredited investors for aggregate consideration of \$5,000,000.
- (8) On October 30, 2003, we issued and sold 660,000 shares of common stock to one of our executive officers for aggregate consideration of \$66,000.
- (9) On January 9, 2004, we issued and sold an aggregate of 232,500 shares of common stock to one of our executive officers for aggregate consideration of \$23,250.
- (10) On January 14, 2004, we issued and sold an aggregate of 7,850,000 shares of Series A preferred stock to a total of five accredited investors for aggregate consideration of \$7,850,000.
- (11) On February 18, 2004, we issued and sold an aggregate of 17,307,128 shares of Series B preferred stock to a total of thirty-one accredited investors for aggregate consideration of \$23,599,999.74.
- (12)

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

On February 18, 2004, we issued and sold an aggregate of 19,067,175 shares of Series B Prime preferred stock to a total of two institutional and accredited investors for aggregate consideration of \$25,999,999.83.

- (13) On April 6, 2004, we issued and sold an aggregate of 293,341 shares of Series B preferred stock to a total of two accredited investors for aggregate consideration of \$399,999.79.
- (14) On September 24, 2004, we issued and sold an aggregate of 146,671 shares of common stock to one of our directors for aggregate consideration of \$200,000.58.
- (15) On June 20, 2005, we issued and sold an aggregate of 35,200,937 shares of Series B preferred stock to a total of thirty-four accredited investors for aggregate consideration of \$47,999,997.69.
- (16) On June 20, 2005, we issued and sold an aggregate of 38,134,351 shares of Series B Prime preferred stock to a total of two accredited investors for aggregate consideration of \$52,000,001.02.
- (17) On June 24, 2005, in connection with the issuance of our senior secured notes in the aggregate principal amount of \$80,000,000, we issued and sold warrants to purchase an aggregate of 8,695,652 shares of Series BB preferred stock to a total of eight accredited investors. Pursuant to the terms of

**Table of Contents**

the agreement governing the issuance of the senior secured notes and warrants, the aggregate consideration allocated to the warrants was \$5,360,000.00.

- (18) On January 26, 2006, we issued and sold an aggregate of 12,320,326 shares of Series B preferred stock to a total of thirty-two accredited investors for aggregate consideration of \$16,799,996.53.
- (19) On January 26, 2006, we issued and sold an aggregate of 13,347,023 shares of Series B Prime preferred stock to a total of two accredited investors for aggregate consideration of \$18,200,000.56.
- (20) On December 14, 2006, we issued and sold an aggregate of 22,880,598 shares of Series B preferred stock to a total of thirty-two institutional and accredited investors for aggregate consideration of \$31,199,983.44.
- (21) On December 14, 2006, we issued and sold an aggregate of 24,787,326 shares of Series B Prime preferred stock to a total of two institutional and accredited investors for aggregate consideration of \$33,799,997.74.

The offers, sales and issuances of the securities described in Item 15(1) were exempt from registration under the Securities Act under Rule 701 in that the transactions were under compensatory benefit plans and contracts relating to compensation as provided under Rule 701. The recipients of such securities were our employees or directors and received the securities under our 2003 Equity Incentive Plan. 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(2) through 15(21) 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.

**Item 16. Exhibits and Financial Statement Schedules.**

*(a) Exhibits.*

**Exhibit**

<b>Number</b>	<b>Description of Document</b>
1.1	Form of Underwriting Agreement.
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.
3.1	Second Amended and Restated Certificate of Incorporation of the Registrant, currently in effect.
3.2	Form of Third Amended and Restated Certificate of Incorporation of the Registrant to be effective upon the closing of this offering.
3.3	Amended and Restated Bylaws of the Registrant, currently in effect.



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

- 3.4 Form of Amended and Restated Bylaws of the Registrant to be effective upon the closing of this offering.
- 4.1 Reference is made to exhibits 3.1 through 3.4.
- 4.2 Specimen Common Stock Certificate.
- 4.3+ Second Amended and Restated Investor Rights Agreement, dated as of June 24, 2005, by and between the Registrant and the other parties named therein.
- 4.4 Senior Secured Note and Warrant Purchase Agreement, dated as of June 24, 2005, by and among the Registrant, Twist Merger Sub, Inc. and the Purchasers.

