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As filed with the Securities and Exchange Commission on May 24, 2007

Registration No. 333 -141164

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

AMENDMENT NO. 4
TO
FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

JAZZ PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**2834**	**05-0563787**
(State or other jurisdiction of incorporation or organization)	**(Primary Standard Industrial Classification Code Number)**	**(I.R.S. Employer Identification Number)**

3180 Porter Drive
Palo Alto, CA 94304
(650) 496-3777
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Samuel R. Saks, M.D.
Chief Executive Officer
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. ☐

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. ☐

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.

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The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and 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 May 24, 2007

6,000,000 Shares

COMMON STOCK

Jazz Pharmaceuticals, Inc. is offering 6,000,000 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 $24.00 and $26.00 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 9.

PRICE $ A SHARE

	Price to Public	*Underwriting Discounts and Commissions*	*Proceeds to Jazz Pharmaceuticals*
Per Share	*$*	*$*	*$*
Total	*$*	*$*	*$*

We have granted the underwriters the right to purchase up to an additional 900,000 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

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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.

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 marketed products 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. 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. 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. Our net product sales of Xyrem were $29.0 million in 2006 and $8.6 million in the first quarter of 2007. 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 12 countries.
- *Antizol (fomepizole)*. Antizol is the only FDA-approved antidote for suspected or confirmed ethylene glycol or methanol poisonings in humans. We market Antizol primarily to hospitals and emergency rooms. Antizol is distributed to wholesalers in the United States, and we retain the services of a third party to promote the product. Antizol is marketed by our distributors in Canada and Israel. Our net product sales of Antizol were $12.5 million in 2006 and $2.6 million in the first quarter of 2007. We also market Antizol-Vet, an injectable formulation of fomepizole approved as an antidote for suspected

or confirmed ethylene glycol poisonings in dogs. Net product sales of Antizol-Vet were $313,000 in 2006 and $65,000 in the first quarter of 2007.

- *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, which has been developed for the treatment of obsessive compulsive disorder and social anxiety disorder. Selective serotonin reuptake inhibitors are a class of antidepressants used in the treatment of depression, anxiety disorders and some personality disorders. According to the National Institute of Mental Health, obsessive compulsive disorder and social anxiety disorder affect approximately 2.2 million and 15 million adults in the United States, respectively. Luvox CR was developed by Solvay Pharmaceuticals, Inc., or Solvay, in collaboration with Elan Pharma International Limited, or Elan. We obtained the exclusive rights to market and distribute Luvox CR in the United States from Solvay in January 2007. Solvay retains the rights to market and distribute Luvox CR outside of the United States. In addition, Solvay has assigned to us its rights and obligations under its license and supply agreement with Elan. Under this agreement, Elan has the right and obligation to manufacture the worldwide commercial requirements of Luvox CR. Under the terms of our license agreement with Solvay, we made an initial payment to Solvay, and we are required to make additional payments to Solvay if various development and commercial milestones are achieved. We have also agreed to pay royalties to Solvay at specified rates based on net product sales and to pay to Elan development and commercial milestone payments, royalties on net product sales and supply price payments for the supply of Luvox CR.

  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 to Solvay. 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 active pharmaceutical ingredient in Luvox CR, the submission of additional information relating to the chemistry, manufacturing and controls section of the NDA and the re-analysis by Solvay of certain data set forth in the NDA. Under our agreement with Solvay, Solvay has primary responsibility for the NDA for Luvox CR and communications with the FDA until after such time, if ever, as the FDA approves the NDA for Luvox CR. Subject to the satisfaction of the requirements set forth in the approvable letter and receipt of 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 in Xyrem, for the treatment of fibromyalgia syndrome. Fibromyalgia syndrome 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 fibromyalgia syndrome. We have successfully completed a Phase II clinical trial of this product candidate for the treatment of fibromyalgia syndrome. 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 have planned two proof of concept clinical trials designed to provide evidence of therapeutic activity of JZP-4. A proof of concept study is performed in a small group of subjects to test whether a product candidate is likely to have the desired therapeutic effect. The results from the first proof of concept clinical trial indicate potential central nervous system activity of JZP-4, and the second proof of concept clinical trial is expected to commence in the third quarter of 2007. Subject to satisfactory results from the second proof of concept clinical trial, long-term toxicology studies, formulation studies 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.

- *JZP-8 (benzodiazepine).* JZP-8, a novel formulation incorporating a benzodiazepine, is being developed for the treatment of recurrent acute repetitive seizures in epilepsy patients who have been unresponsive to previous treatments. Recurrent acute repetitive seizures are bouts of multiple seizures occurring over a short period of time. According to an article published in the *New England Journal of Medicine*, approximately 30% of epilepsy patients are unresponsive, or refractory, to treatment despite being on an effective dose of an antiepilepsy regimen, and a subset of these refractory patients experience recurrent acute repetitive seizures. We have completed development activities to select the active pharmaceutical ingredient 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 recurrent acute repetitive seizures in refractory epilepsy patients in the fourth 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. Dopamine is naturally produced by the human body, and in the brain, dopamine functions to help nerve cells communicate. A dopamine agonist is a drug compound that mimics the effects of dopamine. According to the Restless Legs Syndrome Foundation, up to 10% of the U.S. population suffers from restless legs syndrome. We have completed development activities to select the active pharmaceutical ingredient for this product candidate and are conducting further development activities related to formulation, safety and tolerance. We intend to conduct an additional pharmacokinetic study, or a study designed to assess how the body processes a drug once the drug is delivered to the body, in 2007 prior to commencing Phase II clinical trials for the treatment of restless legs syndrome.
- *JZP-2 (benzodiazepine).* JZP-2, a formulation of a benzodiazepine that is designed to enter the bloodstream faster than a dose from a conventional tablet form, is being developed for the acute, or short-term, treatment of panic attacks associated with panic disorder. Benzodiazepines are a class of psychoactive drugs with varying hypnotic, sedative, anti-anxiety, anticonvulsant, muscle relaxant and amnesic properties. 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 sodium oxybate, the active pharmaceutical ingredient in Xyrem, for the treatment of movement disorders. We are working on ways to expand our Xyrem franchise by developing improvements to Xyrem, such as new dosage forms that could be more convenient for patients. These activities are in the early stages of development.

Our executive management team has substantial experience in developing and commercializing novel therapeutic products. During their time 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 9. 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.
- 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 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.

- From our inception in 2003 through March 31, 2007, we incurred net losses of $191.5 million, 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. 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.

THE OFFERING

Common stock offered by us	6,000,000 shares
Common stock outstanding after this offering	24,550,554 shares
Over-allotment option	900,000 shares
Use of proceeds	We expect to use the net proceeds from this offering (1) to fund activities and make milestone payments related to the planned U.S. launch and commercialization of Luvox CR, (2) to fund our Phase III pivotal clinical trials of JZP-6, (3) to fund continued development and feasibility activities related to our portfolio of clinical and early-stage product candidates and (4) for working capital, capital expenditures and other general corporate purposes. See "Use of Proceeds."
Proposed NASDAQ Global Market symbol	JAZZ

The number of shares of common stock outstanding immediately after this offering is based on 18,550,554 shares of common stock outstanding as of March 31, 2007. This number excludes:

- 1,862,530 shares of common stock issuable upon the exercise of options outstanding as of March 31, 2007, having a weighted average exercise price of $21.34 per share;
- 215,792 shares of common stock reserved for future issuance under our 2003 Equity Incentive Plan as of March 31, 2007; 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 up to 5,175,042 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
- 785,728 shares of common stock issuable upon the exercise of warrants outstanding as of March 31, 2007, having an exercise price of $20.36 per share.

Except as otherwise indicated, all information in this prospectus assumes:

- the conversion of all our outstanding shares of preferred stock into 17,921,551 shares of common stock immediately prior to the closing of this offering;
- the filing of our fourth 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.

We completed a 1-for-11.06701 reverse stock split of our common stock and preferred stock on May 15, 2007. All share and per share amounts have been retroactively adjusted to give effect to this stock split.

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. The summary of our consolidated statements of operations data for the three months ended March 31, 2006 and 2007, and the consolidated balance sheet data as of March 31, 2007, have been derived from our unaudited consolidated financial statements included elsewhere in this prospectus, which in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary to state fairly our financial position and results of operations. 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 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. 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 $25.00 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,			Three Months Ended March 31,	
	2004	2005(1)	2006	2006	2007
				(Unaudited)	
	(In thousands, except per share amounts)				
Consolidated Statements of Operations Data:					
Revenues:					
Product sales, net	$ —	$ 18,796	$ 43,299	$ 9,771	$ 11,625
Royalties, net	—	146	594	66	211
Contract revenue	—	2,500	963	—	2,252
Total revenues	—	21,442	44,856	9,837	14,088
Operating expenses:					
Cost of product sales (excluding amortization of acquired developed technology)	—	4,292	6,968	1,569	2,003
Research and development	17,988	45,783	54,956	12,894	14,867
Selling, general and administrative	7,459	23,551	51,384	12,219	14,339
Amortization of intangible assets	—	4,960	9,600	2,400	2,362
Purchased in-process research and development	—	21,300	—	—	—
Total operating expenses	25,447	99,886	122,908	29,082	33,571
Loss from operations	(25,447)	(78,444)	(78,052)	(19,245)	(19,483)
Interest income	643	1,318	2,307	581	1,091
Interest expense (including $4,595 and $9,024 for the years ended December 31, 2005 and 2006, respectively, and $2,185 and $2,254 for the three months ended March 31, 2006 and 2007, respectively, pertaining to related parties)	—	(7,129)	(14,129)	(3,777)	(3,268)
Other income (expense)	—	(901)	(1,109)	62	(3,069)
Gain on extinguishment of development financing obligation	—	—	31,592	—	—
Gain on sale of product rights	—	—	—	—	5,145
Net loss	(24,804)	(85,156)	(59,391)	(22,379)	(19,584)
Beneficial conversion feature	—	—	(21,920)	(3,501)	—
Loss attributable to common stockholders	$ (24,804)	$ (85,156)	$ (81,311)	$ (25,880)	$ (19,584)
Loss per share attributable to common stockholders, basic and diluted	$(1,550.25)	$(14,192.67)	$(6,254.69)	$ (2,875.56)	$ (851.48)
Weighted-average common shares used in computing loss per share attributable to common stockholders, basic and diluted	16	6	13	9	23
Pro-forma loss per share attributable to common stockholders (unaudited), basic and diluted(2)			$ (6.04)		$ (1.11)
Weighted-average common shares used in computing pro forma loss per share attributable to common stockholders (unaudited), basic and diluted(2)			13,466		17,666

	As of March 31, 2007		
	Actual	Pro Forma (Unaudited)	Pro Forma As Adjusted(3)
	(In thousands, except per share data)		
Consolidated Balance Sheet Data:			
Cash and cash equivalents	$ 67,667	$ 67,667	$ 204,867
Working capital	46,673	58,261	195,461
Total assets	197,910	197,910	335,110
Senior secured notes (including $52,100 as of March 31, 2007 (unaudited), held by related parties)	74,429	74,429	74,429
Convertible preferred stock	263,852	—	—
Common stock subject to repurchase	8,749	12,954	12,954
Accumulated deficit	(197,227)	(197,227)	(197,227)
Total stockholders' equity (deficit)	(195,420)	75,815	213,015

(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 and March 31, 2007, as applicable, into common stock.
(3) Each $1.00 increase (decrease) in the assumed initial public offering price of $25.00 per share, would increase (decrease) each of cash and cash equivalents, working capital, total assets and total stockholders' equity by approximately $5.6 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 (decrease) of one million shares in the number of shares offered by us would increase (decrease) each of cash and cash equivalents, working capital, total assets and total stockholders' equity by approximately $23.3 million, assuming that the assumed initial public offering price remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. 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.

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 rights to market and distribute Luvox CR and Luvox in the United States. Solvay retains the rights to market and distribute Luvox CR outside of the United States. Luvox CR was developed by Solvay in collaboration with Elan Pharma International Limited. In December 2000, Solvay submitted an NDA to the FDA for Luvox CR for the treatment of obsessive compulsive disorder and social anxiety disorder. 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 obsessive compulsive disorder and social anxiety disorder. Under our agreement with Solvay, Solvay has primary responsibility for the NDA for Luvox CR and communications with the FDA until after such time, if ever, as the FDA approves the NDA. In February 2007, the FDA issued an approvable letter to Solvay. 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 active pharmaceutical ingredient in Luvox CR, the submission of additional information relating to the chemistry, manufacturing and controls section of the NDA and the re-analysis by Solvay of certain data set forth in the NDA. 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 or the approval could be delayed.

Under the terms of our license agreement with Solvay, we made an initial payment of $2.0 million to Solvay. Although it is still uncertain when, or if, Luvox CR will be approved by the FDA, we intend to significantly expand our sales force, marketing and commercial operations departments and administrative staff in 2007 in anticipation of the commercial launch of Luvox CR. In addition, we have engaged numerous third party vendors, such as contract manufacturers, advertising agencies, market research firms and other service providers, to assist in the anticipated launch of Luvox CR, including Elan, who will manufacture quantities of Luvox CR sufficient for commercial launch. These expenses are significant and must be incurred prior to the approval of Luvox CR in order for us to be prepared to launch the product as soon as possible following approval. The costs cannot be recouped or applied to other products if the FDA does not approve Luvox CR. In addition, the failure to obtain FDA approval for Luvox CR would result in the loss of a major source of potential near-term revenue for us and postpone the time at which we could become profitable.

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

We are currently conducting two Phase III pivotal clinical trials for the use of JZP-6 to treat fibromyalgia syndrome, both of which must have statistically significant positive results before we can submit an NDA to the FDA seeking approval of JZP-6 for the treatment of fibromyalgia syndrome. 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 fibromyalgia syndrome, or if the FDA or other regulatory authorities will approve JZP-6 for the treatment of fibromyalgia syndrome. Favorable results from our prior Phase II clinical trials with JZP-6 for the treatment of fibromyalgia syndrome may not be indicative of the clinical results from our Phase III pivotal clinical trials. Further, although JZP-6 has the same active pharmaceutical ingredient as Xyrem, which has been approved by the FDA for the treatment of cataplexy and excessive daytime sleepiness in patients with narcolepsy, this does not assure approval by the FDA, or any other regulatory authorities, of this active pharmaceutical ingredient for the treatment of fibromyalgia syndrome. Unsuccessful Phase III pivotal clinical trials or a failure to obtain FDA or other regulatory approval of JZP-6 for fibromyalgia syndrome 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 fibromyalgia syndrome, the FDA is likely to require us to have a risk management program similar to the one we use for Xyrem. Under the Xyrem risk management program, Xyrem must be distributed through a single central pharmacy. The central pharmacy must maintain physician and patient registries, and the product may not be stocked in retail pharmacies. Each physician and patient must be educated about the risks and benefits of the product before the physician can prescribe, or a patient can receive, Xyrem. Whenever a prescription is received by the central pharmacy, the central pharmacy must verify the prescription and obtain additional information by contacting the physician's office and the patient's insurance company. The central pharmacy must also speak with the patient before it can ship any Xyrem to the patient. The central pharmacy must ship the product directly to the patient by a courier service, and the patient or his/her designee must sign for the package. The initial shipment may only be for a one-month supply, and patients may not receive more than a three-month supply at any time.

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

Many of our product candidates are in preclinical or early-stage clinical development. 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;
- 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 fibromyalgia syndrome. Some of these companies have more significant financial and human resources than we do.

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

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

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

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

generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that any of our clinical trials comply with good clinical practices. In addition, our clinical trials must be conducted with product produced under the FDA's current Good Manufacturing Practices, or cGMP, regulations. Our failure, or the failure of our contract manufacturers, to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

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

The commercial success of our products 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.

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 fibromyalgia syndrome 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 fibromyalgia syndrome 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. While we have entered into an agreement with the central pharmacy for Xyrem, Express Scripts Specialty Distribution Services, Inc., 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 active pharmaceutical ingredient in Xyrem, is regulated by the U.S. Drug Enforcement Administration, or DEA, as a controlled substance. The new distributor would need to be registered with the DEA and would also need to develop the particular processes, procedures and activities necessary to distribute Xyrem, including the risk management program approved by the FDA. If we change distributors, new contracts might also be required with government and other insurers who pay for Xyrem. Transitioning to a new distributor could result in product shortages, which would adversely affect sales of Xyrem in the United States.

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

The DEA limits the quantity of certain Schedule I and II controlled substances that may be produced in the United States in any given calendar year through a quota system. Because sodium oxybate, the active pharmaceutical ingredient in Xyrem and JZP-6, is a Schedule I controlled substance, our supplier of the active pharmaceutical ingredient 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 quotas from the DEA, and without sufficient DEA quotas, there could be shortages of Xyrem for the marketplace or JZP-6 for use in our clinical studies, or both.

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

We do not have, and do not intend to establish in the near term, our own manufacturing or packaging capability for our products or product candidates, or their active pharmaceutical ingredients. Accordingly, we have entered into manufacturing and supply agreements with single source suppliers and manufacturers for our commercialized products and product candidates. Our suppliers and contract manufacturers may not be able to

manufacture our products or product candidates without interruption, or may not comply with their obligations to us under our supply and manufacturing arrangements. We may not have adequate remedies for any breach and their failure to supply us could result in a shortage of our products or product candidates.

The availability of our products for commercial sale is dependent upon our ability to procure the ingredients, packaging materials and finished products we need. If one of our suppliers or product manufacturers fails or refuses to supply us for any reason, it would take a significant amount of time and expense to qualify a new supplier or manufacturer. The loss of one of our suppliers or product manufacturers could require us to obtain regulatory clearance in the form of a "prior approval supplement" and to incur validation and other costs associated with the transfer of the active pharmaceutical ingredient or product manufacturing process. We believe that it could take as long as two years to qualify a new supplier or manufacturer. Should we lose either an active pharmaceutical ingredient supplier or a product manufacturer, we could run out of salable product to meet market demands or investigational product for use in clinical trials while we wait for FDA approval of a new active pharmaceutical ingredient supplier or product manufacturer. For Xyrem, JZP-6 or sodium oxybate, the new supplier or manufacturer would also need to be registered with the DEA and obtain a DEA quota. In addition, the FDA must approve suppliers of the active and inactive pharmaceutical ingredients and certain packaging materials used in our products, as well as suppliers of finished products. The qualification of new suppliers and manufacturers could potentially delay the manufacture of our products and product candidates and result in shortages in the marketplace or for our clinical trials, or both, particularly since we do not have secondary sources of supply of the active pharmaceutical ingredient or backup manufacturers for our products and product candidates. If there are delays in qualifying the new manufacturer or the new manufacturer is unable to obtain a sufficient quota from the DEA, there could be a shortage of Xyrem for the marketplace. For example, we entered into an agreement with Patheon Pharmaceuticals, Inc., or Patheon, in March 2007 for the supply of Xyrem in connection with the planned termination, effective January 1, 2008, of our supply agreement with our current supplier. Patheon has not yet been qualified by the FDA to manufacture Xyrem, and we cannot assure you that Patheon will be qualified by the FDA to manufacture Xyrem on a timely basis, or at all, nor can we assure you that Patheon will obtain a quota from the DEA, or a quota that is sufficient to satisfy our commercial requirements of Xyrem. Furthermore, we may not be able to obtain active pharmaceutical ingredients, 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 active pharmaceutical ingredient, drug product and packaging; however, unexpected market requirements or problems with vendors' facilities, among other things, could result in shortages of one or more of our products for the marketplace or product candidates for use in our clinical studies, or both.

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

Any delay in supplying, or failure to supply, products by any of our suppliers could result in our inability to meet the commercial demand for our products or our needs for use in clinical trials, and could adversely affect our business, financial condition, results of operations and growth prospects. For example, under our agreement with Solvay, Solvay is responsible for providing fluvoxamine, the active pharmaceutical ingredient in Luvox CR, to us for use in the manufacture of Luvox CR by Elan. If Solvay fails to provide fluvoxamine in the quantities we need, our launch of Luvox CR could be delayed or there could be an interruption in the supply of Luvox CR to the market. 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, for which we have obtained the exclusive rights to market and distribute in the United States from Solvay, is approved for commercial sale, Elan will manufacture Luvox CR for us 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 to Solvay, 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 active pharmaceutical ingredient in Xyrem and JZP-6, is a derivative of gamma hydroxybutyrate, or GHB, which has been a drug of abuse and may not be sold legally in the United States. If physicians and patients perceive Xyrem and JZP-6 to be the same as or similar to GHB, sales of Xyrem and JZP-6 could be adversely affected.

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

An investigation by the U.S. Attorney's Office for the Eastern District of New York concerning the sales and marketing of Xyrem is likely to result in fines, penalties or other adverse consequences that could result in adverse publicity and could harm our business.

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

We and Orphan Medical are discussing a possible settlement with the United States, acting through the Department of Justice, the U.S. Attorney's Office for the Eastern District of New York and other federal agencies, including the Office of Inspector General, U.S. Department of Health and Human Services, relating to this matter. If we complete a settlement on the terms that we are currently discussing, Orphan Medical would plead guilty to one felony count of introducing a misbranded drug into interstate commerce and would pay a total of approximately $20.5 million in civil and criminal payments over the next several years in connection with this matter. We would guarantee payment of these amounts by Orphan Medical.

If we complete a settlement on the terms that we are currently discussing, the U.S. Attorney has indicated that we would not be prosecuted. As part of the settlement, we would enter into a corporate integrity agreement with the Office of Inspector General, U.S. Department of Health and Human Services, which would require us to maintain a comprehensive compliance program. We would have additional ongoing compliance-related operating costs related to this compliance program.

The settlement terms described above are subject to the negotiation and execution of definitive agreements. These agreements, if executed, could result in additional negative publicity for us and for Xyrem. Even if we execute the definitive agreements, we might still be subject to regulatory and/or enforcement action by federal agencies that are not parties to the settlement, private insurers and states' attorneys general with respect to the activities covered by the settlement. We cannot assure you that the definitive agreements will be executed. If we do not execute them, we would be required to spend significant amounts defending ourselves and Orphan Medical. This could involve criminal charges and civil and criminal fines and penalties against Orphan Medical or us, or both. If we are unable to complete the settlement described above, 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, and such an 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. Provigil (modafinil), the only other product approved by the FDA specifically for the treatment of excessive daytime sleepiness in patients with narcolepsy, does not have a box warning and can be advertised directly to consumers. In addition, Xyrem's type of FDA approval under the FDA's Subpart H regulations requires that all of the promotional materials for Xyrem be provided to the FDA for review at least 30 days prior to the intended time of first use. Unlike Xyrem, Provigil was not approved under the FDA's Subpart H regulations and is not subject to the pre-review requirements. Accordingly, promotional materials for Provigil are not subject to the same delays that we experience with respect to new promotional materials for Xyrem.