II-4

**Table of Contents**

**Exhibit**

<b>Number</b>	<b>Description of Document</b>
4.5	Form of Senior Secured Note of the Registrant.
4.6	Form of Series BB Preferred Stock Warrant of the Registrant.
5.1	Opinion of Cooley Godward Kronish LLP.
9.1	Second Amended and Restated Voting Agreement, dated as of June 24, 2005, by and among the Registrant and the other parties named therein.
10.1+	Form of Indemnification Agreement between the Registrant and its officers and directors.
10.2+	Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Bruce Cozadd.
10.3+	Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Samuel Saks.
10.4+	Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Robert Myers.
10.5+	Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Matthew Fust.
10.6+	Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Carol Gamble.
10.7+	Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Janne Wissel.
10.8+	Stock Purchase Agreement, dated as of September 24, 2004, by and between the Registrant and Alan Sebulsky.
10.9+	Common Stock Purchase Agreement, dated as of March 20, 2003, by and between the Registrant and Bruce Cozadd.
10.10+	Stock Restriction Agreement, dated as of April 30, 2003, by and between the Registrant and Bruce Cozadd.
10.11+	Amendment to Stock Restriction Agreement, dated as of October 30, 2003, by and between the Registrant and Bruce Cozadd.
10.12+	Common Stock Purchase Agreement, dated as of October 30, 2003, by and between the Registrant and Bruce Cozadd.
10.13+	Common Stock Purchase Agreement, dated as of March 20, 2003, by and between the Registrant and Samuel Saks.
10.14+	Stock Restriction Agreement, dated as of April 30, 2003, by and between the Registrant and Samuel Saks.
10.15+	Amendment to Stock Restriction Agreement, dated as of October 30, 2003, by and between the Registrant and Samuel Saks.
10.16+	Amended and Restated Stock Purchase Agreement, dated as of April 30, 2003, by and between the Registrant and Robert Myers.
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 Myers.
10.18+	Common Stock Purchase Agreement, dated as of January 9, 2004, by and between the Registrant and Robert Myers.
10.19+	Amended and Restated Stock Purchase Agreement, dated as of April 30, 2003, by and between the Registrant and Matthew Fust.
10.20+	Amended and Restated Stock Purchase Agreement, dated as of April 30, 2003, by and between the Registrant and Carol Gamble.

**Table of Contents**

<b>Exhibit</b>	
<b>Number</b>	<b>Description of Document</b>
10.21+	2003 Equity Incentive Plan, as amended.
10.22+	Form of Stock Option Agreement and Form of Option Grant Notice under the 2003 Equity Incentive Plan.
10.23+	2007 Equity Incentive Plan.
10.24+	Form of Option Agreement and Form of Option Grant Notice under the 2007 Equity Incentive Plan.
10.25+	2007 Non-Employee Directors Stock Option Plan.
10.26+	Form of Stock Option Agreement and Form of Option Grant Notice under the 2007 Non-Employee Directors Stock Option Plan.
10.27+	2007 Employee Stock Purchase Plan.
10.28+	Form of 2007 Employee Stock Purchase Plan Offering Document.
10.29+	Jazz Pharmaceuticals, Inc. Cash Bonus Plan.
10.30	Asset Purchase Agreement, dated as of October 4, 2004, by and among the Registrant, Glaxo Group Limited and SmithKline Beecham Corporation dba GlaxoSmithKline.
10.31	Sodium Gamma Hydroxybutyrate Development and Supply Agreement, dated as of November 6, 1996, as amended, by and between Orphan Medical, Inc. and Lonza, Inc.
10.32	Services Agreement dated as of July 29, 2002, as amended, between Orphan Medical, Inc. and Express Scripts Specialty Distribution Services, Inc.
10.33	Xyrem Supply Agreement dated as of June 30, 2000, as amended, by and between Orphan Medical, Inc. and DSM Pharmaceuticals, Inc.
10.34	Amended and Restated Xyrem License and Distribution Agreement, dated as of June 30, 2006, by and between the Registrant and UCB Pharma Limited.
10.35	License Agreement, dated as of January 31, 2007, by and between the Registrant and Solvay Pharmaceuticals, Inc.
10.36	Supply Agreement, dated as of January 31, 2007, by and between the Registrant and Solvay Pharmaceuticals, Inc.
10.37	Trademark License Agreement, dated as of January 31, 2007, by and between the Registrant and Solvay Pharmaceuticals, Inc.
10.38	Assignment, Assumption and Consent, dated as of January 31, 2007, by and among the Registrant, Solvay Pharmaceuticals, Inc and Elan Pharma International Limited.
10.39	License Agreement, dated as of December 22, 1997, as amended, by and among Solvay Pharmaceuticals, Inc and Elan Pharma International Limited.
10.40	Commercial Lease, dated as of June 2, 2004, by and between the Registrant and The Board of Trustees of the Leland Stanford Junior University.
10.41	Sublease Agreement, dated as of February 25, 2007, by and between Xerox Corporation and the Registrant.
21.1	Subsidiaries of the Registrant.
23.1	Consent of Independent Registered Public Accounting Firm.
23.2	Consent of Independent Auditors.
23.3	Consent of Cooley Godward Kronish LLP (included in Exhibit 5.1).
24.1	Power of Attorney (see page II-10 to this Registration Statement on Form S-1).