Since JZP-6 contains the same active pharmaceutical ingredient as Xyrem, we anticipate that the label for JZP-6, if approved by the FDA, will also include a box warning. Although there are no current FDA-approved treatments for fibromyalgia syndrome, future competing products may not be subject to this restriction, and the box warning may negatively affect potential JZP-6 sales if competing products can be advertised directly to consumers.

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

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

We intend to market Luvox CR in the United States for the treatment of obsessive compulsive disorder and social anxiety disorder. Selective serotonin reuptake inhibitors are the standard treatment for anxiety disorders, including obsessive compulsive disorder and social anxiety disorder. Four branded products are currently approved by the FDA for the treatment of obsessive compulsive disorder, including three selective serotonin reuptake inhibitors: Paxil (paroxetine HCl), which is marketed by GlaxoSmithKline, Zoloft (sertraline HCl), which is marketed by Pfizer, and Prozac (fluoxetine hydrochloride), which is marketed by Eli Lilly. Anafranil (clomipramine hydrochloride), the other branded product approved by the FDA for the treatment of obsessive compulsive disorder, is a tricyclic antidepressant marketed by Mallinckrodt in the United States. Each of these products currently has generic equivalents. Generic products are generally sold at significantly lower prices than branded products, tending to both take market share away from branded products and put downward pricing pressure on branded products. Fluvoxamine, the generic equivalent of Luvox and a selective serotonin reuptake inhibitor, is the only other drug currently approved for the treatment of obsessive compulsive disorder. Four products are currently approved by the FDA for the treatment of social anxiety disorder, including three selective serotonin reuptake inhibitors: Zoloft, Paxil and Paxil CR, an extended release version of Paxil, and one serotonin-norepinephrine reuptake inhibitor, Effexor XR (venlafaxine HCl). Paxil CR and Effexor XR, developed and sold by GlaxoSmithKline and Wyeth, respectively, do not have generic competitors, whereas Paxil and Zoloft have generic competitors.

We are developing JZP-6 for the treatment of fibromyalgia syndrome. There are currently no products approved by the FDA for the treatment of fibromyalgia syndrome. In clinical practice, a variety of drugs is often prescribed to address individual symptoms of fibromyalgia syndrome, including antidepressants, pain medications, muscle relaxants, hypnotics and anticonvulsants. In addition to JZP-6, there are currently four programs that have completed or are in Phase III clinical development for the treatment of fibromyalgia syndrome, including programs being conducted by large pharmaceutical companies with far greater resources than we have. In particular, Lyrica (pregabalin), an anticonvulsant being developed by Pfizer, 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 fibromyalgia syndrome, or certain symptoms associated with fibromyalgia syndrome.

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, four major pharmaceutical companies are conducting, or have computed, Phase III clinical trials of product candidates for the treatment of fibromyalgia syndrome and Pfizer has submitted a supplemental NDA to the FDA with respect to one of these products, Lyrica. These product candidates may reach the market before JZP-6, or may be better accepted by physicians and patients. Thus, even if we successfully complete our Phase III clinical trials for JZP-6 for the treatment of fibromyalgia syndrome and achieve FDA approval, JZP-6 may not result in significant commercial revenues for us.

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

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

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

Part of our business strategy includes the ongoing development of proprietary product improvements to Xyrem, including new and enhanced dosage forms. However, we may not be successful in developing or obtaining FDA and other regulatory approvals of these improvements. Although the active pharmaceutical ingredient in Xyrem and JZP-6 is a DEA scheduled compound for which a quota is required and the FDA has required a risk management program for its distribution, and therefore generic competition may be more difficult and expensive than it might be for other products not requiring a risk management program for distribution, our

competitors will not be prevented from introducing a generic equivalent. We have filed a patent application with claims covering the method for distributing sodium oxybate using a centralized distribution system, but we cannot assure you that this patent will issue or, if issued, whether it will provide any significant protection of Xyrem from generic competition.

Luvox CR is covered by a patent application filed by Elan with claims covering the orally administered extended release formulation of fluvoxamine. This patent may not issue, and even if this patent issues, it is possible that other companies could manufacture similar or therapeutically equivalent products in ways that are not covered by the claims of the patent. 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 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 203 full-time employees as of March 31, 2007, approximately 36% 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.

Risks Related to Our Intellectual Property

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

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

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

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

- others may be able to make products that are similar to our product candidates but that are not covered by the claims of our patents, or for which we are not licensed under our license agreements;
- we or our licensors or partners might not have been the first to make the inventions covered by our issued patents or pending patent applications or the pending patent applications or issued patents of our licensors or partners;
- we or our licensors or partners might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative products without infringing our intellectual property rights;
- our pending patent applications may not result in issued patents;
- our issued patents and the issued patents of our licensors or partners may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges by third parties;
- we may not develop additional proprietary products that are patentable; or
- the patents of others may have an adverse effect on our business.

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

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

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;
- cease the development, manufacture, use and sale of our products that infringe the patent rights of others through a court-imposed sanction such as an injunction;
- expend significant resources to redesign our products so 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.

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 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 of that product, or if it is greater, the difference between the average manufacturing price and the best price we make available to any customer. The rebate amount also includes an inflation adjustment, if necessary.

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

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

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

In both U.S. and foreign markets, our ability to commercialize our products successfully, and to attract strategic partners for our products, depends in significant part on the availability of adequate financial coverage and reimbursement from third party payors, including, in the 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 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, which accounted for $12.5 million and $2.6 million in net product sales in 2006 and the first quarter of 2007, respectively, and the market participants to whom we expect to sell most of our future products, including Luvox CR, have undergone significant consolidation, marked by mergers and acquisitions among wholesale distributors and the growth of large retail drugstore chains. As a result, a small number of large wholesale distributors control a significant share of the market, and the number of independent drug stores and small drugstore chains has decreased. In addition, excess inventory levels held by large distributors can lead to periodic and unanticipated reductions in our revenues and cash flows. Consolidation of drug wholesalers and retailers, as well as any increased pricing pressure that those entities face from their customers, including the U.S. government, may increase pricing pressure and place other competitive pressures on drug manufacturers, including us.

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

Under current U.S. law, there is a general prohibition on imports of unapproved products. The FDA has published internal guidance that sets forth the agency's enforcement priorities for imported drugs. Under this policy, the FDA allows its personnel to use their discretion in permitting entry into the United States of personal use quantities of FDA-regulated products in personal baggage and mail when the product does not present an unreasonable risk to the user. Thus, individuals may import prescription drugs that are unavailable in the United States from Canada and other countries for their personal use under specified circumstances. Other imports, although illegal under U.S. law, also enter the country as a result of the resource constraints and enforcement priorities of the FDA and the U.S. Customs Services. In addition, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and 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, including the active pharmaceutical ingredient in Luvox CR and its immediate release formulation Luvox, may increase the risk of suicidal behavior in adults and adolescents. In addition, the current selective serotonin reuptake inhibitor products used to treat obsessive compulsive disorder and social anxiety disorder, particularly those formulated for immediate release, all have significant adverse side effects. Side effects associated with selective serotonin reuptake inhibitors include sexual dysfunction, adverse drug interaction and risk of hypertension. Claims may be brought by individuals seeking relief for themselves or by groups seeking to represent a class. While we have not had to defend against any product liability claims to date, as sales of our products increase, we believe 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.

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 losses for the year ended December 31, 2006 and the quarter ended March 31, 2007 were $59.4 million and $19.6 million, respectively, and we had an accumulated deficit of $197.2 million at March 31, 2007. 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 March 31, 2007, we had approximately $67.7 million in cash, cash equivalents and marketable securities. Our cash flows used in operations were approximately $57.4 million and $20.9 million during 2006 and the first quarter of 2007, respectively. Substantially all of our $43.3 million and $11.6 million in net product sales during 2006 and the first quarter of 2007, respectively, 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, 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

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 or our products. Our failure to raise capital when needed may harm our business and operating results.

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

As of March 31, 2007, we had secured indebtedness of $83.1 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;

- 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. Based on the number of shares of common stock outstanding as of March 31, 2007, upon completion of this offering, we will have 24,550,554

shares of common stock outstanding, or 25,450,554 shares if the underwriters exercise their over-allotment option in full, assuming no exercise of outstanding options or warrants.

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 18,550,554 shares of common stock outstanding after this offering, based on shares outstanding as of March 31, 2007, 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;
- approximately 14,219,877 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.

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 19,306,128 shares of common stock, based on shares outstanding as of March 31, 2007, including 785,728 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 5,175,042 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 83.5% of our capital stock as of March 31, 2007, and we expect that upon completion of this offering, that same group will beneficially own at least 64.0% of our capital stock, of which 7.1% will be beneficially owned by our executive officers. 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, and may prevent attempts by our stockholders to replace or remove our board of directors or management.

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 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.

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

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

- authorizing the issuance of "blank check" preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;
- dividing our board of directors into three classes;
- limiting the removal of directors by the stockholders;
- eliminating cumulative voting rights and therefore allowing the holders of a majority of the shares of our common stock to elect all of the directors standing for election, if they should so choose;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;
- eliminating the ability of stockholders to call a special meeting of stockholders; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

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

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

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

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," "predict," "project," "potential," "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;
- 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.

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 $137.2 million, or approximately $158.1 million if the underwriters exercise their over-allotment option in full, based upon an assumed initial public offering price of $25.00 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 $1.00 increase (decrease) in the assumed initial public offering price of $25.00 per share would increase (decrease) the net proceeds to us from this offering by approximately $5.6 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 (decrease) of one million shares in the number of shares offered by us would increase (decrease) the net proceeds to us from this offering by approximately $23.3 million, assuming that the assumed initial public offering price remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. 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 $90.0 million to fund the planned U.S. launch and commercialization of Luvox CR, including $41.0 million for development and commercial milestone payments to Solvay in connection with the acquisition of our U.S. rights to Luvox CR, approximately $39.0 million for activities related to our preparation for marketing, promotion and expansion of our specialty sales force and approximately $10.0 million for production of initial commercial quantities of Luvox CR;
- approximately $25.0 million to fund our Phase III pivotal clinical trials of JZP-6 through the completion of the first Phase III clinical trial, after which, if the trial is successful, we would need an estimated $50.0 million to complete development and commercial launch of JZP-6; and
- the remainder to fund continued development of and feasibility activities for our portfolio of clinical and early-stage product candidates during the next 12 to 18 months, as well as working capital, capital expenditures and other general corporate purposes. The completion of development activities and commercial launch of each of our early stage product candidates would require substantial additional funds.

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.

We may also seek to obtain debt or other non-equity financing for a portion of the costs to launch and commercialize Luvox CR, to complete the development and planned commercial launch of JZP-6, to fund continued development and commercialization of our portfolio of clinical and early-stage product candidates and/or for the acquisition or in-licensing of, or investment in, products, product candidates, or companies that complement our business. We have no current understandings, commitments or agreements with respect to any such potential financing.

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 Solvay obtains 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, any settlement of 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 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.

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.

CAPITALIZATION

The following table sets forth our cash, cash equivalents and capitalization as of March 31, 2007:

- on an actual basis;
- on a pro forma basis to reflect the conversion of all of our outstanding shares of preferred stock into 17,921,551 shares of common stock immediately prior to the closing of this offering, the transfer of common stock subject to repurchase from stockholders' equity to temporary equity and the reclassification of preferred stock warrant liability to additional paid-in capital upon conversion of the preferred stock underlying the warrants into common stock; and
- on a pro forma as adjusted basis to reflect the sale of 6,000,000 shares of common stock in this offering at an assumed initial public offering price of $25.00 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 March 31, 2007		
	Actual	Pro Forma (Unaudited)	Pro Forma As Adjusted(1)
	(In thousands, except per share data)		
Cash and cash equivalents	$ 67,667	$ 67,667	$ 204,867
Senior secured notes (including $52,100 as of March 31, 2007 held by related parties)	$ 74,429	$ 74,429	$ 74,429
Preferred stock warrant liability (including $8,469 as of March 31, 2007 held by related parties)	11,588	—	—
Convertible preferred stock, $.0001 par value; issuable in series, 27,851,839 authorized, 17,921,551 shares issued and outstanding, actual; 27,851,839 authorized, no shares issued and outstanding, pro forma and pro forma as adjusted	263,852	—	—
Common stock subject to repurchase	8,749	12,954	12,954
Stockholders' equity (deficit):			
Preferred stock, $.0001 par value, no shares authorized, issued and outstanding, actual and pro forma; 20,000,000 shares authorized, no shares issued and outstanding, pro forma as adjusted	—	—	—
Common stock, $.0001 par value, 22,835,080 shares authorized, 629,003 shares issued and outstanding, actual; 22,835,080 shares authorized, 18,550,554 shares issued and outstanding, pro forma (unaudited); 150,000,000 shares authorized, 24,550,554 shares issued and outstanding, pro forma as adjusted	—	2	2
Additional paid-in capital	1,807	273,040	410,240
Accumulated other comprehensive income	—	—	—
Accumulated deficit	(197,227)	(197,227)	(197,227)
Total stockholders' equity (deficit)	(195,420)	75,815	213,015
Total capitalization	$ 163,198	$ 163,198	$ 300,398

(1) Each $1.00 increase (decrease) in the assumed initial public offering price of $25.00 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 and total

capitalization by approximately $5.6 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 (decrease) of one million shares in the number of shares offered by us would increase (decrease) each of additional paid-in capital, total stockholders' equity and total capitalization by approximately $23.3 million, assuming that the assumed initial public offering price remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. 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 March 31, 2007:

- 1,862,530 shares of common stock issuable upon the exercise of outstanding options with a weighted average exercise price of $21.34 per share;
- 215,792 shares of common stock reserved for future issuance under our 2003 Equity Incentive Plan as of March 31, 2007; 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 up to 5,175,042 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
- 785,728 shares of common stock issuable upon the exercise of outstanding warrants with an exercise price of $20.36 per share.

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 March 31, 2007, we had a historical net tangible book value (deficit) of our common stock of $(296.9) million, or approximately $(471.97) per share. The pro forma net tangible book value (deficit) of our common stock as of March 31, 2007 was approximately $(25.6) million, or approximately $(1.38) per share, based on the number of shares of common stock outstanding as of March 31, 2007, 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 $25.00 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 March 31, 2007 would have been approximately $111.6 million, or approximately $4.54 per share of common stock. This represents an immediate increase in pro forma as adjusted net tangible book value of $5.92 per share to existing stockholders, and an immediate dilution of $20.46 per share to investors participating in this offering. The following table illustrates this per share dilution:

Assumed initial public offering price per share		$25.00
Historical net tangible book value (deficit) per share as of March 31, 2007	$(471.97)	
Pro forma increase in net tangible book value per share attributable to conversion of convertible preferred stock	470.59	
Pro forma net tangible book value (deficit) per share before this offering	$ (1.38)	
Pro forma increase in net tangible book value per share attributable to investors participating in this offering	5.92	
Pro forma as adjusted net tangible book value per share after this offering		4.54
Pro forma dilution per share to investors participating in this offering		$20.46

Each $1.00 increase (decrease) in the assumed initial public offering price of $25.00 per share would increase (decrease) our pro forma as adjusted net tangible book value by approximately $5.6 million, or approximately $.23 per share, and the pro forma dilution per share to investors in this offering by approximately $.77 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 one million shares in the number of shares offered by us would increase our pro forma as adjusted net tangible book value by approximately $23.3 million, or $.73 per share, and the pro forma dilution per share to investors in this offering would be $19.72 per share, assuming that the assumed initial public offering price remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, a decrease of one million shares in the number of shares offered by us would decrease our pro forma as adjusted net tangible book value by approximately $23.3 million, or $.79 per share, and the pro forma dilution per share to investors in this offering would be $21.25 per share, assuming that the assumed initial public offering price remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. 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.

If the underwriters exercise their option in full to purchase 900,000 additional shares of common stock in this offering, the pro forma as adjusted net tangible book value per share after the offering would be $5.21 per share, the increase in the pro forma net tangible book value per share to existing stockholders would be $6.59 per share and the pro forma dilution to new investors purchasing common stock in this offering would be $19.79 per share.

The following table summarizes, on a pro forma basis as of March 31, 2007, 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 $25.00 per share, before deducting underwriting discounts and commissions and estimated offering expenses:

	Shares Purchased		Total Consideration		Weighted Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders before this offering	18,550,554	76%	$266,807,000	64%	$ 14.38
Investors participating in this offering	6,000,000	24	150,000,000	36	25.00
Total	24,550,554	100%	$416,807,000	100%	

The above discussion and tables are based on 18,550,554 shares of common stock outstanding as of March 31, 2007. This number excludes, as of March 31, 2007:

- 1,862,530 shares of common stock issuable upon the exercise of outstanding options with a weighted average exercise price of $21.34 per share;
- 215,792 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 up to 5,175,042 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
- 785,728 shares of common stock issuable upon the exercise of outstanding warrants with an exercise price of $20.36 per share.

The following table summarizes, on a pro forma basis as of March 31, 2007, after giving effect to the exercise of all stock options and warrants outstanding as of March 31, 2007, 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 $25.00 per share, before deducting underwriting discounts and commissions and estimated offering expenses:

	Shares Purchased		Total Consideration		Weighted Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders before this offering	21,198,812	78%	$322,550,000	68%	$15.22
Investors participating in this offering	6,000,000	22	150,000,000	32	25.00
Total	27,198,812	100%	$472,550,000	100%	

The number of shares of common stock outstanding in the table above is based on the pro forma number of shares outstanding as of March 31, 2007 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 75% 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 6,900,000 shares or 25% 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 up to 5,175,042 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.

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. The selected consolidated statements of operations data for the three month periods ended March 31, 2006 and 2007, and the selected consolidated balance sheet data as of March 31, 2007, have been derived from our unaudited consolidated financial statements included elsewhere in this prospectus, which, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary to state fairly our financial position and results of operations.

	Period from March 20, 2003 (Inception) to December 31, 2003	Year Ended December 31,			Three Months Ended March 31,	
		2004	2005(1)	2006(2)	2006	2007
					(Unaudited)	
	(In thousands, except per share amounts)					
Consolidated Statements of Operations Data:						
Revenues:						
Product sales, net	$ —	$ —	$ 18,796	$ 43,299	$ 9,771	$ 11,625
Royalties, net	—	—	146	594	66	211
Contract revenue	—	—	2,500	963	—	2,252
Total revenues	—	—	21,442	44,856	9,837	14,088
Operating expenses:						
Cost of product sales (excluding amortization of acquired developed technology)	—	—	4,292	6,968	1,569	2,003
Research and development	—	17,988	45,783	54,956	12,894	14,867
Selling, general and administrative	2,538	7,459	23,551	51,384	12,219	14,339
Amortization of intangible assets	—	—	4,960	9,600	2,400	2,362
Purchased in-process research and development	—	—	21,300	—	—	—
Total operating expenses	2,538	25,447	99,886	122,908	29,082	33,571
Loss from operations	(2,538)	(25,447)	(78,444)	(78,052)	(19,245)	(19,483)
Interest income	10	643	1,318	2,307	581	1,091
Interest expense (including $4,595 and $9,024 for the years ended December 31, 2005 and 2006, respectively, and $2,185 and $2,254 for the three months ended March 31, 2006 and 2007 (unaudited), respectively, pertaining to related parties)	—	—	(7,129)	(14,129)	(3,777)	(3,268)
Other income (expense)	—	—	(901)	(1,109)	62	(3,069)
Gain on extinguishment of development financing obligation	—	—	—	31,592	—	—
Gain on sale of product rights	—	—	—	—	—	5,145
Net loss	(2,528)	(24,804)	(85,156)	(59,391)	(22,379)	(19,584)
Beneficial conversion feature	—	—	—	(21,920)	(3,501)	—
Loss attributable to common stockholders	$ (2,528)	$ (24,804)	$ (85,156)	$ (81,311)	$ (25,880)	$(19,584)
Loss per share attributable to common stockholders, basic and diluted	$ (81.55)	$(1,550.25)	$(14,192.67)	$(6,524.69)	$(2,875.56)	$(851.48)
Weighted-average common shares used in computing loss per share attributable to common stockholders, basic and diluted	31	16	6	13	9	23
Pro-forma loss per share attributable to common stockholders (unaudited), basic and diluted(3)				$ (6.04)		$ (1.11)
Weighted-average common shares used in computing pro-forma loss per share attributable to common stockholders (unaudited), basic and diluted				13,466		17,666

(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 and March 31, 2007, as applicable, into common stock.

	As of December 31,				As of March 31, 2007
	2003	2004	2005	2006	(Unaudited)
Consolidated Balance Sheet Data:					
Cash and cash equivalents	$ 4,460	$ 33,678	$ 20,614	$ 78,948	$ 67,667
Working capital	4,488	36,663	8,048	61,043	46,673
Total assets	4,900	42,850	164,781	214,571	197,910
Senior secured notes (including $50,620 and $51,998 as of December 31, 2005 and 2006, respectively, and $52,100 as of March 31, 2007 (unaudited), held by related parties)	—	—	73,629	74,283	74,429
Convertible preferred stock	7,076	64,009	163,862	263,852	263,852
Common stock subject to repurchase	—	3,665	5,924	8,183	8,749
Accumulated deficit	(2,528)	(27,332)	(118,252)	(177,643)	(197,227)
Total stockholders' (deficit)	(2,512)	(30,923)	(118,248)	(176,296)	(195,420)

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 were $29.0 million in 2006 and $8.6 million in the first quarter of 2007. 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 approved Xyrem for the treatment of cataplexy associated with narcolepsy and in March 2007, the European Agency for the Evaluation of Medical Products approved the product for the treatment of narcolepsy with cataplexy in adult patients. UCB has commercially launched Xyrem in 12 countries.

- *Antizol (fomepizole).* Antizol is the only FDA-approved antidote for suspected or confirmed ethylene glycol or methanol poisonings in humans. We market Antizol primarily to hospitals and emergency rooms. Net product sales of Antizol were $12.5 million in 2006 and $2.6 million in the first quarter of 2007. Antizol is distributed to wholesalers in the United States, and we retain the services of a third party to promote the product. Antizol is marketed by our distributors in Canada and Israel. We also market Antizol-Vet, an injectable formulation of fomepizole approved as an antidote for suspected or confirmed ethylene glycol 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, which has been developed for the treatment of obsessive compulsive disorder and social anxiety disorder. We obtained the exclusive rights to market and distribute Luvox CR in the United States from Solvay Pharmaceuticals, Inc., or Solvay, in January 2007. Solvay retains the rights to market and distribute Luvox CR outside of the United States. 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. Under our agreement with Solvay, Solvay has primary responsibility for the NDA for Luvox CR and communications with the FDA until after such time, if ever, as the FDA approves the NDA for Luvox CR. Subject to the satisfaction of the requirements set forth in an approvable letter issued by the FDA to Solvay 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 in Xyrem, for the treatment of fibromyalgia syndrome. We have successfully completed a Phase II clinical trial of this product candidate for the treatment of fibromyalgia syndrome. 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 a proof of concept clinical trial, formulation studies 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 fourth quarter of 2007.
- *JZP-7 (dopamine agonist).* We intend to conduct an additional pharmacokinetic 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.

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 785,728 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 fibromyalgia syndrome. We are also entitled to additional development and commercialization milestone payments of up to $146.0 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.

Revenues

Product Sales, Net

The following is a summary of our product sales, net for the years ended December 31, 2005 and 2006 and the three months ended March 31, 2006 and 2007. We had no product sales prior to our acquisition of Orphan Medical in June 2005.

	Year Ended December 31,		Three Months Ended March 31,	
	2005	2006	2006	2007
	(In thousands)			
Xyrem	$ 11,200	$ 29,049	$ 6,153	$ 8,624
Antizol(1)	6,782	12,813	3,131	2,636
Cystadane	814	1,437	487	365
Total	$ 18,796	$ 43,299	$ 9,771	$ 11,625

(1) Includes sales of Antizol-Vet, which were $99,000 and $313,000 in 2005 and 2006, respectively, and $80,000 and $65,000 in the three months ended March 31, 2006 and 2007, 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. Approximately half of our royalties in the year ended December 31, 2006 resulted from minimum royalty payments under our agreement with UCB. Royalty income was $146,000 and $594,000 in the years ended December 31, 2005 and 2006, respectively, and $66,000 and $211,000 in the three months ended March 31, 2006 and 2007, 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. UCB made a nonrefundable development milestone payment to us of $2.5 million in November 2005 and nonrefundable commercial milestone payments of $500,000 and $2.0 million in June 2006 and March 2007, respectively, which we recognized upon achievement of the milestones. In connection with the expansion of our agreement with UCB in 2006, UCB made an upfront payment of $5.0 million and subsequently an additional payment of $10.0 million upon exercise of its rights to develop and commercialize JZP-6 for the treatment of fibromyalgia syndrome. These payments are being amortized through 2019, the estimated performance period of the contract. This amortization resulted in $463,000 and $252,000 of contract revenues during the year ended December 31, 2006 and the three months ended March 31, 2007, respectively.

Significant Customers

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

	Year Ended December 31,		Three Months Ended March 31,	
	2005	2006	2006	2007
Express Scripts	51%	65%	63%	61%
Cardinal Health	*	12%	15%	*
Amerisource Bergen	15%	*	*	*
UCB	12%	*	*	17%
McKesson Corporation	*	*	11%	*

* Less than 10% of our total revenues.

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 March 31, 2007, we had incurred approximately $133.6 million in research and development expenses 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 and the three months ended March 31, 2007. 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,			Three Months Ended March 31,	
	2004	2005	2006	2007	Total
			(In thousands)		
Luvox CR	$ —	$ —	$ —	$ 2,254	$ 2,254
Ongoing JZP Projects:					
JZP-6	—	—	14,209	5,219	19,428
JZP-4	2,077	2,141	6,699	1,963	12,880
JZP-8	—	313	1,403	162	1,878
JZP-7	4	150	1,328	386	1,868
JZP-2	58	1,570	395	272	2,295
Terminated Projects:					
JZP-3(1)	12,577	27,305	14,797	—	54,679
Other terminated projects	1,437	5,878	752	10	8,077
Other projects	1	97	1,834	151	2,083
R&D support	1,834	8,329	13,539	4,450	28,152
Total	$17,988	$45,783	$54,956	$ 14,867	$133,594

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

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

Product Sales, Net

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

Revenues from sales of products within the United States are recorded net of estimated allowances for specialty distributor and wholesaler fees, prompt payment discounts, Medicaid rebates, government chargebacks and a customer rebate. Calculating these items involves estimates and judgments based primarily on sales or invoice data and historical experience. Due to the nature of our current products, product returns have been infrequent and immaterial. Our allowances and adjustments to estimates for allowances have not historically been material.

Specialty Distributor and Wholesaler Fees. Express Scripts, our sole Xyrem distributor in the United States, provides services such as collecting patient registry information, providing reimbursement support, and distributing educational materials. The fee we pay to Express Scripts for these services is recorded as a reduction of Xyrem product sales and is based on actual invoices for services performed rather than estimates. Since the fee

is based primarily on product shipments, our allowance related to these fees would generally increase in proportion to increases in sales. Fees paid to Express Scripts totaled $546,000 and $1.4 million for the years ended December 31, 2005 and 2006, respectively, and $298,000 and $363,000 for the three months ended March 31, 2006 and 2007, respectively.

Our service agreements with certain U.S. wholesaler customers for Antizol require, and, prior to the sale of our rights, our service agreements for wholesale customers for Cystadane required, us to pay fees to the customer based on actual product sales made to such customer. If the gross product sales of Antizol sold to U.S. wholesaler customers with such service agreements increases, our allowance related to these discounts could increase. Wholesaler fees totaled $64,000 and $203,000 for the years ended December 31, 2005 and 2006, respectively, and $60,000 and $10,000 for the three months ended March 31, 2006 and 2007, respectively.

Prompt Payment Discounts. We offer Express Scripts and our U.S. wholesaler customers a 2% prompt payment discount as an incentive to remit payment within the first 30 days after the date of our invoice. Because Express Scripts and our U.S. wholesaler customers typically take the prompt payment discount, we accrue 100% of the prompt payment discounts, based on the gross amount of each invoice, at the time of our original sale to them, and we apply earned discounts at the time of payment. We adjust the allowance to reflect actual experience as necessary and, as a result, the actual amount recognized in any period may be slightly different from our allowance amount. Adjustments have not been material and we do not anticipate that changes to estimates will have a material impact on product sales, net. Prompt payment discounts were $381,000 and $880,000 for the years ended December 31, 2005 and 2006, respectively, and $198,000 and $240,000 for the three months ended March 31, 2006 and 2007, respectively.

Medicaid Rebates. Our products are subject to state government-managed Medicaid programs under which rebates are provided to participating state governments. We record accruals for rebates to be provided through the Medicaid drug rebate program as a reduction of product sales when the product is sold. We pay rebates to states for all eligible units purchased under the Medicaid program based on a rebate per unit calculation, which is derived from our average manufacturer price. We determine our estimate of the Medicaid rebate accrual primarily based on historical experience regarding Medicaid rebates, as well as current and historical prescription activity and our current sales prices. We also examine the historical rebate trends and any changes expected to these trends. We adjust the accrual throughout each period to reflect actual experience, expected changes in future prescription volumes and any changes in business circumstances or trends. Rebate amounts are generally invoiced quarterly in arrears and paid 30 days after they are invoiced. As a result, our accrual consists of an estimate of the amount expected to be incurred for the current quarter's prescriptions and an estimate for prior quarters' unpaid rebates. Based on our history of estimating Medicaid rebates, we do not anticipate that changes to our estimated allowance for Medicaid rebates for our current commercial products will have a material impact on product sales, net. Medicaid rebates totaled $135,000 and $229,000 for the years ended December 31, 2005 and 2006, respectively, and $108,000 and $94,000 for the three months ended March 31, 2006 and 2007, respectively.

Chargebacks. Our products are subject to certain programs with federal government entities under which pricing on our products is extended below U.S. wholesaler list price to participating entities. These entities purchase our products through U.S. wholesalers at the lower vendor price, and the U.S. wholesalers charge the difference between their acquisition cost and the lower vendor price back to us. We account for chargebacks by establishing an accrual in an amount equal to our estimate of chargeback claims. We determine our estimate of the chargebacks primarily based on historical experience regarding chargebacks and current contract prices under the vendor programs. We consider vendor payments and our claim processing time lag and adjust the accrual throughout each period to reflect actual experience and any changes in business circumstances or trends. Due to estimates and assumptions inherent in determining the amount of chargebacks, the actual amount of claims for chargebacks may be slightly different from our estimates. Based on our experience with chargebacks, we do not believe that a material change to our estimated allowance for chargebacks is reasonably likely or will have a material impact on product sales, net. Chargebacks from U.S. wholesalers were $57,000 and $212,000 for the

years ended December 31, 2005 and 2006, respectively, and $56,000 and $70,000 for the three months ended March 31, 2006 and 2007, respectively.

Customer Rebate. Under our agreement with our Antizol distributor in Canada, we pay a rebate, either in cash or as a credit against future purchases, based upon year-over-year unit sales increases. We account for the rebate by establishing an accrual equal to our estimate of the rebate amount. We determine our estimate of the rebate primarily based on historical experience regarding rebate payments and our Antizol distributor's current year sales forecast. The rebate was $44,000 for the year ended December 31, 2006 and $5,000 for the three months ended March 31, 2007. There was no rebate for the year ended December 31, 2005 or the three months ended March 31, 2006.

Royalties, Net

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

Contract Revenues

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

UCB Agreement

In June 2006, we entered into an agreement with UCB that amended and restated a prior agreement between Orphan Medical and UCB. Under the terms of the amended agreement, UCB has the right to market Xyrem for the treatment of narcolepsy and JZP-6 for the treatment of fibromyalgia syndrome 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 nonrefundable commercial milestone payments of $500,000 and $2.0 million in June 2006 and March 2007, respectively, 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 fibromyalgia syndrome. We recognized contract revenues of $463,000 and $252,000 related to these upfront payments during the year ended December 31, 2006 and the three months ended March 31, 2007, respectively. The remaining $14.3 million was recorded as deferred revenues as of March 31, 2007 and is being recognized ratably through 2019, the expected performance period under the agreement. There has been no change in the expected performance period since its establishment in 2006 at the time of the initial upfront payment. The amended agreement requires UCB to make additional milestone payments of up to $146.0 million, of which up to $6.0 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 fibromyalgia syndrome and up to $100.0 million relate primarily to the commercialization of JZP-6 for the treatment of fibromyalgia syndrome as well as additional sales of Xyrem for the treatment of narcolepsy.

Goodwill and Intangible and Long-Lived Assets

Goodwill represents the excess of the purchase price over the fair value of assets acquired and liabilities assumed. We have determined that we operate in a single segment and have a single reporting unit associated with the development and commercialization of pharmaceutical products. The annual test for goodwill impairment is a two-step process. The first step is a comparison of the fair value of the reporting unit with its carrying amount, including goodwill. If this step indicates 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 March 31, 2007 as follows:

	Gross Carrying Amount	Accumulated Amortization	Net Book Value	Weighted Average Remaining Useful Life
		(In thousands)		(Years)
Developed technology—Xyrem	$ 39,700	$ 7,370	$32,330	7.8
Developed technology—Antizol	31,100	5,773	25,327	7.8
Agreements not to compete	5,600	2,379	3,221	2.8
Trademarks	2,600	483	2,117	7.8
Other	400	156	244	2.8
Amortizable intangible assets	79,400	16,161	63,239	
Goodwill	38,213			
Total	$117,613			

Stock-Based Compensation

Stock-Based Compensation Under SFAS 123

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

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.

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,			Three Months Ended March 31,	
	2004	2005	2006	2006	2007
Weighted-average volatility	80%	60%	61%	61%	61%
Weighted-average expected term	5.0	5.0	6.0	6.0	6.5
Range of risk-free rates	3.0-4.0%	3.9-4.4%	4.6-5.1%	4.6%	4.5-4.8%
Expected dividend yield	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 $8.96, $8.66 and $10.68, respectively. The weighted-average grant date fair value per share of employee stock options granted during the three months ended March 31, 2006 and 2007 was $10.05 and $12.07, 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 specialty pharmaceutical 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 and the three months ended March 31, 2007, the expected term was estimated using the short-cut method allowed under Securities and Exchange Commission Staff Accounting Bulletin No. 107 *Share-Based Payment*. 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.

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.

Common Stock Fair Value. The fair value of our common stock during the years ended December 31, 2004 and 2005 was determined by our board of directors with assistance from management. In May 2006, our board of directors directed management to perform an in-depth contemporaneous valuation of our common stock. In conducting this valuation, we 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 the "income approach" to estimate enterprise value. This enterprise value was then validated utilizing the "market approach." The income approach involved projecting future cash flows, discounting them to present value using a discount rate of 15% based upon a risk adjusted weighted average cost of capital of comparable companies, and applying probabilities for success of our product candidates to the resulting discounted cash flows. The projection of future cash flows, the determination of an appropriate discount rate and the estimates of probability for success of our product candidates each involved a significant degree of judgment. For product candidates other than JZP-6 and an alternative dosage form of Xyrem, the probabilities for success ranged from five percent to 30%. For JZP-6, a project for which we were preparing to commence Phase III clinical trials, the probability of success ranged from 60% to 70% and for an alternative dosage form of Xyrem, probabilities of success ranged from 50% to 100%. The present value of projected future cash flows after application of the discount rate and, for product candidates, our probabilities of success, ranged from $113.5 million to $124.1 million for our existing products, $112.8 to $156.1 million for JZP-6 and $66.7 million to $142.8 million for our other product candidates, including an alternative dosage form of Xyrem, resulting in a range of enterprise values from $293.0 million to $423.0 million. The market approach used to validate the determination of enterprise value involved selecting a range of possible valuations by comparing a group of 14 publicly-traded specialty pharmaceutical and biotechnology companies with products and product candidates in similar stages of development. The range of enterprise values derived through application of the market approach method was $300.0 million to $350.0 million. As these values fell within the range of enterprise values suggested by application of the income approach, we determined that the market approach provided an appropriate validation of our estimated enterprise value.

In order to allocate the enterprise value to the various securities that comprise our capital structure, the option-pricing method was used. For purposes of applying the option-pricing method, we estimated our stock price volatility to be 60% and our time to liquidity to be one year. A 10% discount was then applied to account for a lack of marketability of our common stock based upon the assumed time to liquidity. The contemporaneous valuation of our common stock suggested a range of probable fair values from $12.17 per share to $17.26 per share. On June 28, 2006, our board of directors made a determination that the fair market value of our common stock was $16.60 per share, after taking into consideration the contemporaneous valuation as well as other factors including our financial performance, the development status of our product candidates and our research and development efforts and the likelihood of achieving a liquidity event for the shares of common stock underlying stock options, such as an initial public offering or sale of the company, given prevailing market conditions. The fair market value determination made by our board of directors as of June 28, 2006 represents a discount of $8.40 per share from our assumed initial public offering price of $25.00 per share, which discount is attributable to our receipt of the FDA's approvable letter to Solvay for Luvox CR, our progress in the development of our product candidates and our financial performance in the period from June 28, 2006 to the date of this prospectus and our progress towards our initial public offering and the related reduction in market and liquidity risk associated with our common stock over the period from June 28, 2006 to the date of this prospectus.

In December 2006, our board of directors directed management to perform a second in-depth contemporaneous valuation with an effective date of December 31, 2006. In conducting this valuation, we used the same methodology and assumptions as in the prior contemporaneous valuation for determining enterprise value, with the exception of adjustments in our estimated future cash flows for certain of our existing products and product candidates and our estimated probabilities of success for certain of our product candidates for

purposes of the income approach. We also made modifications to the comparison group of companies utilized for the market approach to reflect business developments at comparable companies and achieve an appropriate sample size. The present value of projected future cash flows after application of the discount rate and, for product candidates, our probabilities of success ranged from $83.6 million to $93.2 million for our existing products, $138.5 to $186.0 million for JZP-6 and $94.9 million to $184.8 million for our other product candidates, including an alternative dosage form of Xyrem, resulting in a range of enterprise values from $317.0 million to $464.0 million. A number of companies included in the comparison group for purposes of the market approach in the June 28, 2006 contemporaneous valuation were not included in the comparison group as of December 31, 2006 as a result of material adverse events associated with significant development projects at these companies that we believe made their market values incomparable to our own. Appropriate specialty pharmaceutical and biotechnology companies were added to the comparison group for purposes of the December 31, 2006 contemporaneous valuation to provide an appropriate sample size of 13 comparable companies. The range of enterprise values derived through the application of the market approach method was $350.0 million to $425.0 million. As these values fell within the range of enterprise values suggested by application of the income approach, we determined that the market approach provided an appropriate validation of our estimated enterprise value.

For purposes of allocating enterprise value to our common stock, time to liquidity assumed in the option pricing method was reduced to six months and the discount for marketability was consequently reduced to five percent. In addition to the option-pricing method, we also considered the probability weighted expected return method. The application of this method yielded a result within the range of probable fair values suggested by the option pricing method. For purposes of applying the probability-weighted expected return method we considered six potential liquidity scenarios. Two potential scenarios were each given a probability of five percent and involved the distressed sale or liquidation of the company at alternative valuations of $10.0 million and $100.0 million. Two other potential scenarios were each given a probability of 7.5% and involved the sale of the company following the failure to achieve positive clinical trial results for certain of our product candidates at alternative valuations of $200.0 million and $270.0 million. The remaining potential scenarios involved the successful sale of the company or an initial public offering of our common stock at alternative valuations of $500.0 million and $800.0 million, which were given probabilities of 70% and five percent, respectively. The contemporaneous valuation of our common stock suggested a range of probable fair values from $13.94 per share to $21.36 per share. On February 13, 2007, our board of directors made a determination that the fair market value of our common stock was $19.37 per share after taking into consideration the contemporaneous valuation as well as other factors, including our financial performance, the development status of our product candidates and our research and development efforts, the likelihood of achieving a liquidity event for the shares of common stock underlying stock options, such as an initial public offering or sale of the company, given prevailing market conditions and initial estimates of the potential initial public offering price of our common stock based on initial valuation discussions by and between management and the proposed underwriters for our initial public offering. This determination was confirmed by the compensation committee of our board of directors as of February 27, 2007, the last date in the three month period ended March 31, 2007 on which we granted stock options. The fair market value determination made by our board of directors as of February 13, 2007, and confirmed as of February 27, 2007, represents a discount of $5.63 per share from our assumed initial public offering price of $25.00, which discount is primarily attributable to our receipt, on February 28, 2007, of the FDA's approvable letter to Solvay for Luvox CR, and, to a lesser extent, to our progress towards our initial public offering and the related reduction in market and liquidity risk associated with our common stock over the periods from February 13, 2007 and February 27, 2007 to the date of this prospectus and our progress in the development of our product candidates and our financial performance in the periods from February 13, 2007 and February 27, 2007 to the date of this prospectus.

In connection with the preparation of our financial statements for the year ended December 31, 2006, we reassessed the fair value of our common stock at option grant dates from June 28, 2006 through December 31, 2006 by reviewing our corporate developments from June 28, 2006 through February 13, 2007. In undertaking this assessment, we determined that the increase in value from June 28, 2006 to December 31, 2006 was

attributable to a decrease in expected timing to liquidity and general progress in the development status of our product candidates and not the achievement of any particular business milestones that individually would reasonably be expected to significantly change the relative timing or likelihood of expected future net cash flows. We also determined that no such milestones had been achieved during the period from December 31, 2006 to February 13, 2007. As a result, we concluded that a ratable increase to the estimated fair value of our common stock from $16.60 to $19.37 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 was appropriate. In connection with the grant of stock options on February 27, 2007, the compensation committee of our board of directors confirmed that the fair market value of our common stock was $19.37 on the basis that we had not achieved any particular business milestone that would reasonably be expected to significantly change the relative timing or likelihood of expected future net cash flows in the period from February 13, 2007 to February 27, 2007. Therefore, we have determined that no reassessment of the fair value of our common stock as of February 27, 2007 was appropriate.

On February 28, 2007, Solvay informed us that the FDA had issued an approvable letter to Solvay for Luvox CR dated February 27, 2007. In April 2007, the audit committee of our board of directors determined that as of March 31, 2007, the fair value of our common stock was $24.79 per share after taking into account the valuation conducted in December 2006, the achievement of a significant business milestone associated with the issuance of the approvable letter for Luvox CR to Solvay, the likelihood of achieving a liquidity event for the shares of common stock underlying stock options, such as an initial public offering or sale of the company, given prevailing market conditions and our then ongoing process to prepare for an initial public offering, and estimates of the potential initial public offering price of our common stock based on valuation discussions by and between management and the proposed underwriters for our initial public offering. We did not perform a contemporaneous valuation of our enterprise value or common stock using the income approach or market approach as of March 31, 2007. The fair market value determination made by our board of directors as of March 31, 2007 was based on the midpoint of the valuation range then suggested by our proposed underwriters in connection with the contemplated initial public offering and represents a discount of $0.21 per share from our assumed initial public offering price of $25.00, which discount is primarily attributable to remaining risks related to the completion of our initial public offering.

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 1,133,862 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 the year ended December 31, 2006 or the three months ended March 31, 2007. 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 expense, respectively. During the three months ended March 31, 2007, we recognized $940,000 of stock-based compensation expense, of which $4,000, $201,000 and $735,000 were charged to cost of product sales, research and development and selling, general and administrative expense, respectively. During the three months ended March 31, 2006, we recognized $820,000 of stock-based compensation expense, of which $1,000, $144,000 and $675,000 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 $267.71 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 March 31, 2007 was $7.2 million, and the weighted-average period over which these grants are expected to vest is 2.7 years.

Based on an assumed initial public offering price of $25.00 per share, the intrinsic value of stock options outstanding at March 31, 2007 was $12.6 million, of which $7.0 million and $5.6 million related to stock options that were vested and unvested, respectively, at that date.