\* Previously filed.

To be filed by amendment.

+ Indicates management contract or compensatory plan.

**Table of Contents**

(b) *Financial Statement Schedules.* The following financial statement schedule is included herewith:

**Schedule II****Valuation and Qualifying Accounts**

(In thousands)

	Balance at beginning of period	Additions(3)	Additions charged to costs and expenses(4)	Deductions	Balance at end of period
For the year ended December 31, 2006					
Allowance for doubtful accounts(1)	\$ 25	\$	\$ 28	\$ (3)	\$ 50
Allowance for sales discounts(1)	71		880	(857)	94
Allowance for chargebacks(1)	26		212	(233)	5
Allowance for customer rebates(1)			44	(26)	18
Allowance for wholesaler fees(1)	153		203	(325)	31
Allowance for government rebates(2)	88		229	(254)	63
For the year ended December 31, 2005					
Allowance for doubtful accounts(1)	\$	\$ 25	\$ 14	\$ (14)	\$ 25
Allowance for sales discounts(1)		62	381	(372)	71
Allowance for chargebacks(1)		25	57	(56)	26
Allowance for customer rebates(1)					
Allowance for wholesaler fees(2)		134	64	(45)	153
Allowance for government rebates(2)		115	135	(162)	88
For the year ended December 31, 2004					
Allowance for doubtful accounts	\$	\$	\$	\$	\$
Allowance for sales discounts					
Allowance for chargebacks					
Allowance for customer rebates					
Allowance for wholesaler fees					
Allowance for government rebates					

**Notes**

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

All other schedules are omitted because they are inapplicable or the requested information is shown in the consolidated financial statements of the registrant or related notes thereto.

**Item 17. Undertakings.**

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

The undersigned Registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreement, certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act 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 Securities 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

**Table of Contents**

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 Securities Act and will be governed by the final adjudication of such issue.

The undersigned Registrant hereby undertakes that:

- (1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this Registration Statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this Registration Statement as of the time it was declared effective.
- (2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus 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.

Table of Contents

**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, the Registrant has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Palo Alto, State of California, on the 8<sup>th</sup> day of March, 2007.

JAZZ PHARMACEUTICALS, INC.