Beneficial Conversion Feature

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

Accrued Expenses

As part of the process of preparing financial statements, we are required to estimate accrued expenses. This process involves identifying services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for such service as of each balance sheet date in our financial statements. Examples of estimated accrued expenses include marketing and promotional materials, professional service fees, such as fees to lawyers and accountants, and contract service fees, such as amounts paid to clinical monitors, data management organizations, clinical research organizations and fees paid to contract manufacturers in conjunction with the production of clinical materials. In connection with such service fees, our estimates are most affected by our understanding of the status and timing of services provided relative to the actual levels of services incurred by such service providers. The majority of our service providers invoice us monthly in arrears for services performed. In the event that we do not identify certain costs that have begun to be incurred or we under- or overestimate the level of services performed or the costs of such services, our reported expenses for such period would be too low or too high. The date on which certain services commence, the level of services performed on or before a given date and the cost of such services are often subject to our judgment. We make these judgments in accordance with the facts and circumstances known to us through our internal processes. Our internal processes require substantially all of our spending for services to be under contracts with our service providers and to be documented and tracked under internally-generated purchase orders based on designated spending authorizations. As of each balance sheet date, company personnel who are responsible for managing the contracts, and who are in contact with the outside service providers as to progress or stage of completion of the services and the agreed upon fee to be paid for such services, review current contracts and the related open purchase orders. We adjust for spending not already reflected in our accounting records in accordance with generally accepted accounting principles. To date, there have been no material differences between the amounts of expenses accrued at our balance sheet dates and the amount at which such expenses were subsequently invoiced. Although we do not expect our current estimates to be materially different when invoiced, our understanding of the status and timing of services provided relative to the actual timing and levels of service provided may vary and may result in adjustments in future periods.

In-Process Research and Development

In connection with the acquisition of Orphan Medical, we recorded a charge of $21.3 million in 2005 for acquired in-process research and development. This amount represented the estimated fair value related to three

incomplete product candidate development projects for which technological feasibility had not been established and that had no alternative future use at the time of the acquisition.

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

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

Results of Operations

Comparison of Three Months Ended March 31, 2006 and 2007

	2006	2007	Increase/ (Decrease)	% Increase/ (Decrease)
		(In thousands)		
Product sales, net	$ 9,771	$11,625	$ 1,854	19%
Royalties, net	66	211	145	220%
Contract revenues	—	2,252	2,252	N/A(1)
Cost of product sales	1,569	2,003	434	28%
Research and development expenses	12,894	14,867	1,973	15%
Selling, general and administrative expenses	12,219	14,339	2,120	17%
Amortization of intangible assets	2,400	2,362	(38)	(2)%
Interest income	581	1,091	510	88%
Interest expense	3,777	3,268	(509)	(13)%
Other income (expense)	62	(3,069)	(3,131)	N/A(1)
Gain on sale of product	—	5,145	5,145	N/A(1)

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

Product Sales, Net

The increase in product sales, net in the three months ended March 31, 2007 compared to the three months ended March 31, 2006 was primarily due to the growth of our Xyrem product sales, which increased by $2.5 million. The increase in Xyrem product sales was attributable to an increase in the price we charge Express Scripts instituted in August 2006 and, we believe, our investments in Xyrem marketing programs and sales training programs during 2006. Sales of Antizol and Antizol-Vet decreased by $495,000 in the three months ended March 31, 2007 compared to the three months ended March 31, 2006. Antizol is stocked by hospitals for use in emergency poisonings and sales are typically uneven from quarter to quarter. Sales of Cystadane decreased

by $122,000 in the three months ended March 31, 2007 compared to the three months ended March 31, 2006. This decrease resulted from the sale of our rights to Cystadane in March 2007.

Royalties, Net

The increase in royalties, net in the three months ended March 31, 2007 compared to the three months ended March 31, 2006 was primarily due to an increase in royalties on sales of Xyrem by UCB from $19,000 in the three months ended March 31, 2006 to $127,000, the pro rata portion of the minimum royalty payable pursuant to the agreement with UCB, in the three months ended March 31, 2007.

Contract Revenues

Contract revenues in the three months ended March 31, 2007 consisted of a $2.0 million milestone payment from UCB in March 2007, triggered by regulatory approval of Xyrem in Europe for the treatment of narcolepsy with cataplexy, and $252,000 related to the amortization of deferred revenues on $15.0 million of payments received in the second half of 2006 from UCB related to JZP-6. There were no contract revenues recognized in the three months ended March 31, 2006.

Cost of Product Sales

The increase in cost of product sales in the three months ended March 31, 2007 compared to the three months ended March 31, 2006 was primarily due to an increase in product sales. Cost of product sales in the three months ended March 31, 2007 increased to 17.2% of product sales as compared to 16.1% of product sales in the three months ended March 31, 2006, primarily due to a failed production run of Antizol.

Research and Development Expenses

Higher research and development expenses in the three months ended March 31, 2007 as compared to the three months ended March 31, 2006 resulted primarily from our initial $2.0 million payment to Solvay in January 2007 for the exclusive right to market and distribute Luvox CR and Luvox in the United States under the terms of a product license agreement.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were higher in the three months ended March 31, 2007 as compared to the three months ended March 31, 2006 primarily due to growth in headcount. This growth resulted in a $1.2 million increase in salaries and benefits and a $1.3 million related increase in departmental operating expenses. In addition, selling, general and administrative expenses in the three months ended March 31, 2007 include $1.0 million of legal costs associated with the U.S. Attorney's investigation of activities by Orphan Medical related to the promotion of Xyrem. These increases were partially offset by a decrease of $1.4 million in product launch costs associated with an expanded label indication of Xyrem for the treatment of excessive daytime sleepiness in patients with narcolepsy that we incurred in the three months ended March 31, 2006.

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, that are amortized on a straight-line basis over their estimated useful lives. Amortization costs in the three months ended March 31, 2007 were lower as compared to the three months ended March 31, 2006 as a result of the sale of our rights to Cystadane in March 2007.

Interest Income

Interest income was higher in the three months ended March 31, 2007 as compared to the three months ended March 31, 2006 primarily due to higher average cash balances.

Interest Expense

Interest expense in the three months ended March 31, 2007 primarily related to interest on our $80.0 million principal amount of senior secured notes. 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. In the three months ended March 31, 2006, interest expense also included $599,000 of accrued interest on the development financing of JZP-3.

Other Income (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 $3.1 million of expense and a benefit of $62,000 in the three months ended March 31, 2007 and March 31, 2006, respectively. 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' equity (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' equity.

Gain on Sale of Product

In March 2007, we entered into an agreement under which an unrelated third party purchased our rights to Cystadane, along with the associated product registrations, commercial inventory and trademarks, for $9.0 million in cash. In connection with this transaction, we recorded a $5.1 million gain in the three months ended March 31, 2007.

Comparison of Years Ended December 31, 2005 and 2006

	2005	2006	Increase/ (Decrease)	% Increase/ (Decrease)
		(In thousands)		
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

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

Contract Revenues

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

Cost of Product Sales

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

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.

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, both of which were recorded using the effective interest method. $5.6 million of the increase in interest expense in 2006 as compared to 2005 was attributable to the fact the notes were outstanding for the full year in 2006. Interest expense related to the development financing was $445,000 in 2005, compared with $1.1 million 2006.

Other Expense

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

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.

Comparison of Years Ended December 31, 2004 and 2005

	2004	2005 (In thousands)	Increase	% Increase
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 European Agency for the Evaluation of Medical Products 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

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 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 March 31, 2007, we had an accumulated deficit of $197.2 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 $375.0 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 2006 – March 2007	3,104	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 785,728 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 to June 2011 by paying a premium, which was 28.3% of the principal amount of the notes as of March 31, 2007 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, 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 March 31, 2007. At March 31, 2007, $3.1 million was outstanding under the agreement. See Note 7 to our financial statements appearing elsewhere in this prospectus for additional information.

As of March 31, 2007, we had $67.7 million in cash and cash equivalents, excluding $12.4 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 the periods indicated:

	Years ended December 31,			Three Months Ended March 31,	
	2004	2005	2006	2006	2007
			(In thousands)	(Unaudited)	
Cash provided by (used in):					
Operating activities	$(21,156)	$ (52,162)	$ (57,350)	$(21,913)	$(20,914)
Purchases of property and equipment	(992)	(1,413)	(1,682)	(121)	(271)
Acquisition of Orphan Medical	—	(146,116)	—	—	—
Other investing activities	(5,796)	(6,225)	175	—	8,915
Financing activities	57,162	192,852	117,191	49,994	989

Net cash used in operating activities during the three months ended March 31, 2007 primarily reflected the net loss and changes in working capital, offset in part by depreciation and amortization and the change in the preferred stock warrant liability. 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 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. In addition, investing activities during the three months ended March 31, 2007 included proceeds of $9.0 million from the sale of our rights to Cystadane. 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;
- 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 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:

	Payments due by period				
Contractual Obligations(1)	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
			(In thousands)		
Senior secured notes(2)	$ 133,800	$12,000	$24,000	$97,800	$ —
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	—	—	—
Total	$139,945	$16,961	$25,167	$97,817	$ —

(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 include interest and principal repayments on these notes. See Note 7 to our consolidated financial statements appearing elsewhere in this prospectus for additional information.

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

- In January 2007, we entered into a product license agreement with Solvay for the right to market and distribute Luvox and Luvox CR in the United States. Under the terms of the agreement, we made a $2.0 million payment upon execution of the agreement, and we are required to make additional payments of up to $138.0 million if various commercial and development milestones are achieved. These payments include $10.0 million triggered by FDA marketing approval for the first indication for Luvox CR, $5.0 million triggered by FDA marketing approval for the second indication for Luvox CR, $13.0 million triggered by the first commercial sale of Luvox CR, $8.0 million triggered by the first commercial sale of Luvox CR after FDA approval of the second indication and $5.0 million triggered by FDA approval of a Luvox CR label with expiration dating of at least 18 months, any or all of which could occur in late 2007 or early 2008. 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 acquire worldwide rights to the active pharmaceutical ingredient in JZP-4. We paid $2.0 million upon execution of the agreement and $3.0 million in July 2006 upon achievement of a development milestone. We also agreed to pay up to $113.5 million upon the achievement of future development and commercial milestones and royalties at specified rates based on net product sales. We will owe a $5.0 milestone payment to GlaxoSmithKline upon the enrollment of the first patient in a JZP-4 Phase II clinical trial, which could occur as early as late 2007.

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. We adopted the provisions of FIN 48 effective January 1, 2007. No cumulative adjustment to our accumulated deficit was required upon adoption.

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 was adopted by us in the first quarter of 2007. We have determined that the adoption of SAB 108 has no material effect 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.

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

Off-Balance Sheet Arrangements

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.

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 March 31, 2007 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.

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 marketed products 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. 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. 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 12 countries. In 2006, Xyrem represented $29.0 million, or 69%, of our net product sales from our currently marketed products.
- *Antizol (fomepizole)*. Antizol is the only FDA-approved antidote for suspected or confirmed ethylene glycol or methanol poisonings in humans. We market Antizol primarily to hospitals and emergency rooms. Antizol is distributed to wholesalers in the United States, and we retain the services of a third party to promote the product. Antizol is marketed by our distributors in Canada and Israel. We also market Antizol-Vet, an injectable formulation of fomepizole approved as an antidote for suspected or confirmed ethylene glycol poisonings in dogs. In 2006, Antizol and Antizol-Vet represented $12.8 million, or 31%, of our net product sales from our currently marketed products.
- *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, which has been developed for the treatment of obsessive compulsive disorder and social anxiety disorder. Selective serotonin reuptake inhibitors are a class of antidepressants used in the treatment of depression, anxiety disorders and some personality disorders. According to the National Institute of Mental Health, obsessive compulsive disorder and social anxiety disorder affect approximately 2.2 million and 15 million adults in the United States, respectively. Luvox CR was developed by Solvay Pharmaceuticals, Inc., or Solvay, in collaboration with Elan Pharma International Limited, or Elan. We obtained the exclusive rights to market and distribute Luvox CR in the United States from Solvay in January 2007. Solvay retains the rights to market and distribute Luvox CR outside of the United States. 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 to Solvay. Subject to the satisfaction

of the 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 in Xyrem, for the treatment of fibromyalgia syndrome. According to the American College of Rheumatology, between two and four percent of the U.S. population suffers from fibromyalgia syndrome. There are currently no products approved by the FDA for the treatment of fibromyalgia syndrome. We have successfully completed a Phase II clinical trial of this product candidate for the treatment of fibromyalgia syndrome. 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 accepted by the FDA and the European Agency for the Evaluation of Medicinal Products 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 expect to market JZP-6 in the United States to rheumatologists and other specialists who treat fibromyalgia syndrome 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 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 recurrent acute repetitive seizures in epilepsy patients who have been unresponsive to previous treatments. Recurrent acute repetitive seizures are bouts of multiple seizures occurring over a short period of time. According to an article published in the *New England Journal of Medicine*, approximately 30% of epilepsy patients are unresponsive, or refractory, to treatment despite being on an effective dose of an antiepilepsy regimen, and a subset of these refractory patients experience recurrent acute repetitive seizures.
- *JZP-7 (dopamine agonist).* JZP-7, a novel formulation incorporating a dopamine agonist, is being developed for the treatment of restless legs syndrome. Dopamine is naturally produced by the human body, and in the brain, dopamine functions to help nerve cells communicate. A dopamine agonist is a drug compound that mimics the effects of dopamine. According to the Restless Legs Syndrome Foundation, up to 10% of the U.S. population suffers from restless legs syndrome.
- *JZP-2 (benzodiazepine).* JZP-2, a formulation of a benzodiazepine that is designed to enter the bloodstream faster than a dose from a conventional tablet form, is being developed for the acute, or short-term, treatment of panic attacks associated with panic disorder. Benzodiazepines are a class of psychoactive drugs with varying hypnotic, sedative, anti-anxiety, anticonvulsant, muscle relaxant and amnesic properties. 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 active pharmaceutical ingredient in Xyrem, for the treatment of movement disorders. We are working on ways to expand our Xyrem franchise by developing improvements to Xyrem, such as new dosage forms that could be more convenient for patients. These activities are in the early stages of development.

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 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 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 fibromyalgia syndrome 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.

Products and Product Candidates

Product/Product Candidate	Active Pharmaceutical Ingredient/Mechanism of Action	Primary Indication(s)	Status	Commercialization Rights
Xyrem	Sodium oxybate	Cataplexy and excessive daytime sleepiness in patients with narcolepsy	Marketed	U.S. and countries not licensed to UCB or Valeant
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	Recurrent acute repetitive seizures	Phase 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 active pharmaceutical ingredient in Xyrem, is a formulation of the sodium salt of g-hydroxybutyrate, an endogenous neurotransmitter and metabolite of g-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.

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. As published in *SLEEP* in 2002, the 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. As published in *Sleep Medicine* in 2004, clinical trial results indicated that Xyrem is an effective treatment for the long-term management of cataplexy in patients with narcolepsy.

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 $9.5 million in connection with Xyrem for the treatment of narcolepsy. UCB has commercially launched the product in 12 countries. In October 2005, the European Agency for the Evaluation of Medical Products approved the product for the treatment of cataplexy in adult patients with narcolepsy, and in March 2007, the European Agency for the Evaluation of Medical Products 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 fibromyalgia syndrome in exchange for additional upfront and milestone payments. We are entitled to additional commercial milestone payments of up to $6.0 million specifically associated with Xyrem and royalties on all commercial sales of Xyrem 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 European

Agency for the Evaluation of Medical Products 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. A patent application covering Xyrem's distribution system is currently pending, and the patent, if issued, would expire in 2022. In addition, we believe that the strict manufacturing and distribution controls on sodium oxybate and Xyrem, and the complicated risk management procedures required to market and sell the product, may make it difficult for other companies to manufacture and market generic formulations of Xyrem.

Our marketing and sale of Xyrem is subject to a risk management program required by the FDA and the U.S. Drug Enforcement Agency, or DEA, in conjunction with Xyrem's approval by the FDA. Under the Xyrem risk management program, Xyrem must be distributed through a single central pharmacy, Express Scripts Specialty Distribution Services, Inc., or Express Scripts. The central pharmacy must maintain physician and patient registries, and the product may not be stocked in retail pharmacies. Each physician and patient must be educated about the risks and benefits of the product before the physician can prescribe, or a patient can receive, Xyrem. Whenever a prescription is received by the central pharmacy, the central pharmacy must verify the prescription and obtain additional information by contacting the physician's office and the patient's insurance company. The central pharmacy must also speak with the patient before it can ship any Xyrem to the patient. The central pharmacy must ship the product directly to the patient by a courier service, and the patient or his/her designee must sign for the package. The initial shipment may only be for a one-month supply, and patients may not receive more than a three-month supply at any time.

Pursuant to our agreement with Express Scripts, Express Scripts provides distribution and other customer support services to us related to the sale and marketing of Xyrem in the United States. We are billed monthly for the services performed by Express Scripts. The term of the agreement with Express Scripts expires on July 31, 2008, subject to automatic one-year extensions thereafter until either party provides notice to the other of its intent to terminate the agreement at least 120 days prior to the end of the term. We may terminate the agreement with Express Scripts upon five days' notice if Express Scripts is not in compliance with applicable regulatory requirements.

We have contracted separately with third parties to supply the sodium oxybate used to produce Xyrem and to manufacture the product. We rely on a single source for our supply of sodium oxybate. Quotas from the 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.

Competition

As an alternative to Xyrem, cataplexy is often treated with tricyclic antidepressants and selective serotonin reuptake inhibitors, although none of these compounds has been approved by the FDA for the treatment of cataplexy. Tricyclic antidepressants are a class of antidepressant drugs first used in the 1950s. The use of these drugs can often result in somnolence, which exacerbates excessive daytime sleepiness already experienced by all patients with narcolepsy. Other treatments for excessive daytime sleepiness in patients with narcolepsy consist primarily of stimulants and wakefulness promoting agents, including Provigil (modafinil). Xyrem and Provigil are both approved for the treatment of excessive daytime sleepiness in patients with narcolepsy, but Xyrem is also approved for the treatment of cataplexy, the most well-recognized symptom of narcolepsy. Provigil is also approved for the treatment of excessive daytime sleepiness in patients with obstructive sleep apnea/hypopnea syndrome and shift work sleep disorder, which may help make it more well-known to physicians and patients.

Xyrem is a liquid solution that is taken twice nightly. Provigil is a pill that is usually taken once in the morning for excessive daytime sleepiness by patients with narcolepsy. Provigil is distributed by numerous pharmacies. Xyrem's risk management program requires that it be distributed in the United States through a single central pharmacy, and it takes longer for a patient to receive medicine under the Xyrem distribution system than it takes to fill a typical prescription at a pharmacy. Xyrem is administered at night and can be used in conjunction with Provigil, which is administered during the day. During the pivotal Phase III trials of Xyrem, approximately 80% of patients maintained concomitant stimulant use, and clinical trial results indicated that Xyrem reduced the severity of daytime sleepiness when used alone or in combination with stimulants during the day.

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.

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.

Product Candidates

Luvox CR (fluvoxamine maleate extended release capsules)

In January 2007, we licensed from Solvay the exclusive rights to market and distribute Luvox CR in the United States. Solvay retains the rights to market and distribute Luvox CR outside of the United States. Luvox CR, an extended release formulation of fluvoxamine maleate developed by Solvay in collaboration with Elan, is a selective serotonin reuptake inhibitor for which Solvay is seeking approval from the FDA for the treatment of obsessive compulsive disorder and social anxiety disorder. Luvox, an immediate release formulation of fluvoxamine maleate, was previously approved by the FDA and marketed by Solvay for the treatment of obsessive compulsive disorder, and generic fluvoxamine remains one of the leading treatments for the disorder. Luvox CR incorporates 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 to Solvay for Luvox CR setting forth certain conditions necessary for receiving approval to market Luvox CR for the treatment of obsessive compulsive disorder and social anxiety disorder. 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. Obsessive compulsive disorder is a chronic anxiety disorder characterized by persistent, unwanted thoughts, or obsessions, and repetitive behaviors or rituals, or compulsions. According to the National Institute of Mental Health, Obsessive compulsive disorder affects approximately 2.2 million adults in the United States. According to an article published in the *International Journal of Clinical Practice*, it is estimated that 60% of patients with obsessive compulsive disorder worldwide receive no treatment for their disorder. As physicians have improved their ability to recognize symptoms, the number of diagnosed cases of obsessive compulsive disorder has increased by 78% from 1995 to 2005, as measured by the 2005 Physicians Drug and Diagnosis Audit conducted by Verispan, Inc. Patients with obsessive compulsive disorder use rituals to help control anxiety related to their obsessive thoughts, and these rituals become disruptive to their daily life. While these patients often realize that their obsessions and compulsions are irrational or excessive, they frequently have little or no control over them. Typical obsessions include concerns with dirt, germs and contamination, fear of acting on violent or aggressive impulses or feeling overly responsible for the safety of others. Rituals adopted by obsessive compulsive disorder patients may provide them with transient relief from anxiety, but the rituals do not provide sustained comfort. Frequently, the rituals become so overwhelming that patients are unable to function normally in their daily lives. Symptoms of obsessive compulsive disorder typically appear in childhood, adolescence or early adulthood. According to an article published in the *Journal of Clinical Psychiatry*, a significant portion of obsessive compulsive disorder patients are believed to have one or more concomitant psychiatric disorders, such as depression or social anxiety disorder.

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

Competition

Selective serotonin reuptake inhibitors have become the standard treatment for anxiety disorders, including obsessive compulsive disorder and social anxiety disorder. According to the Pharmaceutical Audit Suite published by Wolters Kluwer Health, more than 142 million total prescriptions were written for selective serotonin reuptake inhibitors and serotonin-norepinephrine reuptake inhibitors in the United States in 2006, accounting for approximately $16 billion in sales. Serotonin-norepinephrine reuptake inhibitors are a class of antidepressants used in the treatment of clinical depression and sometimes used to treat anxiety disorders, obsessive compulsive disorder and other conditions. Since the approval of Prozac (fluoxetine) in the United States in 1987, the use of selective serotonin reuptake inhibitors and serotonin-norepinephrine reuptake inhibitors 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 selective serotonin reuptake inhibitor and serotonin-norepinephrine reuptake inhibitor prescriptions are for the treatment of depression and that obsessive compulsive disorder and social anxiety disorder constitute approximately three percent of total selective serotonin reuptake inhibitor and serotonin-norepinephrine reuptake inhibitor prescriptions.

Four branded products are currently approved by the FDA for the treatment of obsessive compulsive disorder, including three selective serotonin reuptake inhibitors: Paxil (paroxetine HCl), which is marketed by GlaxoSmithKline, Zoloft (sertraline HCl), which is marketed by Pfizer, and Prozac (fluoxetine hydrochloride), which is marketed by Eli Lilly. Anafranil (clomipramine hydrochloride), the other branded product approved by the FDA for the treatment of obsessive compulsive disorder, is a tricyclic antidepressant marketed by Mallinckrodt in the United States. The relative use of each of these products for the treatment of obsessive compulsive disorder has varied over the past ten years, and each currently has generic equivalents. Generic products are generally sold at significantly lower prices than branded products, tending to both take market share away from branded products and put downward pricing pressure on branded products. Fluvoxamine, the generic equivalent of Luvox and a selective serotonin reuptake inhibitor, is the only other drug currently approved for the treatment of obsessive compulsive disorder.

Based on data from the 2006 Physicians Drug and Diagnosis Audit, we estimate that fluvoxamine use represented approximately 11% of total drug usage for the treatment of obsessive compulsive disorder in 2006. Prior to the introduction of generic fluvoxamine in 2000, Luvox was considered one of the preferred treatments of obsessive compulsive disorder. Based on data from the 2005 Physicians Drug and Diagnosis Audit, we estimate that Luvox accounted for 21% of total drug usage for the treatment of obsessive compulsive disorder in 1999.

The market for drugs to treat obsessive compulsive disorder is extremely fragmented. Based on data from the 2006 Physicians Drug and Diagnosis Audit, we estimate that Paxil, Zoloft, Prozac and Anafranil (and each of their generic equivalents) and fluvoxamine accounted for 48% of the total drug usage for the treatment of obsessive compulsive disorder in 2006. Although not FDA-approved for the treatment of obsessive compulsive disorder, based on data from the 2006 Physicians Drug and Diagnosis Audit, we estimate that more than 15 additional products and their generic equivalents accounted for over 47% of total drug usage for the treatment of obsessive compulsive disorder in 2006. Given the prevalence of generic products, in order to gain significant market acceptance, we will need to demonstrate that the benefits of Luvox CR to patients justify the higher price of a branded product.

Four products are currently approved by the FDA for the treatment of social anxiety disorder, including three selective serotonin reuptake inhibitors: Zoloft, Paxil and Paxil CR, an extended release version of Paxil, and one serotonin-norepinephrine reuptake inhibitor, Effexor XR (venlafaxine HCl). Paxil CR and Effexor XR, developed and sold by GlaxoSmithKline and Wyeth, respectively, do not have generic equivalents, whereas Paxil and Zoloft have generic equivalents. Paxil CR was approved for the treatment of social anxiety disorder in 2003, and Effexor XR was approved for the treatment of social anxiety disorder in 2003.

Based on limited data from the 2005 Physicians Drug and Diagnosis Audit, we estimate that Paxil CR use represented approximately 5%, and Effexor XR use represented approximately 9%, of total drug usage for the

treatment of social anxiety disorder in 2006. As is the case with obsessive compulsive disorder, the market for drugs to treat social anxiety disorder is extremely fragmented. Based on data from the 2006 Physicians Drug and Diagnosis Audit, we estimate that Zoloft, Paxil and their generic equivalents, and Paxil CR and Effexor XR, in the aggregate accounted for only 27% of the total drug usage for the treatment of social anxiety disorder in 2006. Although they are not approved for the treatment of social anxiety disorder, based on data from the 2006 Physicians Drug and Diagnosis Audit, we estimate that approximately 18 other products accounted for over 59% of total drug usage for the treatment of social anxiety disorder in 2006. As with obsessive compulsive disorder, in order to gain significant market acceptance, we will need to demonstrate that the benefits of Luvox CR to patients justify the higher price of a branded product.

The presence in a particular patient of more than one psychiatric condition is an important consideration by physicians in the selection of drugs to treat social anxiety disorder. For patients with multiple conditions, a selective serotonin reuptake inhibitor or a serotonin-norepinephrine reuptake inhibitor with demonstrated efficacy in multiple indications is generally the preferred treatment option. Zoloft, Paxil, Paxil CR and Effexor XR are approved for additional psychiatric disorders, such as depression, in addition to social anxiety disorder, which may give them broader recognition by physicians and patients. These products therefore may be more likely to be prescribed than Luvox CR which, if approved, would at most be indicated for the treatment of obsessive compulsive disorder and social anxiety disorder.

Although selective serotonin reuptake inhibitors have a favorable side-effect profile compared to other classes of agents, the current selective serotonin reuptake inhibitor products used to treat obsessive compulsive disorder and social anxiety disorder, particularly those formulated for immediate release, all have significant adverse side effects. Adverse side effects associated with selective serotonin reuptake inhibitors include nausea, sleep disturbances, sexual dysfunction, weight gain, adverse drug interactions, risk of hypertension and, in adolescents, increased suicidal tendencies. Selective serotonin reuptake inhibitors 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 selective serotonin reuptake inhibitors 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 obsessive compulsive disorder and for its introduction for the treatment of social anxiety disorder, and that Luvox CR offers a compelling opportunity to improve upon existing formulations of fluvoxamine, the active pharmaceutical ingredient in Luvox CR, in treating these disorders. Fluvoxamine, in its immediate release form, is already a broadly prescribed therapy for the treatment of obsessive compulsive disorder. The market potential for Luvox CR is demonstrated by the significant ongoing prescription rates for the generic formulations of fluvoxamine despite the absence of active marketing and sales activity. 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 social anxiety disorder.

In a Phase III clinical trial for obsessive compulsive disorder, patients taking Luvox CR demonstrated a statistically significant improvement compared to patients receiving placebo as assessed by the Yale-Brown Obsessive Compulsive Scale as early as week two of the trial. In Phase III clinical trials for social anxiety disorder, patients receiving Luvox CR demonstrated statistically significant improvement compared to patients receiving placebo as assessed by the Liebowitz Social Anxiety Scale total score 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.

Product Development

In January 2007, we licensed the exclusive rights to market and distribute Luvox CR in the United States 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 obsessive compulsive disorder and social anxiety disorder. Under our agreement with Solvay, Solvay retains primary responsibility for the NDA for Luvox CR and communications with the FDA until after such time, if ever, as the FDA approves the NDA. In February 2007, the FDA issued an approvable letter for Luvox CR to Solvay. 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 active pharmaceutical ingredient 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 social anxiety disorder and a long-term safety study. We, with Solvay, will also need to finalize product labeling with the FDA. Under 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.

Obsessive Compulsive Disorder Phase III Clinical Trial Results. Solvay conducted one Phase III pivotal clinical trial with Luvox CR for the treatment of obsessive compulsive disorder. Since fluvoxamine is currently approved for the treatment of obsessive compulsive disorder, the FDA only requires one successful Phase III trial for approval of the extended release formulation for use in obsessive compulsive disorder. In the 12-week, multi-center, placebo-controlled trial of roughly 250 patients, patients receiving Luvox CR demonstrated statistically significant improvements on the Yale-Brown Obsessive Compulsive Scale compared to patients receiving placebo as early as week two of the study. The Yale-Brown Obsessive Compulsive Scale 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 Yale-Brown Obsessive Compulsive Scale has been the primary outcome measure in virtually all multi-center clinical trials of selective serotonin reuptake inhibitors for the treatment of obsessive compulsive disorder. The Luvox CR group mean total change from baseline on the Yale-Brown Obsessive Compulsive Scale was -8.5 compared to -5.6 for placebo, for a p-value of $p<0.01$ 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.

Social Anxiety Disorder Phase III Clinical Trial Results. The effectiveness of Luvox CR in the treatment of social anxiety disorder 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 Liebowitz Social Anxiety Scale. The Liebowitz Social Anxiety Scale 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 Liebowitz Social Anxiety Scale 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 Liebowitz Social Anxiety Scale total score as early as week four of the study. As presented in the *Journal of Clinical Pharmacology* in April 2004, in one study of 279 patients, mean change in the Liebowitz Social Anxiety Scale total score was -26.7 for Luvox CR and -12.9 for placebo, for a p-value of $p<0.01$ at 12

weeks. As presented in the *Journal of Clinical Pharmacology* in February 2004, in the other study of 300 patients, mean change in the Liebowitz Social Anxiety Scale 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 expect to commence promotion in the United States in the first quarter of 2008. To effectively market Luvox CR, we intend to significantly expand our already established specialty sales force. A substantial majority of prescriptions for the treatment of obsessive compulsive disorder and social anxiety disorder are written by psychiatrists. We believe that this concentration provides an attractive, focused market opportunity for us.

Through our license agreement with Solvay, we have obtained the exclusive rights to market and distribute Luvox CR in the United States, and Solvay retained the rights to market and distribute Luvox CR outside of the United States. In addition, Solvay assigned to us its rights and obligations under its license and supply agreement with Elan, and we have sublicensed back to Solvay the rights under that agreement outside of the United States. If Solvay decides not to pursue marketing of Luvox CR in any countries to which it has rights, we have a right of first offer with respect to any license of rights to market and distribute Luvox CR in those countries. Pursuant to a supply agreement with Solvay, we are responsible for purchasing, and Solvay is responsible for providing us with, the active pharmaceutical ingredient necessary to manufacture Luvox CR. We are responsible for providing the active pharmaceutical ingredient free of charge to Elan pursuant to the license and supply agreement with Elan. Pursuant to that license and supply agreement with Elan, Elan has the right and obligation to manufacture the worldwide commercial requirements of Luvox CR. We will be responsible for satisfying Solvay's commercial requirements of Luvox CR outside of the United States in exchange for supply price payments to us. We paid Solvay $2.0 million upon signing of the license agreement, and we are obligated to pay Solvay up to $138.0 million in development and commercial milestone payments associated with Luvox CR, as well as royalties on any net product sales. Up to $41.0 million of the milestone payments are payable at or prior to commercial launch. We are obligated to pay Elan development and commercial milestone payments, royalties on net product sales and supply price payments for the supply of Luvox CR. Solvay will be responsible for paying us for a portion of any payments due to Elan under the license and supply agreement with Elan, including those payments that relate to the countries in which Solvay holds marketing and distribution rights, as well as certain remaining development milestones owed to Elan.

Our license and supply agreements with Solvay will remain in force until terminated by either us or Solvay as a result of an uncured breach by the other party. We may also terminate the agreements with Solvay if the FDA has not approved Luvox or Luvox CR by a date specified in the license agreement or upon 180 days' notice to Solvay. The license and supply agreement with Elan that was assigned to us by Solvay will expire upon the later of 10 years after commercial launch of Luvox CR, or the last to expire patent licensed under the agreement with Elan.

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)

In January 2007, we licensed from Solvay the exclusive rights to market and distribute Luvox in the United States. Solvay retains the rights to market and distribute Luvox CR outside of the United States. Luvox, an immediate release formulation of fluvoxamine maleate, was approved by the FDA for the treatment of obsessive compulsive disorder 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 obsessive compulsive disorder. 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 license agreement with Solvay, we have the right to market and distribute Luvox in the United States and to manufacture or to have manufactured Luvox for use and sale 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 obsessive compulsive disorder. In the event that we market Luvox supplied to us by Solvay 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 active pharmaceutical ingredient in Xyrem, for the treatment of fibromyalgia syndrome. We are currently conducting two Phase III pivotal clinical trials for JZP-6 in fibromyalgia syndrome. We have completed a Phase II clinical trial for JZP-6 in which fibromyalgia syndrome 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 as the primary endpoint for our Phase III pivotal clinical trials.

Market Opportunity

Fibromyalgia syndrome is a chronic pain syndrome defined by widespread pain lasting at least three months. According to the American College of Rheumatology between two and four percent of the U.S. population suffers from fibromyalgia syndrome. Fibromyalgia syndrome is believed to be a central nervous system condition. In addition to pain, fibromyalgia syndrome 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 fibromyalgia syndrome, it may be triggered by physical trauma, emotional stress or infection. The criteria established by the American College of Rheumatology for the classification of fibromyalgia require the application of pressure at 18 different points on the body and measurement of pain induced by such pressure. If at least 11 of the 18 points are painful and have been painful for three months, the patient is diagnosed with fibromyalgia syndrome.

Competition

There are currently no products approved by the FDA for the treatment of fibromyalgia syndrome. In clinical practice, a variety of drugs are often prescribed to address individual symptoms of fibromyalgia syndrome, including antidepressants, pain medications, muscle relaxants, hypnotics and anticonvulsants. Based on available market data, we estimate that more than 6.3 million total prescriptions were written to treat fibromyalgia syndrome symptoms in 2006, of which approximately 32% were for antidepressants, 25% were for opioids and 30% were for muscle relaxants. Physicians generally prescribe one or more drug therapies based on the dominant symptom or symptoms of fibromyalgia syndrome in a particular patient. This “polypharmacy” approach has significant limitations as none of the current therapies used to address the symptoms of fibromyalgia syndrome 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 fibromyalgia syndrome. 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 fibromyalgia syndrome, or certain symptoms associated with fibromyalgia syndrome.

Attributes of JZP-6

JZP-6 is being developed to provide an effective treatment for fibromyalgia syndrome and pain associated with fibromyalgia syndrome. While the primary symptom of fibromyalgia syndrome 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 European Agency for the Evaluation of Medical Products 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 follows: by the FDA as a greater than 20%, and by the European Agency for the Evaluation of Medical Products as a greater than 30%, reduction in the pain visual analog scale; by the FDA as a greater than 20%, and by the European Agency for the Evaluation of Medical Products as a greater than 30%, improvement in the fibromyalgia impact questionnaire score; and by the FDA and the European Agency for the Evaluation of Medical Products as 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 fibromyalgia syndrome 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 was a composite of change from baseline in three co-primary measures of patients' pain: the pain visual analog scale, the fibromyalgia impact questionnaire and patient global impression of change. Secondary endpoints included measurement of a tender point count, tender point index, Epworth sleepiness scale, Jenkins scale for sleep, global score on the functional outcome of sleep questionnaire, severity of fatigue and clinical global impression of change. The Phase II clinical trial demonstrated significant improvement in the composite endpoint results in both dosage strengths. In addition, the study demonstrated significant improvements in secondary measures of fatigue, sleepiness and sleep quality. There were no unexpected adverse events in the study.

JZP-6 also demonstrated statistically significant improvement in each of the co-primary measures that comprise the composite endpoint in either one or both dosage strengths. The visual analog scale is a self-assessed measurement of pain in which zero is no pain at all and 100 is the worst pain experienced. The baseline pain for the fibromyalgia syndrome 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 at least 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 31, 2007, more than 100 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 fourth 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 fibromyalgia syndrome or other, more limited indications such as pain associated with fibromyalgia syndrome.

Commercialization Strategy

If JZP-6 is approved by the FDA, we believe that the majority of prescriptions for the product to treat fibromyalgia syndrome 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 fibromyalgia syndrome.

In 2006, we amended our agreement with UCB to grant UCB the right to market JZP-6 for the treatment of fibromyalgia syndrome 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 fibromyalgia syndrome. We are entitled to up to $40.0 million in additional development milestone payments associated with JZP-6, and additional commercial milestone payments of up to $100.0 million related primarily to JZP-6 for the treatment of fibromyalgia syndrome as well as Xyrem for the treatment of narcolepsy. The term of our agreement with UCB, as it applies to JZP-6, extends to the later of the expiration of our associated patent rights in the territories covered by the agreement or ten years from the date of European Agency for the Evaluation of Medical Products approval to commercially promote and distribute the product for the treatment of fibromyalgia syndrome, subject to automatic extension unless UCB provides 12 months' notice. UCB may terminate our agreement for any reason upon 18 months' notice. We are responsible for supplying commercial quantities of JZP-6 to UCB in exchange for supply price payments. If we are unable to comply with our obligations to supply JZP-6 to UCB, UCB has the right under certain circumstances to terminate our agreement upon nine months' notice.

Pursuant to our agreement with Valeant, Valeant has the option to acquire the rights to market JZP-6 for treatment of fibromyalgia syndrome 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 active pharmaceutical ingredient 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 fibromyalgia syndrome. 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 antiepileptic drug 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 a proof of concept clinical trial, long-term toxicology studies and formulation 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 the Pharmaceutical Audit Suite. 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.

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 antiepileptic drugs were sold for the treatment of bipolar disorder in 2005. People suffering from the condition experience dramatic mood swings from an overly “high” mania state to an overly “low” or depressive state, often with periods of normal mood in between.

Competition

Epilepsy. Seizures in epileptic patients are typically controlled by treatment with one or more antiepileptic drugs. 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 antiepileptic drugs, the remaining patients fail treatment either because the drugs do not stop their seizures or because they cannot tolerate the side effects. These patients usually end up taking more than one antiepileptic drug at a time and are therefore more susceptible to adverse effects associated with drug interactions. Selection of the appropriate medication for an individual patient is typically based on the type of epilepsy from which a patient suffers, the genesis of the disease, and the patient’s age and gender. Side effects and tolerability are significant concerns with currently available antiepileptic drugs. Side effects for most antiepileptic drugs include sleepiness, cognitive impairment, weight gain, mood changes, dizziness and potentially life-threatening immune system reactions. Doctors generally start their patients on a low dose of antiepileptic drugs, and titration may take up to 12 weeks. During this period, patients often continue to suffer from epileptic seizures of various severities.

Bipolar Disorder. Bipolar disorder is typically managed with drugs from a variety of different drug classes. While treatment duration varies for each patient, treatment of an acute phase of the disease generally lasts 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 antiepileptic drug, in addition to an atypical antipsychotic. Patients in the acute depression phase are initially treated with Lamictal, Symbyax (olanzapine and fluoxetine HCl capsules), a combination antidepressant and antipsychotic, or Seroquel (quetiapine), an antipsychotic. For long-term maintenance, the same medications that were effective for the acute episodes are typically continued at the same or lower doses. Many of the drugs currently used in the treatment of bipolar disorder have adverse drug interactions affecting each drug's efficacy and safety as well as adverse tolerability and other negative side effects such as sedation, weight gain, involuntary movements, tremors, stiffness orthostatic hypotension and potentially life-threatening immune system reactions. These side effects discourage compliance and may pose serious health risks. 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 antiepileptic drug in the same class of drugs, and with a similar chemical structure, as Lamictal, an antiepileptic drug approved for the treatment of epilepsy and bipolar disorder. We believe that JZP-4 has the potential to provide the demonstrated efficacy of antiepileptic drugs in treating these conditions while addressing many of the adverse side effects of current therapies. In particular, our pharmacokinetic studies indicate that the active pharmaceutical ingredient in JZP-4 may result in a favorable titration schedule. Preclinical studies also indicate that the active pharmaceutical ingredient in JZP-4 may have fewer adverse drug interactions than current therapies. In addition, we believe that JZP-4 has the potential to be effective in treating bipolar depression with minimal sedation, low incidence of weight gain and limited risk of causing mood switches, thereby addressing a significant unmet need for this patient population.

Product Development

We acquired the worldwide rights to the active pharmaceutical ingredient in JZP-4 from 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 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 antiepileptic drugs.

Our preclinical development has involved a range of preclinical studies to determine how the active pharmaceutical ingredient in JZP-4 works and its potential to treat epilepsy. The results of these studies indicate that the active pharmaceutical ingredient in JZP-4 is a broad spectrum antiepileptic drug with sodium and calcium channel blockade as the primary mechanisms of action. From the results of these preclinical studies, we believe that the active pharmaceutical ingredient has a broad spectrum of activity, which indicates that it may be effective in treating many different types of epileptic seizures. We have also completed preliminary toxicology 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 that showed the viability of once-a-day dosing. Following completion of this study we are continuing development activities for a once-a-day formulation, and we currently expect to complete these activities in the fourth 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 study, is a non-randomized, single blind placebo-

controlled study of JZP-4 in healthy volunteers with lamotrigine as a positive control. The transcranial magnetic stimulation 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 antiepileptic drug 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 antiepileptic drugs. Initial dosing for this study is expected to commence in the third quarter of 2007.

Our completed toxicology studies support use of the active pharmaceutical ingredient 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 second quarter of 2007. Subject to satisfactory results from these long-term toxicology studies, formulation 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 mid-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 development milestone payments of $5.0 million and will pay up to $113.5 million in additional development 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 active pharmaceutical ingredient 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 active pharmaceutical ingredient 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 active pharmaceutical ingredient in JZP-4 that expires in 2021. A patent application covering a sustained release composition for delivering the active pharmaceutical ingredient in JZP-4 is currently pending in the U.S. Patent and Trademark Office and would, if issued, expire in 2026.

JZP-8 (benzodiazepine)

We are developing JZP-8, a novel formulation incorporating a benzodiazepine, for the treatment of recurrent acute repetitive seizures 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

Recurrent acute repetitive seizures are bouts of acute seizure activity within a 24-hour period in adults and a 12-hour period in children. According to the Epilepsy Foundation, approximately 2.7 million people in the United States have epilepsy. According to an article published in the *New England Journal of Medicine*, approximately 30% of epilepsy patients are refractory to treatment despite being on an effective dose of an antiepilepsy regimen, and a subset of these refractory patients experience recurrent acute repetitive seizures. Recurrent acute repetitive seizures are an acute and repetitive reaction to the abnormal electrical activity that

builds up and releases in the brain. Epilepsy patients and their caregivers are usually able to distinguish between a regular seizure and the first seizure in a series of recurrent acute repetitive seizures.

Competition

Quick identification and treatment of the first seizure in a series of recurrent acute repetitive seizures can often interrupt the ongoing seizure, reduce its severity, and prevent subsequent seizures. Interrupting a seizure cluster may also lessen the severity of post-seizure symptoms. In the United States, Diastat (diazepam rectal gel), marketed by Valeant Pharmaceuticals, is the only FDA-approved, acute, outpatient treatment for patients on stable antiepileptic drugs who experience bouts of increased seizure activity. In 2006, sales of Diastat totaled approximately $73.0 million in the United States as measured by the Pharmaceutical Audit Suite. Although generally considered safe and effective for patients of all ages, because it is a rectally administered gel, Diastat is 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 recurrent acute repetitive seizures. These medications, all available in intravenous formulations, provide rapid onset of action and known efficacy for patients. However, treatment in an emergency 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, or a benzodiazepine that enters the bloodstream faster than a dose from a conventional tablet form. 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 active pharmaceutical ingredient for this product candidate and are conducting further development activities related to formulation, safety and tolerance. We have completed a pharmacokinetics and pharmacodynamics study in healthy volunteers. Pharmacokinetics deals with the absorption, distribution, biotransformation and excretion of drugs, which, coupled with dosage, determines the concentration of a drug in the body and, hence, the intensity of its effects as a function of time. Pharmacodynamics is the study of the biochemical and physiological effects of drugs and their mechanisms of action. These pharmacokinetic and pharmacodynamic results demonstrate that JZP-8 has an acceptable plasma profile. We plan to commence a Phase II clinical trial of JZP-8 for the treatment of recurrent acute repetitive seizures in refractory epilepsy patients in the fourth 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 second 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 active pharmaceutical ingredient 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. Based on our preclinical development, we believe JZP-7 offers the potential for effective treatment of restless legs syndrome while reducing adverse effects associated with existing treatments.