By:           /s/   SAMUEL R. SAKS, M.D.  
                  **Samuel R. Saks, M.D.**  
                  *Chief Executive Officer*

II-9

**Table of Contents**

KNOW ALL BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Samuel R. Saks, M.D., Matthew K. Fust and Carol A. Gamble, and each of them, as his or her true and lawful attorneys-in-fact and agents, each with the full power of substitution, for him or her and in his or her name, place or stead, in any and all capacities, to sign any and all amendments to this Registration Statement (including post-effective amendments), and to sign any registration statement for the same offering covered by this Registration Statement that is to be effective upon filing pursuant to Rule 462(b) promulgated under the Securities Act, and all post-effective amendments thereto, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or their, his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

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

Signature	Title	Date
/s/ SAMUEL R. SAKS, M.D.  <b>Samuel R. Saks, M.D.</b>	Chief Executive Officer and Member of the Board of Directors ( <i>Principal Executive Officer</i> )	March 8, 2007
/s/ MATTHEW K. FUST  <b>Matthew K. Fust</b>	Senior Vice President and Chief Financial Officer ( <i>Principal Accounting and Financial Officer</i> )	March 8, 2007
/s/ ADAM H. CLAMMER  <b>Adam H. Clammer</b>	Director	March 8, 2007
/s/ SAMUEL D. COLELLA  <b>Samuel D. Colella</b>	Director	March 8, 2007
/s/ BRUCE C. COZADD  <b>Bruce C. Cozadd</b>	Director	March 8, 2007
/s/ BRYAN C. CRESSEY  <b>Bryan C. Cressey</b>	Director	March 8, 2007
/s/ MICHAEL W. MICHELSON  <b>Michael W. Michelson</b>	Director	March 8, 2007
/s/ JAMES C. MONTAZEE  <b>James C. Montazee</b>	Director	March 8, 2007
/s/ KENNETH W. O'KEEFE  <b>Kenneth W. O'Keefe</b>	Director	March 8, 2007



Edgar Filing: JAZZ PHARMACEUTICALS INC - Form S-1

/s/ ALAN M. SEBULSKY

Director

March 8, 2007

**Alan M. Sebulsky**

/s/ JAMES B. TANANBAUM, M.D.

Director

March 8, 2007

**James B. Tananbaum, M.D.**

II-10

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

<b>Number</b>	<b>Description of Document</b>
1.1	Form of Underwriting Agreement.
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.
3.1	Second Amended and Restated Certificate of Incorporation of the Registrant, currently in effect.
3.2	Form of Third Amended and Restated Certificate of Incorporation of the Registrant to be effective upon the closing of this offering.
3.3	Amended and Restated Bylaws of the Registrant, currently in effect.
3.4	Form of Amended and Restated Bylaws of the Registrant to be effective upon the closing of this offering.
4.1	Reference is made to exhibits 3.1 through 3.4.
4.2	Specimen Common Stock Certificate.
4.3+	Second Amended and Restated Investor Rights Agreement, dated as of June 24, 2005, by and between the Registrant and the other parties named therein.
4.4	Senior Secured Note and Warrant Purchase Agreement, dated as of June 24, 2005, by and among the Registrant, Twist Merger Sub, Inc. and the Purchasers.
4.5	Form of Senior Secured Note of the Registrant.
4.6	Form of Series BB Preferred Stock Warrant of the Registrant.
5.1	Opinion of Cooley Godward Kronish LLP.
9.1	Second Amended and Restated Voting Agreement, dated as of June 24, 2005, by and among the Registrant and the other parties named therein.
10.1+	Form of Indemnification Agreement between the Registrant and its officers and directors.
10.2+	Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Bruce Cozadd.
10.3+	Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Samuel Saks.
10.4+	Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Robert Myers.
10.5+	Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Matthew Fust.
10.6+	Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Carol Gamble.
10.7+	Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Janne Wissel.
10.8+	Stock Purchase Agreement, dated as of September 24, 2004, by and between the Registrant and Alan Sebulsky.
10.9+	Common Stock Purchase Agreement, dated as of March 20, 2003, by and between the Registrant and Bruce Cozadd.
10.10+	Stock Restriction Agreement, dated as of April 30, 2003, by and between the Registrant and Bruce Cozadd.
10.11+	Amendment to Stock Restriction Agreement, dated as of October 30, 2003, by and between the Registrant and Bruce Cozadd.