Market Opportunity

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

Competition

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

Attributes of JZP-7

We are developing JZP-7 as a novel formulation incorporating a dopamine agonist to provide the effective treatment of restless legs syndrome while addressing adverse events associated with current therapies. We are seeking to develop JZP-7 as a once daily formulation. We believe this formulation has the potential to significantly reduce the titration schedule associated with Requip and adverse events associated with 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 restless legs syndrome 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 active pharmaceutical ingredient for this product candidate and are conducting further development activities related to formulation, safety and tolerance. We have completed a pharmacokinetic study in healthy volunteers. The pharmacokinetic results demonstrated that our JZP-7 product has a pharmacokinetic profile consistent with our development target. We intend to conduct an additional pharmacokinetic study in 2007 prior to commencing Phase II clinical trials for the treatment of restless legs syndrome.

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 active pharmaceutical ingredient 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 six 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.

Competition

Currently there is no drug approved for the acute treatment of a panic attack. The current leading treatments for panic disorder are selective serotonin reuptake inhibitors taken prophylactically on a daily basis. Alternative treatments to selective serotonin reuptake inhibitors include drugs in other classes, such as benzodiazepines, tricyclic antidepressants and monoamine oxidase inhibitors. Based on data from the 2005 Physicians Drug and Diagnosis Audit, we estimate that approximately 27% of drug usages for benzodiazepines are taken on an “as-needed” basis, indicating a level of ineffective treatment with selective serotonin reuptake inhibitors alone. In

addition, patients initiating selective serotonin reuptake inhibitor 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 selective serotonin reuptake inhibitors cannot tolerate these medications or will have an unfavorable or incomplete response to treatment. Benzodiazepines are well-understood drugs, and physicians continue to prescribe them despite the availability of a number of selective serotonin reuptake inhibitors 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 selective serotonin reuptake inhibitors. In addition, severe panic disorder patients continue to experience multiple panic attacks per week while on chronic selective serotonin reuptake inhibitor 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 active pharmaceutical ingredient. 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, we expect to commence a Phase II clinical trial of JZP-2. If successful, the outcome from these clinical trials will be used to determine clinical endpoints for Phase III clinical trials. The focus of our completed and ongoing development activities 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.

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 active pharmaceutical ingredient 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 active pharmaceutical ingredient 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 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 obsessive compulsive disorder and social anxiety disorder. 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 fibromyalgia syndrome.

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 active pharmaceutical ingredients, or the capability to package 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 active pharmaceutical ingredient and a separate drug product manufacturer. We have agreements with these suppliers and manufacturers for Xyrem, Antizol and Antizol-Vet.

Pursuant to an agreement with Lonza, Inc., or Lonza, which was originally executed in November 1996 and subsequently amended, we must purchase our worldwide supply of sodium oxybate, the active pharmaceutical ingredient in Xyrem, from Lonza. Our purchase price for this supply is volume-based. Our agreement with Lonza will continue until August 1, 2008 and will automatically extend for three-year terms thereafter until either party gives notice of its intent to terminate the agreement at least 18 months prior to the end of any such term. We may terminate the agreement upon 30 days' notice if Lonza is unable to meet our minimum requirements or timeframes for supply. We also have an agreement with DSM Pharmaceuticals, Inc., or DSM, under which DSM supplies us with Xyrem. We and DSM have mutually agreed to terminate our agreement, effective January 1, 2008. In connection with this planned termination, we entered into an agreement with Patheon Pharmaceuticals, Inc., or Patheon, in March 2007 under which we agreed to purchase, and Patheon agreed to supply us with Xyrem commencing in 2008. Under the agreement with Patheon, our price for the manufacture and supply of Xyrem is volume-based. The initial term of the agreement with Patheon will extend until five years following the commencement of manufacturing activities by Patheon, and may be extended, at our option, for additional two-year terms.

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 active pharmaceutical ingredient, and Elan will manufacture our commercial requirements, for Luvox CR. We are also obligated under our agreement with Solvay to supply Solvay with its commercial requirements of Luvox CR for sale outside of the United States. We have contracted with our existing contract manufacturers of Xyrem for the active pharmaceutical ingredient and drug product for our clinical requirements of JZP-6. As with Xyrem, we will be

responsible for supplying JZP-6 to UCB 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.

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

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

Government Regulation

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

Drug Approval Process

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

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

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

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

Preclinical studies may include laboratory evaluations of the product chemistry, toxicity, and formulation, as well as animal studies to assess the potential safety and efficacy of the product candidate. The conduct of the preclinical tests and formulation of the compounds for testing must comply with federal regulations and requirements. The results of the preclinical studies, together with manufacturing information and analytical data, are submitted to the FDA as part of the IND, which must become effective before clinical trials may be commenced. The IND will become effective automatically 30 days after receipt by the FDA, unless the FDA raises concerns or questions about the conduct of the clinical trials as outlined in the IND 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 active pharmaceutical ingredient as products already on the market, may be able to skip or have abbreviated Phase II studies.
- *Phase III.* If a compound is found to be potentially effective and to have an acceptable safety profile in Phase II (or sometimes Phase I) studies, the clinical trial program will be expanded to further demonstrate clinical efficacy, optimal dosage and safety within an expanded patient population at geographically dispersed clinical trial sites. Phase III studies usually include several hundred to several thousand patients. Generally, two adequate and well-controlled Phase III clinical trials are required by the FDA for approval of an NDA, but for some product candidates, particularly those using the same active pharmaceutical ingredient as products already on the market, only one Phase III trial may be required.

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

The applicant must submit to the FDA the results of the preclinical and clinical trials, together with, among other things, detailed information on the manufacture and composition of the product candidate and proposed labeling, in the form of an NDA, including payment of a user fee. The FDA reviews all NDAs submitted before it accepts them for filing and may request additional information rather than accepting an NDA for filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, the FDA has ten months in which to complete its initial review of a standard NDA and respond to the applicant, and six months for a priority NDA. The FDA does not always meet its PDUFA goal dates for standard and priority NDAs. The review process and the PDUFA goal date may be extended by three months if the FDA requests or the NDA sponsor otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date. 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.

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

Section 505(b)(1) New Drug Applications

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

Section 505(b)(2) New Drug Applications

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

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

- the listed patent has expired;
- the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or
- the listed patent is invalid or will not be infringed by the manufacture, use or sale of the new product.

A certification that the new product will not infringe the already approved product's Orange Book-listed patents or that such patents are invalid is called a paragraph IV certification. If the applicant does not challenge the listed patents, the Section 505(b)(2) application will not be approved until all the listed patents claiming the referenced product have expired, as well as any additional period of exclusivity that might be obtained for

completing pediatric studies pursuant to the FDA's written request. The Section 505(b)(2) application may also not be approved until any applicable non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired.

If the applicant has provided a paragraph IV certification to the FDA, the applicant must also send notice of the paragraph IV certification to the holder of the NDA and the relevant patent holders once the 505(b)(2) NDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a legal challenge to the paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of their receipt of a paragraph IV certification automatically prevents the FDA from approving the Section 505(b)(2) NDA until the earliest of 30 months, expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the Section 505(b)(2) applicant. For drugs with five-year exclusivity, 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 active pharmaceutical ingredient, drug product (formulation and composition), and method-of-use for which the applicant submitted the NDA and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. Generic applicants that wish to rely on the approval of a drug listed in the Orange Book must certify to each listed patent, as discussed above. We intend to submit for Orange Book listing all relevant patents for our 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 active pharmaceutical ingredient, is eligible for the extension, and it must be applied for prior to expiration of the patent. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for patent term extension. We will consider applying for a patent term extension for some of our patents, to add patent life beyond the expiration date, depending on our ability to meet certain legal requirements permitting such extension, and the expected length of clinical trials and other factors involved in the submission of an NDA.

Orphan Drug Designation and Exclusivity

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

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

Fast Track Designation

The FDA's fast track program is intended to facilitate the development and to expedite the review of drugs that are intended for the treatment of a serious or life-threatening condition and that demonstrate the potential to address unmet medical needs. Under the fast track program, applicants may seek traditional approval for a product based on data demonstrating an effect on a clinically meaningful endpoint, or approval based on a well-established surrogate endpoint. The sponsor of a new drug candidate may request the FDA to designate the drug candidate for a specific indication as a fast track drug at the time of original submission of its IND, or at any time thereafter prior to receiving marketing approval of a marketing application. The FDA will determine if the drug candidate qualifies for fast track designation within 60 days of receipt of the sponsor's request.

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

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

Other Regulatory Requirements

In addition to regulation by the FDA and certain state regulatory agencies, the DEA imposes various registration, recordkeeping and reporting requirements, procurement and manufacturing quotas, labeling and packaging requirements, security controls and a restriction on prescription refills on certain pharmaceutical products under the Controlled Substances Act. A principal factor in determining the particular requirements, if any, applicable to a product is the actual or potential abuse profile. The DEA regulates drug substances as Schedule I, II, III, IV or V substances, with Schedule I substances considered to present the highest risk of substance abuse and Schedule V substances the lowest risk. Sodium oxybate in its base form is regulated by the DEA as a Schedule I controlled substance but when contained in 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 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 relating to our products and product candidates and methods for producing our products and product candidates. However, patent protection is not available for the active pharmaceutical ingredients in most of our products and product candidates, including Xyrem, Luvox CR and JZP-6. Patents extend for varying periods according to the date of the patent filing or grant and the legal term of patents in the various countries where patent protection is obtained. The actual protection afforded by a patent, which can vary from country to country, depends on the type of patent, the scope of its coverage and the availability of legal remedies in the country. The patents and patent applications that relate to our products and product candidates include the following:

- *Xyrem*. Xyrem is covered by 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. We obtained a license to this patent application and any resulting patent that issues as a result of Solvay's assignment of its license and supply agreement with Elan to us in connection with our exclusive license of the rights to market and distribute Luvox CR in the U.S.
- *JZP-6*. We expect that our current patents associated with Xyrem will be applicable to JZP-6. We also own patents with claims covering the use of sodium oxybate for the treatment of fibromyalgia syndrome 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 active pharmaceutical ingredient 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 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 18 registered trademarks and service marks in the United States and 29 registered trademarks and service marks in other countries. We also have 9 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, such as Pfizer and GlaxoSmithKline, as well as specialty pharmaceutical companies that market psychiatry and neurology products. Most of these companies have financial resources and marketing capabilities substantially greater than ours. Our ability to remain competitive in the marketplace is also impacted by our ability to compete successfully with other specialty pharmaceutical companies for product and product candidate acquisition and in-licensing opportunities. Some of these competitors include Cephalon, Inc., Shire Pharmaceuticals Group plc, Endo Pharmaceuticals Holdings Inc. and Forest Laboratories. These established companies may have a competitive advantage over us due to their size and financial resources.

Our products and product candidates may also compete with new products currently under development by others, alternate therapies during the period of patent protection and generic equivalents once patent protection is no longer available. Any products that we develop are likely to be in a highly competitive market, and many of our competitors may succeed in developing products that may render our products obsolete or noncompetitive. In

particular, our most significant marketed product and late stage product candidates face competition from the following products:

- *Xyrem*. We believe that the primary competition for Xyrem is Provigil, a wakefulness promoting agent and the only other FDA-approved product for the treatment of excessive daytime sleepiness in patients with narcolepsy.
- *Luvox CR*. We believe that the primary competition for Luvox CR in the treatment of obsessive compulsive disorder is Prozac, Zoloft and Paxil, and their generic equivalents. In the treatment of social anxiety disorder, we believe that Luvox CR's primary competition will also include Paxil CR and Effexor XR.
- *JZP-6*. Although there currently are no FDA-approved treatments for fibromyalgia syndrome, several large pharmaceutical companies, including Pfizer and Eli Lilly, have stated that they have products for the treatment of fibromyalgia syndrome in development. In particular, in December 2006, Pfizer filed a supplemental NDA for Lyrica for the treatment of fibromyalgia syndrome.

For a more detailed description of current products that compete with Xyrem, please see "—Marketed Products—Xyrem (sodium oxybate oral solution)—Competition." For a more detailed description of current products that may be competitive with our product candidates, please see the descriptions under the headings "—Competition" for each our product candidates described under "—Product Candidates."

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

- efficacy, safety and reliability of our product candidates;
- the timing and scope of regulatory approvals;
- product acceptance by physicians and other health care providers;
- our ability to expand and grow our specialty sales force;
- protection of our proprietary rights and the level of generic competition;
- the speed 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;
- our ability to recruit and retain skilled employees; and
- availability of substantial capital resources to fund development and commercialization activities.

Employees

As of March 31, 2007, we had 203 full-time employees. Of the full-time employees, 87 were engaged in sales and marketing, 66 were engaged in manufacturing, product development and clinical activities, and 50 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 three months and that anticipated future growth thereafter can be accommodated by leasing additional space near our current facilities.

Legal Proceedings

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

We and Orphan Medical are discussing a possible settlement with the United States, acting through the Department of Justice, the U.S. Attorney's Office for the Eastern District of New York and other federal agencies, including the Office of Inspector General, U.S. Department of Health and Human Services, relating to this matter. If we complete a settlement on the terms that we are currently discussing, Orphan Medical would plead guilty to one felony count of introducing a misbranded drug into interstate commerce and would pay a total of approximately $20.5 million in civil and criminal payments over the next several years in connection with this matter, with approximately $1.5 million payable in 2007, $2.0 million payable in 2008, $2.5 million payable in 2009, $3.0 million payable in 2010, $3.0 million payable in 2011 and $8.5 million payable in 2012. We would guarantee payment of these amounts by Orphan Medical.

If we complete a settlement on the terms that we are currently discussing, the U.S. Attorney has indicated that we would not be prosecuted. As part of the settlement, we would enter into a corporate integrity agreement with the Office of Inspector General, U.S. Department of Health and Human Services, which would require us to maintain a comprehensive compliance program. We previously have implemented, in certain cases prior to learning of the investigation, some of the compliance obligations likely to be included in a corporate integrity agreement, such as designation of a senior-level compliance officer and adoption of sales and marketing compliance policies. We would have additional ongoing compliance-related operating costs related to this compliance program, which we do not expect to be material, as a result of the corporate integrity agreement.

The settlement terms described above are subject to the negotiation and execution of definitive agreements. Even if we reach a settlement agreement with the U.S. Attorney's Office, we might still be subject to regulatory and/or enforcement action by federal agencies that are not parties to the settlement, private insurers and states' attorneys general with respect to activities covered by the settlement. If we do not reach a settlement, we could be required to spend significant amounts to defend ourselves and Orphan Medical, and the investigation could involve criminal charges, as well as criminal and/ or civil fines and penalties, against us, Orphan Medical, or both. If we are unable to complete the settlement described above, 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, and such an 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. On March 14, 2007, the plaintiff filed an amended complaint, and the defendants responded with a motion to dismiss on March 16, 2007. 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.

MANAGEMENT

Directors and Executive Officers

The following table sets forth certain information concerning our directors and executive officers as of March 31, 2007:

Name	Age	Position
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	36	Director
Samuel D. Colella(2)(3)	67	Director
Bryan C. Cressey	57	Director
Michael W. Michelson(2)	56	Director
James C. Momtazee(1)(3)	35	Director
Kenneth W. O'Keefe(1)	40	Director
Jaimin R. Patel	25	Director
Alan M. Sebulsky(1)	48	Director
James B. Tananbaum, M.D.(2)	44	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 board of Trubion Pharmaceuticals, a biopharmaceutical company. He received a B.S. and an M.D. from the University of Illinois.

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

Commercial Development. In this role, he was responsible for ALZA Corporation's corporate development, mergers and acquisitions, new product planning and corporate planning. He received B.S. and M.S. degrees from Stanford University and an M.B.A. from the Stanford Graduate School of Business.

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.

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

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.

Jaimin R. Patel has served as a member of our board of directors since 2007. Since June 2006, he has been employed by Kohlberg Kravis Roberts & Co. L.P., where he is an Associate. From August 2004 to June 2006, Mr. Patel was an analyst with UBS Securities LLC. Prior to that, Mr. Patel was a full-time student at the University of Pennsylvania where he received a B.S. in 2004.

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 Dr. Tananbaum and Messrs. Clammer, Cressey and Patel, and whose term will expire at our annual meeting of stockholders to be held in 2008;
- Class II, which will consist of Dr. Saks and Messrs. Colella and Momtazee, and whose term will expire at our annual meeting of stockholders to be held in 2009; and
- Class III, which will consist of Messrs. Cozadd, Michelson, O'Keefe and Sebulsky, and whose term will expire at our annual meeting of stockholders to be held in 2010.

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. 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 at least a majority of our voting stock.

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, as appropriate, 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, as appropriate, 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:

- recommending to our board of directors for approval the compensation and other terms of employment of our Executive Chairman and our Chief Executive Officer;
- determining the compensation and other terms of employment of our other executive officers and senior management;

- reviewing and approving corporate performance goals and objectives relevant to the compensation of our executive officers and other senior management;
- evaluating and recommending to our board of directors for approval 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.

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 Code of Conduct.

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 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 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., Medicis 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

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 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 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 a contemporaneous valuation 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 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 40,662 shares of common stock with the vesting schedule described above. The option has an exercise price of $19.37 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.

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 40,662 shares of common stock with the vesting schedule described above. The option has an exercise price of $19.37 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 31,625 shares of common stock with vesting schedule described above. The option has an exercise price of $19.37 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 22,590 shares of common stock with the vesting schedule described above. The options have an exercise price of $19.37 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 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 Incentive Plan Compensation ($)(2)	All Other Compensation ($)(3)	Total ($)
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.

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

Name	Estimated Possible Payouts Under Non-Equity Incentive Plan Awards Target ($)(1)
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.

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 1/12th 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
  - 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

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 Continuation ($)	COBRA Premiums ($)	Bonus Payment for the Year of Termination ($)	Bonus Payment for the Year Following Termination ($)(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 $1/12^{th}$ 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;
- a single lump sum payment equal to the product of (a) $1/12^{th}$ 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.

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 Payment ($)	COBRA Premiums ($)	Lump Sum Bonus 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	4,100,000
Samuel R. Saks, M.D.	101,441	5,466,675
Robert M. Myers	119,342	2,081,525
Matthew K. Fust	69,616	667,800
Carol A. Gamble	79,562	621,200
Janne L.T. Wissel	65,638	605,675

(1) The value of the put right is calculated assuming a price per share of $25.00 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.

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

with or more than 12 months following, a change in control, then 1/4th 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.

	Full Vesting Acceleration		Partial Vesting Acceleration	
Name	Founder Share Acceleration ($)(1)	Option Acceleration ($)(2)	Founder Share Acceleration ($)(1)	Option Acceleration ($)
Bruce C. Cozadd	372,750	260,102	93,188	—
Samuel R. Saks, M.D.	496,975	260,102	124,244	—
Robert M. Myers	284,725	260,102	71,181	—
Matthew K. Fust	77,650	99,290	19,413	—
Carol A. Gamble	56,475	99,290	14,119	—
Janne L.T. Wissel	139,775	99,290	34,944	—

(1) The value of vesting acceleration is calculated assuming a price per share of $25.00, 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 $25.00, 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 2,125,042 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 March 31, 2007, options to purchase 1,862,530 shares of our common stock at a weighted average exercise price per share of $21.34 remained outstanding under the 2003 plan. No stock appreciation rights, stock issuances, or cash awards have been granted under the 2003 plan. As of March 31, 2007, 215,792 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.

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.

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 take the same action for each award.

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 addition, pursuant to our Executive Change in Control and Severance Benefit Plan, in which our non-executive officer vice presidents are participants, if a participant's employment with us terminates due to an involuntary termination without cause or a constructive termination, in each case within 12 months following a change in control, the vesting and exercisability of all options held by the participant will accelerate in full. 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 May 2007, and our stockholders approved the 2007 incentive plan in May 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 April 30, 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 4,625,042 shares. The share reserve consists of (i) the 2,125,042 shares reserved for issuance under the 2003 plan, plus (ii) an additional 2,500,000 shares reserved for issuance under the 2007 incentive plan. The aggregate reserve number will be reduced by any unused shares of our common stock remaining available for the future grant of stock awards under the 2003 plan on the effective date of the 2007 incentive plan. 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) 4.5% of the total number of shares of our common stock outstanding on December 31st of the preceding calendar year and (b) 3,000,000 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 2,000,000 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 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 will 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 provided that the exercise price of an incentive stock option and nonstatutory stock option cannot be less than 100% of the fair 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, 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 by the plan administrator.

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 2,000,000 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, our board of directors has the discretion to take one or more of the following actions with respect to outstanding stock awards:

- arrange for assumption, continuation, or substitution of a stock award by a surviving or acquiring entity (or its parent company);
- arrange for the assignment of any reacquisition or repurchase rights applicable to any shares of our common stock issued pursuant to a stock award to the surviving or acquiring corporation (or its parent company);
- accelerate the vesting and exercisability of a stock award followed by the termination of the stock award;
- arrange for the lapse of any reacquisition or repurchase rights applicable to any shares of our common stock issued pursuant to a stock award;
- cancel or arrange for the cancellation of a stock award, to the extent not vested or not exercised, in exchange for appropriate cash consideration; and
- arrange for the surrender of a stock award in exchange for a payment equal to the excess of (a) the value of the property the holder of the stock award would have received upon the exercise of the stock award, over (b) any exercise price payable by such holder in connection with such exercise.

Our board of directors need not take the same action for each stock award.

Changes in Control. The form of option agreement adopted by our board under the 2007 incentive plan provides that in the event an optionee'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 the option 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 a stock award agreement or any other written agreement between us or any of our affiliates and a participant.

2007 Employee Stock Purchase Plan

Our board of directors adopted our 2007 Employee Stock Purchase Plan, or 2007 purchase plan, in May 2007 and our stockholders approved the 2007 purchase plan in May 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 350,000 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) 1.5% of the total number of shares of our common stock outstanding on December 31st of the preceding calendar year or (b) 350,000 shares. 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.

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 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.

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

	Option Awards(1)				Stock Awards(2)	
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	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	116,254	47,866	15.09	02/18/14	—	—
	38,753	15,954	30.18	02/18/14	—	—
	38,753	15,954	45.27	02/18/14	—	—
	—	—	—	—	14,910	372,750
Samuel R. Saks, M.D.	116,254	47,866	15.09	02/18/14	—	—
	38,753	15,954	30.18	02/18/14	—	—
	38,753	15,954	45.27	02/18/14	—	—
	—	—	—	—	19,879	496,975
Robert M. Myers	116,254	47,866	15.09	02/18/14	—	—
	38,753	15,954	30.18	02/18/14	—	—
	38,753	15,954	45.27	02/18/14	—	—
	—	—	—	—	11,389	284,725
Matthew K. Fust	44,380	18,272	15.09	02/18/14	—	—
	14,794	6,090	30.18	02/18/14	—	—
	14,794	6,090	45.27	02/18/14	—	—
	—	—	—	—	2,485	62,125
Carol A. Gamble	44,380	18,272	15.09	02/18/14	—	—
	14,794	6,090	30.18	02/18/14	—	—
	14,794	6,090	45.27	02/18/14	—	—
	—	—	—	—	2,259	56,475
Janne L.T. Wissel	44,380	18,272	15.09	02/18/14	—	—
	14,794	6,090	30.18	02/18/14	—	—
	14,794	6,090	45.27	02/18/14	—	—
	—	—	—	—	5,591	139,775

(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 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 $15.09 per share, 20% carry an exercise price equal to $30.18 per share, and 20% carry an exercise price equal to $45.27 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 $25.00, which is the mid-point of the range reflected on the cover page of this prospectus, multiplied by the number of unvested shares.

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

	Stock Awards	
Name	Number of Shares Acquired on Vesting (#)	Value Realized on Vesting ($)(1)
Bruce C. Cozadd	44,727	1,118,175
Samuel R. Saks, M.D.	59,637	1,490,925
Robert M. Myers	23,663	591,575
Matthew K. Fust	7,455	186,375
Carol A. Gamble	6,777	169,425
Janne L.T. Wissel	7,455	186,375

(1) The value realized on vesting has been calculated assuming a price per share of $25.00, 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

Cash Compensation Arrangements

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.

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 $30,000. The chair of the audit committee will receive a supplemental annual retainer of $15,000, the chair of the compensation committee will receive a supplemental annual retainer of $10,000, and the chair of each other committee of the board will receive a supplement annual retainer of $5,000.

Directors Deferred Compensation Plan

Our board of directors adopted the Directors Deferred Compensation Plan, or deferred plan, in May 2007. The deferred plan allows each non-employee director to elect to defer receipt of all or a portion of his or her

annual retainer fees to a future date or dates. Any amounts deferred under the deferred plan are credited to a phantom stock account. The number of phantom shares of our common stock credited to each director's phantom stock account each year will be determined based on the amount of the compensation deferred during any given year, divided by the fair market value of our common stock on the date the retainer fees are due to be paid. Upon a separation from our board of directors or the occurrence of a change in control, each non-employee director will receive (or commence receiving, depending upon whether the director has elected to receive distributions from his or her phantom stock account in a lump sum or in installments over time) a distribution of his or her phantom stock account, in either cash or shares of our common stock (subject to the prior election of each such director). Any distributions in shares of our common stock will be paid with shares reserved under our 2007 Non-Employee Directors Stock Option Plan, which is described below. The deferred plan may be amended or terminated at any time by our board of directors, and in form and operation is intended to be compliant with Section 409A of the Internal Revenue Code of 1986, as amended.

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 May 2007, and our stockholders approved the 2007 directors plan in May 2007. The 2007 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. In addition, the 2007 directors plan provides a source of shares to fund distributions under the deferred plan.

Share Reserve. Following this offering, the aggregate number of shares of common stock that may be issued initially under the 2007 directors plan is 200,000 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 sum of (a) the excess of (i) the number of shares of common stock subject to options granted during the preceding calendar year, over (ii) the number of shares added back to the share reserve during the preceding calendar year and (b) the aggregate number of shares credited to our non-employee directors' stock accounts under the deferred plan. In no event may the amount of such annual increase exceed 200,000 shares.

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. 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. As of the date hereof, no shares of common stock have been issued under the 2007 directors plan.

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 the completion of this offering will automatically be granted an option to purchase 30,000 shares of our common stock. Each initial option will vest with respect to one-third of the shares on the first anniversary of the date of grant, and the balance in a series of 24 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 first trading day on or after August 15 of each year, commencing on August 15, 2007, will automatically be granted an option to purchase 10,000 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 or death, or after any 12-month period 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 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 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 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 maximum number of shares by which the share reserve may increase automatically each year, (c) the number of shares for which options are to be subsequently made to new and continuing non-employee directors and (d) 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.

Director Compensation Table

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 Paid in Cash ($)	Option Awards ($)(2)(3)	Total ($)
Adam H. Clammer	—	—	—
Samuel D. Colella	—	—	—
Bryan C. Cressey(1)	—	—	—
David Mayer(1)	—	—	—
Michael W. Michelson	—	—	—
James C. Momtazee	—	—	—
Kenneth W. O'Keefe	—	—	—
Jaimin R. Patel(4)	—	—	—
Alan M. Sebulsky	9,500(5)	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 9,036 shares of our common stock carrying an exercise price of $15.09 per share, 4,518 shares of which were vested and exercisable at December 31, 2006. In addition, on May 1, 2007, the board approved the grant of a stock option to Mr. Sebulsky to purchase 17,500 shares of our common stock, such option to be granted on the date of the signing of the underwriting agreement for this offering and to have an exercise price equal to the initial public offering price. The stock option vests as to one-third of the shares on the first anniversary of the date of the signing of the underwriting agreement for this offering, and the balance in series of 24 successive equal monthly installments thereafter. None of the other directors listed in the table above held any outstanding stock options at December 31, 2006.
(4) Mr. Patel joined our board of directors in May 2007.
(5) Consists of fees earned for board and committee meeting attendance.

Limitation of Liability and Indemnification

Our fourth 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, Momtazee and Patel 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 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.

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."

Related Party Transaction Policy

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

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

- the risks, costs and benefits to us;
- the impact on a director's independence in the event that the related person is a director, immediate family member of a director or an entity with which a director is affiliated;
- the terms of the transaction;
- the availability of other sources for comparable services or products; and
- the terms available to or from, as the case may be, unrelated third parties or to or from employees generally.

The policy requires that, in determining whether to approve, ratify or reject a related-person transaction, our audit committee (or other independent body of our board of directors) must consider, in light of known circumstances, whether the transaction is in, or is not inconsistent with, our best interests and those of our stockholders, as our audit committee (or other independent body of our board of directors) determines in the good faith exercise of its discretion. All of the transactions described below were entered into prior to the adoption of the policy and were approved by our board of directors.

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 $.03, in April 2003 at per share prices of $.06 and $.11, in October 2003 at a per share price of $1.11, in January 2004 at a per share price of $1.11 and in September 2004 at a per share price of $15.09, for aggregate consideration of $338,033.

During the period from April 2003 through January 2004, we issued and sold an aggregate of 1,355,377 shares of our Series A preferred stock at a per share price of $11.07 for aggregate consideration of $15.0 million. During the period from February 2004 through December 2006, we issued and sold an aggregate of 7,951,755 shares of our Series B preferred stock at a per share price of $15.09 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 8,614,419 shares of our Series B Prime preferred stock at a per share price of $15.09 for aggregate consideration of approximately $130.0 million.

In June 2005, we issued warrants to purchase an aggregate of 785,728 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 $20.36 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.

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	Common Stock	Series A Preferred Stock	Series B Preferred Stock	Series B Prime Preferred Stock	Series BB Preferred Stock Warrants
Executive Officers and Directors					
Bruce C. Cozadd(1)	178,910	—	66,264	—	—
Samuel R. Saks, M.D.(2)	238,546	13,553	66,264	—	—
Robert M. Myers(3)	94,650	—	46,385	—	—
Matthew K. Fust(4)	29,818	—	19,879	—	—
Carol A. Gamble(5)	27,107	—	—	—	—
Janne L.T. Wissel(6)	29,818	—	66,264	—	—
Alan M. Sebulsky(7)	13,252	—	—	—	—
Principal Stockholders(8)					
Entities affiliated with Kohlberg Kravis Roberts & Co. L.P.(9)	—	—	—	8,614,419	245,540
Entities affiliated with Thoma Cressey Bravo, Inc.(10)	—	—	1,987,942	—	—
Entities affiliated with Beecken Petty O'Keefe & Company(11)	—	—	1,325,295	—	—
Entities affiliated with Prospect Venture Partners(12)	—	670,912	563,249	—	—
Entities affiliated with Versant Ventures(13)	—	670,912	563,249	—	—
Entities affiliated with Golden Gate Capital(14)	—	—	993,969	—	—
Entities affiliated with Lehman Brothers Holdings Inc.(15)	—	—	662,645	—	304,469

(1) Includes 3,728 shares of common stock that are subject to our right of repurchase as of March 31, 2007, which such right of repurchase lapsed in full on April 1, 2007.

(2) Includes 4,970 shares of common stock that are subject to our right of repurchase as of March 31, 2007, which such right of repurchase lapsed in full on April 1, 2007.
(3) Includes 5,474 shares of common stock that are subject to our right of repurchase as of March 31, 2007, which such right of repurchase lapses in full on December 18, 2007.
(4) Includes 622 shares of common stock that are subject to our right of repurchase as of March 31, 2007, which such right of repurchase lapses in full on April 30, 2007.
(5) Includes 565 shares of common stock that are subject to our right of repurchase as of March 31, 2007, which such right of repurchase lapsed in full on April 18, 2007.
(6) Includes 3,728 shares of common stock that are subject to our right of repurchase as of March 31, 2007, which such right of repurchase lapses in full on September 3, 2007.
(7) Includes 4,418 shares of common stock that are subject to our right of repurchase as of March 31, 2007, 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	Principal Stockholder
Adam H. Clammer	Entities affiliated with Kohlberg Kravis Roberts & Co. L.P.
Samuel D. Colella	Entities affiliated with Versant Ventures
Bryan C. Cressey	Entities affiliated with Thoma Cressey Bravo
Michael W. Michelson	Entities affiliated with Kohlberg Kravis Roberts & Co. L.P.
James C. Momtazee	Entities affiliated with Kohlberg Kravis Roberts & Co. L.P.
Kenneth W. O'Keefe	Entities affiliated with Beecken Petty O'Keefe & Company
Jaimin R. Patel	Entities affiliated with Kohlberg Kravis Roberts & Co. L.P.
James B. Tananbaum, M.D.	Entities affiliated with Prospect Venture Partners

(9) Consists of 8,577,974 shares of Series B Prime preferred stock held by KKR JP LLC, 36,445 shares of Series B Prime preferred stock held by KKR JP III LLC and warrants to purchase 245,540 shares of Series BB preferred stock held by KKR TRS Holdings, Inc.
(10) Consists of 1,957,380 shares of Series B preferred stock held by Thoma Cressey Fund VII, LP and 30,562 shares of Series B preferred stock held by Thoma Cressey Friends Fund VII, LP.
(11) Consists of 1,325,295 shares of Series B preferred stock held by Jazz Investors LLC.
(12) Consists of 660,849 shares of Series A preferred stock and 554,801 shares of Series B preferred stock held by Prospect Venture Partners II, L.P. and 10,063 shares of Series A preferred stock and 8,448 shares of Series B preferred stock held by Prospect Associates II, L.P.
(13) Consists of 652,693 shares of Series A preferred stock and 547,954 shares of Series B preferred stock held by Versant Venture Capital II, L.P., 12,386 shares of Series A preferred stock and 10,398 shares of Series B preferred stock held by Versant Affiliates Fund II-A, L.P., and 5,833 shares of Series A preferred stock and 4,897 shares of Series B preferred stock held by Versant Side Fund II, L.P.
(14) Consists of 860,336 shares of Series B preferred stock held by CCG Investment Fund, LP, 43,461 shares of Series B preferred stock held by CCG AV, LLC-Series C, 47,269 shares of Series B preferred stock held by CCG Associates-QP, LLC, 11,499 shares of Series B preferred stock held by CCG AV, LLC-Series A, 11,525 shares of Series B preferred stock held by CCG Investment Fund-AI, LP, and 19,879 shares of Series B preferred stock held by CCG CI, LLC.
(15) Consists of 165,661 shares of Series B preferred stock held by Lehman Brothers HealthCare Venture Capital LP, 317,076 shares of Series B preferred stock held by Lehman Brothers PA LLC, 142,858 shares of Series B preferred stock held by Lehman Brothers Partnership Account 2000/2001, LP, 37,050 shares of Series B preferred stock held by Lehman Brothers Offshore Partnership Account 2000/2001 LP, and warrants to purchase 304,469 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 March 31, 2007, 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, 2005 and 2006 and the three months ended March 31, 2007 were approximately $1.9 million, $3.8 million and $.9 million, respectively. The interest payments made to LB I Group during the fiscal years ended December 31, 2005 and 2006 and the three months ended March 31, 2007 were approximately $2.3 million, $4.6 million and $1.2 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 245,540 and 304,469 shares of our Series BB preferred stock to KKR TRS Holdings, Inc. and LB I Group, respectively.

Third 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 March 31, 2007, the holders of 19,306,128 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 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 signing of the underwriting agreement for 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."

PRINCIPAL STOCKHOLDERS

The following table sets forth the beneficial ownership of our common stock as of March 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 18,550,554 shares outstanding as of March 31, 2007, assuming the conversion of all outstanding shares of our preferred stock as of March 31, 2007, and the issuance of 6,000,000 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 May 30, 2007, which is 60 days after March 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.

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 Shares Beneficially Owned	Percentage of Shares Beneficially Owned	
		Before Offering	After Offering
5% Stockholders			
Entities affiliated with Kohlberg Kravis Roberts & Co. L.P.			
KKR JP, LLC(1)	8,577,974	46.24%	34.94%
KKR JP III LLC(1)	36,445	*	*
KKR TRS Holdings, Inc.(2)	245,540	1.31	*
Entities affiliated with Thoma Cressey Bravo, Inc.(3)	1,987,942	10.72	8.10
Entities affiliated with Beecken Petty O'Keefe & Company(4)	1,325,295	7.14	5.40
Entities affiliated with Prospect Venture Partners(5)	1,234,161	6.65	5.03
Entities affiliated with Versant Ventures(6)	1,234,161	6.65	5.03
Entities affiliated with Golden Gate Capital(7)	993,969	5.36	4.05
Entities affiliated with Lehman Brothers Holdings Inc.(8)	967,114	5.13	3.89
Named Executive Officers and Directors			
Bruce C. Cozadd(9)	467,425	2.49	1.89
Samuel R. Saks, M.D.(10)	540,614	2.88	2.18
Robert M. Myers(11)	363,286	1.94	1.47
Matthew K. Fust(12)	134,538	*	*
Janne L.T. Wissel(13)	180,923	*	*
Carol A. Gamble(14)	111,948	*	*
Adam H. Clammer(15)	—	—	—
Samuel D. Colella(16)	1,234,161	6.65	5.03
Bryan C. Cressey(17)	1,987,942	10.72	8.10
Michael W. Michelson(18)	8,859,959	47.14	35.73
James C. Momtazee(19)	—	—	—
Kenneth W. O'Keefe(20)	1,325,295	7.14	5.40
Jaimin R. Patel(21)	—	—	—
Alan M. Sebulsky(22)	17,770	*	*
James B. Tananbaum, M.D.(23)	1,234,161	6.65	5.03
All directors and executive officers as a group (15 persons)(24)	16,458,022	83.45%	63.98%

* 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. Mr. Patel is a member of our board of directors and is an associate of Kohlberg Kravis Roberts & Co. L.P. Each of Messrs. Clammer, Momtazee and Patel 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, Momtazee and Patel 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 245,540 shares that KKR TRS Holdings, Inc. has the right to acquire within 60 days of March 31, 2007 through the exercise of a warrant. All of the outstanding equity interests of KKR TRS Holdings, Inc. are owned by KKR Financial Holdings LLC. KKR Financial Advisors LLC is the manager of KKR Financial Holdings LLC. KKR Financial LLC is the sole member of KKR Financial Advisors LLC. Kohlberg Kravis Roberts & Co. L.P. owns a majority of the 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 reviews the investments held by KKR Financial Holdings LLC. 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 Messrs. Momtazee and Patel) and other executives of Kohlberg Kravis Roberts & Co. L.P. Messrs. Kravis and Roberts, as managing members of KKR & Co. L.L.C., 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 Holdings LLC and KKR Financial LLC is 555 California Street, 50th Floor, San Francisco, CA 94104.

(3) Consists 1,957,380 shares held by Thoma Cressey Fund VII, LP and 30,562 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 1,325,295 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 1,215,650 shares held by Prospect Venture Partners II, L.P. and 18,511 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 1,200,647 shares held by Versant Venture Capital II, L.P., 22,784 shares held by Versant Affiliates Fund II-A, L.P. and 10,730 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 47,269 shares held by CCG Associates-QP, LLC, 11,499 shares held by CCG AV, LLC-Series A, 43,461 shares held by CCG AV, LLC-Series C, 19,879 shares held by CCG CI, LLC, 860,336 shares held by CCG Investment Fund, LP and 11,525 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, 33rd Floor, San Francisco, CA 94111.

(8) Consists of 165,661 shares held by Lehman Brothers HealthCare Venture Capital LP, 317,076 shares held by Lehman Brothers PA LLC, 142,858 shares held by Lehman Brothers Partnership Account 2000/2001, LP, 37,050 shares held by Lehman Brothers Offshore Partnership Account 2000/2001 LP, and warrants to purchase 304,469 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 222,251 shares Mr. Cozadd has the right to acquire within 60 days of March 31, 2007 through the exercise of options.

(10) Includes 222,251 shares Dr. Saks has the right to acquire within 60 days of March 31, 2007 through the exercise of options.

(11) Includes 222,251 shares Mr. Myers has the right to acquire within 60 days of March 31, 2007 through the exercise of options, and 3,064 shares subject to our unvested share repurchase right within 60 days of March 31, 2007.

(12) Includes 84,841 shares Mr. Fust has the right to acquire within 60 days of March 31, 2007 through the exercise of options.

(13) Includes 84,841 shares Ms. Wissel has the right to acquire within 60 days of March 31, 2007 through the exercise of options, and 2,485 shares subject to our unvested share repurchase right within 60 days of March 31, 2007.

(14) Includes 84,841 shares Ms. Gamble has the right to acquire within 60 days of March 31, 2007 through the exercise of options.

(15) See Notes (1) and (2) above.

(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.
(19) See Notes (1) and (2) above.
(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) See Notes (1) and (2) above.
(22) Includes 4,518 shares Mr. Sebulsky has the right to acquire within 60 days of March 31, 2007 through the exercise of options, and 3,865 shares subject to our unvested share repurchase right within 60 days of March 31, 2007.
(23) 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.
(24) Includes 14,641,518 shares held by entities affiliated with certain of our directors, 925,794 shares that certain of our executive officers and directors have the right to acquire within 60 days of March 31, 2007 through the exercise of options and 9,414 shares subject to our unvested share repurchase right within 60 days of March 31, 2007.

DESCRIPTION OF CAPITAL STOCK

Upon the closing of this offering and the filing of our fourth amended and restated certificate of incorporation, our authorized capital stock will consist of 150,000,000 shares of common stock, par value $.0001 per share, and 20,000,000 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 fourth 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 629,003 shares of common stock outstanding as of March 31, 2007, the conversion of outstanding preferred stock as of March 31, 2007 into 17,921,551 shares of common stock upon the completion of this offering, the issuance of 6,000,000 shares of common stock in this offering, and no exercise of options or warrants, there will be 24,550,554 shares of common stock outstanding upon the closing of this offering. As of March 31, 2007, assuming the conversion of all outstanding preferred stock into common stock upon the closing of this offering, we had approximately 47 record holders of our common stock.

As of March 31, 2007, there were 785,728 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 1,862,530 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 fourth 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.

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 fourth amended and restated certificate of incorporation will be amended and restated to delete all references to such shares of preferred stock. Under our fourth amended and restated certificate of incorporation, our board of directors will have the authority, without further action by the stockholders, to issue up to 20,000,000 shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the 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 March 31, 2007, warrants exercisable for 785,728 shares of our Series BB preferred stock at an exercise price of $20.36 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 approximately 19,306,128 shares of common stock, including warrants to purchase 785,728 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

purchaser of at least 4,517,932 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, subject to certain exceptions, 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 Fourth 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

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 2/3% of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, 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.

Fourth Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws

Provisions of our fourth 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 fourth amended and restated certificate of incorporation and amended and restated bylaws:

- permit our board of directors to issue up to 20,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate, including the right to approve an acquisition or other change in our control;
- provide that the authorized number of directors may be changed only by resolution of the board of directors;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- divide our board of directors into three classes;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner, and also specify requirements as to the form and content of a stockholder's notice;

- do not provide for cumulative voting rights (therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose);
- provide that special meetings of our stockholders may be called only by the chairman of the board, our chief executive officer or by the board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors; and
- provide that stockholders will be permitted to amend our amended and restated bylaws only upon receiving at least 66 2/3% of the votes entitled to be cast by holders of all outstanding shares then entitled to vote generally in the election of directors, voting together as a single class.

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

Transfer Agent and Registrar

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

NASDAQ Global Market Listing

We have applied for quotation of our common stock on the NASDAQ Global Market under the trading symbol "JAZZ."

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 March 31, 2007, upon completion of this offering, 24,550,554 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;
- approximately 14,219,877 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 245,506 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. Approximately 1,954,058 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

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 warrantholders 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 approximately 19,306,128 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

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.

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.

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

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
- 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

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.

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.

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.	
Total	6,000,000

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 900,000 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 $.

172,289 shares of common stock acquired by certain affiliates of Lehman Brothers Inc. on December 14, 2006 have been deemed underwriting compensation by the NASD and will therefore be subject to the transfer restrictions in NASD Rule 2710(g).

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".

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;

- 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:

- in our case, (1) the sale of shares to the underwriters, (2) the issuance 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 (3) the issuance of shares of common stock in connection with (a) any strategic transaction that includes a commercial or development relationship involving us and other entities or (b) any equipment loan or leasing arrangement, real property leasing arrangement or debt financing from a bank or similar financial institution; *provided* that, in the case of any issuance pursuant to clause (3), (i) each recipient shall sign and deliver in respect of such shares of common stock a lock-up agreement substantially in the form of the agreement entered into by our directors and officers and (ii) the aggregate number of shares so issued shall not exceed 5% of the number of shares of common stock issued and outstanding immediately following completion of this offering;
- 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 (1) or (2), (i) each donee, distributee or transferee 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 (ii) 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; and
- in the case of any of our executive officers, dispositions by such executive officer or such executive officer's estate of such executive officer's vested shares of restricted common stock to us in connection with such executive officer's death or complete disability as described under "Management—Executive Employment Agreements—Vested Share Repurchase Right; Executive Put Right".

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 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

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.

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.

JAZZ PHARMACEUTICALS, INC.