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

<b>Number</b>	<b>Description of Document</b>
10.12+	Common Stock Purchase Agreement, dated as of October 30, 2003, by and between the Registrant and Bruce Cozadd.
10.13+	Common Stock Purchase Agreement, dated as of March 20, 2003, by and between the Registrant and Samuel Saks.
10.14+	Stock Restriction Agreement, dated as of April 30, 2003, by and between the Registrant and Samuel Saks.
10.15+	Amendment to Stock Restriction Agreement, dated as of October 30, 2003, by and between the Registrant and Samuel Saks.
10.16+	Amended and Restated Stock Purchase Agreement, dated as of April 30, 2003, by and between the Registrant and Robert Myers.
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 Myers.
10.18+	Common Stock Purchase Agreement, dated as of January 9, 2004, by and between the Registrant and Robert Myers.
10.19+	Amended and Restated Stock Purchase Agreement, dated as of April 30, 2003, by and between the Registrant and Matthew Fust.
10.20+	Amended and Restated Stock Purchase Agreement, dated as of April 30, 2003, by and between the Registrant and Carol Gamble.
10.21+	2003 Equity Incentive Plan, as amended.
10.22+	Form of Stock Option Agreement and Form of Option Grant Notice under the 2003 Equity Incentive Plan.
10.23+	2007 Equity Incentive Plan.
10.24+	Form of Option Agreement and Form of Option Grant Notice under the 2007 Equity Incentive Plan.
10.25+	2007 Non-Employee Directors Stock Option Plan.
10.26+	Form of Stock Option Agreement and Form of Option Grant Notice under the 2007 Non-Employee Directors Stock Option Plan.
10.27+	2007 Employee Stock Purchase Plan.
10.28+	Form of 2007 Employee Stock Purchase Plan Offering Document.
10.29+	Jazz Pharmaceuticals, Inc. Cash Bonus Plan.
10.30	Asset Purchase Agreement, dated as of October 4, 2004, by and among the Registrant, Glaxo Group Limited and SmithKline Beecham Corporation dba GlaxoSmithKline.
10.31	Sodium Gamma Hydroxybutyrate Development and Supply Agreement, dated as of November 6, 1996, as amended, by and between Orphan Medical, Inc. and Lonza, Inc.
10.32	Services Agreement dated as of July 29, 2002, as amended, between Orphan Medical, Inc. and Express Scripts Specialty Distribution Services, Inc.
10.33	Xyrem Supply Agreement dated as of June 30, 2000, as amended, by and between Orphan Medical, Inc. and DSM Pharmaceuticals, Inc.
10.34	Amended and Restated Xyrem License and Distribution Agreement, dated as of June 30, 2006, by and between the Registrant and UCB Pharma Limited.
10.35	License Agreement, dated as of January 31, 2007, by and between the Registrant and Solvay Pharmaceuticals, Inc.
10.36	Supply Agreement, dated as of January 31, 2007, by and between the Registrant and Solvay Pharmaceuticals, Inc.

---

**Table of Contents**

**Exhibit**

<b>Number</b>	<b>Description of Document</b>
10.37	Trademark License Agreement, dated as of January 31, 2007, by and between the Registrant and Solvay Pharmaceuticals, Inc.
10.38	Assignment, Assumption and Consent, dated as of January 31, 2007, by and among the Registrant, Solvay Pharmaceuticals, Inc and Elan Pharma International Limited.
10.39	License Agreement, dated as of December 22, 1997, as amended, by and among Solvay Pharmaceuticals, Inc and Elan Pharma International Limited.
10.40	Commercial Lease, dated as of June 2, 2004, by and between the Registrant and The Board of Trustees of the Leland Stanford Junior University.
10.41	Sublease Agreement, dated as of February 25, 2007, by and between Xerox Corporation and the Registrant.
21.1	Subsidiaries of the Registrant.
23.1	Consent of Independent Registered Public Accounting Firm.
23.2	Consent of Independent Auditors.
23.3	Consent of Cooley Godward Kronish LLP (included in Exhibit 5.1).
24.1	Power of Attorney (see page II-10 to this Registration Statement on Form S-1).

---

\* Previously filed.

To be filed by amendment.

+ Indicates management contract or compensatory plan.