Index to Consolidated Financial Statements

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

Palo Alto, California
March 6, 2007
except for the seventh paragraph of Note 2,
as to which the date is May 15, 2007

JAZZ PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share amounts)

	December 31, 2005	December 31, 2006	March 31, 2007 (Unaudited)	Pro Forma March 31, 2007 (Unaudited)
ASSETS				
Current assets:				
Cash and cash equivalents	$ 20,614	$ 78,948	$ 67,667	$ 67,667
Restricted cash	300	275	275	275
Accounts receivable, net of allowances of $122, $198 and $244 at December 31, 2005 and 2006 and March 31, 2007 (unaudited), respectively	3,597	5,380	6,167	6,167
Inventories	3,262	3,026	2,303	2,303
Prepaid expenses	3,240	3,447	2,174	2,174
Other current assets	371	487	680	680
Total current assets	31,384	91,563	79,266	79,266
Property and equipment, net	1,941	2,107	2,116	2,116
Intangible assets, net—purchased developed technology	71,023	63,130	57,657	57,657
Intangible assets, net—other	7,717	6,010	5,582	5,582
Goodwill	38,883	38,213	38,213	38,213
Long-term restricted cash and investments	12,000	12,000	12,085	12,085
Other long-term assets	1,833	1,548	2,991	2,991
Total assets	$ 164,781	$ 214,571	$ 197,910	$ 197,910
LIABILITIES, CONVERTIBLE PREFERRED STOCK, AND STOCKHOLDERS' EQUITY (DEFICIT)				
Current liabilities:				
Line of credit	$ —	$ 2,191	$ 3,104	$ 3,104
Accounts payable	4,786	5,443	3,145	3,145
Accrued liabilities	11,121	12,943	13,097	13,097
Deferred revenue	—	1,422	1,659	1,659
Preferred stock warrant liability (including $5,107, $5,965 and $8,469 as of December 31 2005, December 31, 2006 and March 31, 2007 (unaudited), respectively, held by related parties)	7,429	8,521	11,588	—
Total current liabilities	23,336	30,520	32,593	21,005
Liability for early exercise of options and unvested restricted common stock	184	98	77	77
Deferred rent	649	436	387	387
Non-current portion of deferred revenue	—	13,495	13,243	13,243
Senior secured notes (including $50,620, $51,998 and $52,100 as of December 31, 2005 and 2006 and March 31, 2007 (unaudited), respectively, held by related parties)	73,629	74,283	74,429	74,429
Development financing obligation	15,445	—	—	—
Commitments and contingencies (Note 8)				
Convertible preferred stock, $.0001 par value; 27,851,839 authorized at December 31, 2005 and 2006 and March 31, 2007 (unaudited), none pro forma (unaudited); 11,295,076, 17,921,551 and 17,921,551 shares issued and outstanding at December 31, 2005 and 2006 and March 31, 2007 (unaudited), respectively, none pro forma (unaudited); aggregate liquidation preference of $165,000 at December 31, 2005 and $265,000 at December 31, 2006 and March 31, 2007	163,862	263,852	263,852	—
Common stock subject to repurchase	5,924	8,183	8,749	12,954
Stockholders' equity (deficit):				
Common stock, $.0001 par value; 22,835,080 shares authorized at December 31, 2005, December 31, 2006 and March 31, 2007 (unaudited), respectively; 617,974, 623,986 and 629,003 shares issued and outstanding at December 31, 2005, December 31, 2006 and March 31, 2007 (unaudited), respectively; 18,550,554 issued and outstanding pro forma (unaudited)	—	—	—	2
Additional paid-in capital	—	1,335	1,807	273,040
Accumulated other comprehensive income	4	12	—	—
Accumulated deficit	(118,252)	(177,643)	(197,227)	(197,227)
Total stockholders' equity (deficit)	(118,248)	(176,296)	(195,420)	75,815
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 164,781	$ 214,571	$ 197,910	$ 197,910

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

JAZZ PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share amounts)

	Year Ended December 31,			Three Months Ended March 31,	
	2004	2005	2006	2006	2007
				(Unaudited)	
Revenues:					
Product sales, net	$ —	$ 18,796	$ 43,299	$ 9,771	$ 11,625
Royalties, net	—	146	594	66	211
Contract revenue	—	2,500	963	—	2,252
Total revenues	—	21,442	44,856	9,837	14,088
Operating expenses:					
Cost of product sales (excluding amortization of acquired developed technology)	—	4,292	6,968	1,569	2,003
Research and development	17,988	45,783	54,956	12,894	14,867
Selling, general and administrative	7,459	23,551	51,384	12,219	14,339
Amortization of intangible assets	—	4,960	9,600	2,400	2,362
Purchased in-process research and development	—	21,300	—	—	—
Total operating expenses	25,447	99,886	122,908	29,082	33,571
Loss from operations	(25,447)	(78,444)	(78,052)	(19,245)	(19,483)
Interest income	643	1,318	2,307	581	1,091
Interest expense (including $4,595 and $9,024 for the years ended December 31, 2005 and 2006, respectively, and $2,185 and $2,254 for the three months ended March 31, 2006 and 2007 (unaudited), respectively, pertaining to related parties)	—	(7,129)	(14,129)	(3,777)	(3,268)
Other income (expense)	—	(901)	(1,109)	62	(3,069)
Gain on extinguishment of development financing obligation	—	—	31,592	—	—
Gain on sale of product rights	—	—	—	—	5,145
Net loss	(24,804)	(85,156)	(59,391)	(22,379)	(19,584)
Beneficial conversion feature	—	—	(21,920)	(3,501)	—
Loss attributable to common stockholders	$ (24,804)	$ (85,156)	$ (81,311)	$ (25,880)	$ (19,584)
Loss per share attributable to common stockholders, basic and diluted	$ (1,550.25)	$ (14,192.67)	$ (6,524.69)	$ (2,875.56)	$ (851.48)
Weighted-average common shares used in computing loss per share attributable to common stockholders, basic and diluted	16	6	13	9	23
Pro-forma loss per share attributable to common stockholders (unaudited), basic and diluted			$ (6.04)		$ (1.11)
Weighted-average common shares used in computing pro-forma loss per share attributable to common stockholders (unaudited), basic and diluted			13,466		17,666

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

JAZZ PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT
(In thousands, except share and per share amounts)

	Convertible Preferred Stock						Common Stock Subject to Repurchase	Stockholders' Deficit					
	Series A		Series B		Series B Prime			Common Stock		Additional Paid-in Capital	Other Compre-hensive Income	Accum-ulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Amount	Shares	Amount				
Balance at January 1, 2004	646,060	$ 7,076	—	$ —	—	$ —	$ —	577,841	$ 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	—	—	—	—	—	—	—	40,133	—	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	709,317	7,850	—	—	—	—	—	—	—	—	—	—	—
Issuance of Series B convertible preferred stock, net of issuance costs of $441	—	—	1,590,334	23,560	—	—	—	—	—	—	—	—	—
Issuance of Series B Prime convertible preferred stock, net of issuance costs of $477	—	—	—	—	1,722,883	25,523	—	—	—	—	—	—	—
Net loss and comprehensive loss	—	—	—	—	—	—	—	—	—	—	—	(24,804)	(24,804)
Balance at December 31, 2004	1,355,377	14,926	1,590,334	23,560	1,722,883	25,523	3,665	617,974	—	—	—	(30,923)	(30,923)
Lapse of repurchase rights to shares issued under restricted stock purchase agreements	—	—	—	—	—	—	—	—	—	53	—	—	53
Vesting of common stock subject to repurchase	—	—	—	—	—	—	2,259	—	—	(53)	—	(2,173)	(2,226)
Issuance of Series B convertible preferred stock, net of issuance costs of $11	—	—	3,180,714	47,989	—	—	—	—	—	—	—	—	—
Issuance of Series B Prime convertible preferred stock, net of issuance costs of $136	—	—	—	—	3,445,768	51,864	—	—	—	—	—	—	—
Comprehensive loss:													
Net loss	—	—	—	—	—	—	—	—	—	—	—	(85,156)	(85,156)
Gain on available-for-sale securities	—	—	—	—	—	—	—	—	—	—	4	—	4
Comprehensive loss													(85,152)
Balance at December 31, 2005	1,355,377	14,926	4,771,048	71,549	5,168,651	77,387	5,924	617,974	—	—	4	(118,252)	(118,248)

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	Stockholders' Deficit					
	Series A		Series B		Series B Prime			Common Stock		Additional Paid-in Capital	Other Compre-hensive Income	Accum-ulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Amount	Shares	Amount				
Balance at December 31, 2005	1,355,377	$ 14,926	4,771,048	$ 71,549	5,168,651	$ 77,387	$ 5,924	617,974	$ —	$ —	$ 4	$(118,252)	$ (118,248)
Lapse of repurchase rights to shares issued under restricted stock purchase agreements	—	—	—	—	—	—	—	—	—	53	—	—	53
Vesting of common stock subject to repurchase	—	—	—	—	—	—	2,259	—	—	(2,226)	—	—	(2,226)
Issuance of Series B convertible preferred stock, net of issuance costs of $5	—	—	3,180,707	47,995	—	—	—	—	—	—	—	—	—
Issuance of Series B Prime convertible preferred stock, net of issuance costs of $5	—	—	—	—	3,445,768	51,995	—	—	—	—	—	—	—
Issuance of common stock for cash upon exercise of stock options	—	—	—	—	—	—	—	6,012	—	10	—	—	10
Stock-based compensation	—	—	—	—	—	—	—	—	—	3,498	—	—	3,498
Beneficial conversion feature—deemed dividend on issuance of Series B preferred stock	—	—	—	—	—	—	—	—	—	21,920	—	—	21,920
Beneficial conversion feature	—	—	—	—	—	—	—	—	—	(21,920)	—	—	(21,920)
Comprehensive loss:													
Net loss	—	—	—	—	—	—	—	—	—	—	—	(59,391)	(59,391)
Gain on available-for-sale securities	—	—	—	—	—	—	—	—	—	—	8	—	8
Comprehensive loss													(59,383)
Balance at December 31, 2006	1,355,377	14,926	7,951,755	119,544	8,614,419	129,382	8,183	623,986	—	1,335	12	(177,643)	(176,296)
Lapse of repurchase rights to shares issued under restricted stock purchase agreements (unaudited)	—	—	—	—	—	—	—	—	—	13	—	—	13
Vesting of common stock subject to repurchase (unaudited)	—	—	—	—	—	—	566	—	—	(557)	—		(557)
Issuance of common stock for cash upon exercise of stock options (unaudited)	—	—	—	—	—	—	—	5,017	—	76	—	—	76
Stock-based compensation expense (unaudited)	—	—	—	—	—	—	—	—	—	940	—	—	940
Comprehensive loss:													
Net loss (unaudited)	—	—	—	—	—	—	—	—	—	—	—	(19,584)	(19,584)
Loss on available-for-sale securities (unaudited)	—	—	—	—	—	—	—	—	—	—	(12)	—	(12)
Comprehensive loss (unaudited)													(19,596)
Balance at March 31, 2007 (unaudited)	1,355,377	$ 14,926	7,951,755	$119,544	8,614,419	$129,382	$ 8,749	629,003	$ —	$ 1,807	$ —	$(197,227)	$ (195,420)

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

JAZZ PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31,			Three Months Ended March 31,	
	2004	2005	2006	2006	2007
				(Unaudited)	
Operating activities					
Net loss	$(24,804)	$ (85,156)	$ (59,391)	$ (22,379)	$ (19,584)
Adjustments to reconcile net loss to net cash used in operating activities:					
Depreciation and amortization	122	479	710	161	262
Amortization of intangible assets	—	4,960	9,600	2,400	2,362
Loss on disposal of property and equipment	—	—	481	—	—
Fair value adjustment to acquired finished goods	—	1,584	775	400	54
Purchased in-process research and development	—	21,300	—	—	—
Excess of cash paid over accrued for interest	—	476	949	178	219
Revaluation of preferred stock warrant liability	—	901	1,092	(62)	3,067
Stock-based compensation expense	—	—	3,480	820	940
Interest on development financing	—	445	1,147	599	—
Gain on extinguishment of development financing	—	—	(31,592)	—	—
Gain on sale of product rights	—	—	—	—	(5,145)
Changes in assets and liabilities:					
Accounts receivable	—	(249)	(1,783)	(1,099)	(778)
Inventories	—	(219)	(521)	(121)	344
Prepaid expenses and other current assets	(1,915)	1,158	(473)	(253)	1,080
Other assets	(151)	—	323	(2)	(1,528)
Accounts payable	1,564	2,408	657	(143)	(2,298)
Accrued liabilities	3,340	(210)	2,492	(2,361)	155
Deferred revenue	—	—	14,917	—	(15)
Deferred rent	688	(39)	(213)	(51)	(49)
Net cash used in operating activities	(21,156)	(52,162)	(57,350)	(21,913)	(20,914)
Investing activities					
Purchases of property and equipment	(992)	(1,413)	(1,682)	(121)	(271)
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	—	—
Decrease (increase) in restricted cash and investments	150	(12,175)	25	—	(85)
Proceeds from sale of product rights	—	—	—	—	9,000
Net cash provided by (used in) investing activities	(6,788)	(153,754)	(1,507)	(121)	8,644
Financing activities					
Proceeds from issuances of Convertible Preferred Stock, net of issuance costs	56,933	99,853	99,990	34,994	—
Proceeds from issuances of Common Stock, net of issuance costs	58	—	10	—	76
Proceeds from issuances of Common Stock with repurchase rights and the early exercise of stock options	171	—	—	—	—
Proceeds from line of credit	—	—	3,283	—	6,077
Repayments under line of credit	—	—	(1,092)	—	(5,164)
Proceeds from sale of senior secured notes, net of issuance costs (including $53,624 from related parties)	—	77,999	—	—	—
Proceeds from development financing	—	15,000	15,000	15,000	—
Net cash provided by financing activities	57,162	192,852	117,191	49,994	989
Net increase (decrease) in cash and cash equivalents	29,218	(13,064)	58,334	27,960	(11,281)
Cash and cash equivalents, at beginning of period	4,460	33,678	20,614	20,614	78,948
Cash and cash equivalents, at end of period	$ 33,678	$ 20,614	$ 78,948	$ 48,574	$ 67,667
Supplemental disclosure of cash flow information:					
Cash paid for interest (including $4,263 and $4,556 for the years ended December 31, 2005 and 2006, respectively, and $2,063 and $2,100 for each of the three months ended March 31, 2006, and 2007 (unaudited), paid to related parties)	$ —	$ 6,200	$ 12,000	$ 3,000	$ 3,000
Supplemental disclosure of non-cash financing activities:					
Warrants to purchase Series BB Convertible Preferred Stock issued in conjunction with senior secured notes	$ —	$ 6,696	$ —	$ —	$ —
Beneficial conversion feature—deemed dividend attributable to preferred stockholders	$ —	$ —	$ 21,920	$ 3,501	$ —

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

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.

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.

JAZZ PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Unaudited Interim Financial Data

The accompanying consolidated balance sheet as of March 31, 2007, the consolidated statements of operations and of cash flows for the three months ended March 31, 2006 and 2007 and the consolidated statements of convertible preferred stock and stockholders' deficit for the three months ended March 31, 2007 are unaudited. The unaudited interim financial statements have been prepared on the same basis as the annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary to state fairly the Company's financial position as of March 31, 2007 and the results of its operations and cash flows for the three months ended March 31, 2006 and 2007. The financial data and other information disclosed in these notes to the financial statements related to the three month periods are unaudited. The results for the three months ending March 31, 2007 are not necessarily indicative of the results to be expected for the year ending December 31, 2007 or for any other interim period or for any future year.

Unaudited Pro Forma Balance Sheet

In February 2007, the board of directors authorized management of the Company to file a registration statement with the Securities and Exchange Commission permitting the Company to sell shares of its common stock to the public. The unaudited pro forma balance sheet as of March 31, 2007 and pro forma basic and diluted loss per share attributable to common stockholders reflect the automatic conversion of all of the Series A, Series B and Series B Prime convertible preferred stock outstanding at March 31, 2007 into 17,921,551 shares of common stock immediately prior to the closing of the Company's initial public offering. In addition, the unaudited pro forma balance sheet as of March 31, 2007 reflects the impact of the reclassification of the preferred stock warrant liability into additional paid-in capital as a result of the automatic conversion of warrants to purchase preferred stock into warrants to purchase common stock immediately prior to the closing of the Company's initial public offering and the reclassification of convertible preferred stock owned by certain executive officers, which is subject to a right of repurchase as discussed in Note 13, into common stock subject to repurchase.

Reverse Stock Split

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

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

JAZZ PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

customers accounted for an aggregate of approximately 88%, 90% and 93% of gross accounts receivable as of December 31, 2005, December 31, 2006 and March 31, 2007, 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 and March 31, 2007, 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

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.

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, and $3.1 million during the three months ended March 31, 2007, to reflect the increase in the fair value of the warrants. The Company recorded a benefit of $62,000 during the three months ended March 31, 2006 to reflect a decrease 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' equity (deficit).

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 specialty distributor and wholesaler fees, prompt payment discounts, Medicaid rebates, government chargebacks and a customer rebate. Calculating these items involves estimates and judgments based on sales or invoice data and historical experience. Due to the nature of the Company's current products, product returns have been infrequent and immaterial.

Royalties, Net

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

Contract Revenues

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

and collection is reasonably assured. Refundable fees are deferred and recognized as revenues upon the later of when they become nonrefundable or when performance obligations are completed.

Cost of Product Sales and Concentrations of Supply Risk

Cost of product sales includes third party manufacturing and distribution costs, the cost of drug substance, royalties due to third parties on product sales, product liability insurance, FDA user fees, freight, shipping, handling and storage costs, and salaries and related costs of employees involved with production. The Company's product exchange policy for Antizol allows and, prior to 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. Excluded from cost of product sales as shown on the face of the consolidated statements of operations is amortization of developed technology of $4.1 million and $7.9 million for the years ended December 31, 2005 and 2006, respectively, and $2.0 million and $1.9 million for the three months ended March 31, 2006 and 2007, respectively.

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 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.

JAZZ PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

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. Advertising expenses for the three months ended March 31, 2006 and 2007 were $442,000 and $820,000, respectively.

Income Taxes

The Company utilizes the liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and the tax bases of assets and liabilities and are measured using enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized.

Comprehensive Loss

Comprehensive loss includes net loss and all changes in stockholders' 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 and the three months ended March 31, 2006 and 2007, 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.

The calculation of pro forma basic and diluted net loss per common share assumes conversion of all outstanding shares of preferred stock into shares of common stock using the as-if-converted method as if such conversion had occurred at the beginning of the period or the original issuance date, if later.

JAZZ PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

	Year Ended December 31,			Three Months Ended March 31,	
	2004	2005	2006	2006	2007
				(Unaudited)	
	(In thousands, except per share data)				
Historic					
Numerator:					
Loss attributable to common stockholders	$ (24,804)	$ (85,156)	$ (81,311)	$ (25,880)	$ (19,584)
Denominator:					
Weighted-average common shares outstanding	607	618	620	618	627
Less: weighted-average common shares outstanding subject to repurchase	(591)	(612)	(607)	(609)	(604)
Weighted-average common shares used in computing loss per share attributable to common stockholders, basic and diluted	16	6	13	9	23
Loss per share attributable to common stockholders, basic and diluted	$ (1,550.25)	$ (14,192.67)	$ (6,254.69)	$ (2,875.56)	$ (851.48)
Pro Forma					
Weighted-average shares used in computation of basic and diluted loss per share applicable to common stockholders above			13		23
Pro forma adjustments to reflect assumed conversion of convertible preferred stock (unaudited)			13,453		17,643
Weighted-average shares used to compute pro forma basic and diluted loss per share attributable to common stockholders (unaudited)			13,466		17,666
			$ (6.04)		$ (1.11)

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,			Three Months Ended March 31,	
	2004	2005	2006	2006	2007
				(Unaudited)	
Series A convertible preferred stock (as if converted)	1,355	1,355	1,355	1,355	1,355
Series B convertible preferred stock (as if converted)	1,590	4,771	7,952	5,884	7,952
Series B Prime convertible preferred stock (as if converted)	1,723	5,169	8,614	6,375	8,614
Warrants to purchase Series BB convertible preferred stock (as if exercised and converted)	—	786	786	786	786
Options to purchase common stock	1,277	1,457	1,597	1,515	1,863
Early exercise of options and unvested restricted common stock	371	217	62	178	24
Common shares subject to repurchase	243	393	542	430	580

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.

JAZZ PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

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.

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. The Company adopted the provisions of FIN 48 effective January 1, 2007. No cumulative adjustment to the Company's accumulated deficit was required upon adoption.

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 was adopted by the Company in the first quarter of 2007. The Company has determined that the adoption of SAB 108 had no material effect 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

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

January 1, 2008. The Company is currently evaluating the effect that the adoption of SFAS 157 will have on its results of operations and financial position.

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

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 and March 31, 2007 (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
Total available-for-sale securities	$ 32,910	$ 4	$ —	$ 32,914
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
Total				$ 32,914

	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
Total available-for-sale securities	$ 91,211	$ 12	$ —	$ 91,223
Amounts classified as cash and cash equivalents				$ 78,948
Amounts classified as restricted cash				275
Amounts classified as long-term restricted cash and available-for-sale securities				12,000
Total				$ 91,223

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

	March 31, 2007			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
		(Unaudited)		
Cash	$ 12,641	$ —	$ —	$ 12,641
Obligations of U.S. government agencies	39,503	—	—	39,503
Corporate debt securities	13,319	—	—	13,319
Other debt securities, primarily money market funds	14,564	—	—	14,564
Total available-for-sale securities	$ 80,027	$ —	$ —	$ 80,027
Amounts classified as cash and cash equivalents				67,667
Amounts classified as restricted cash				275
Amounts classified as long-term restricted cash and available-for-sale securities				12,085
				$ 80,027

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.

4. Certain Balance Sheet Items

Inventories consist of the following (in thousands):

	December 31,		March 31,
	2005	2006	2007
			(Unaudited)
Raw materials	$ 1,109	$ 541	$ 550
Finished goods	2,153	2,485	1,753
Total inventories	$ 3,262	$ 3,026	$ 2,303

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

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

	December 31, 2005	December 31, 2006	March 31, 2007 (Unaudited)
Leasehold improvements	$ 616	$ 700	$ 704
Computer equipment	707	873	961
Computer software	558	1,271	1,413
Furniture and fixtures	160	182	208
Construction-in-progress	506	316	327
Total	2,547	3,342	3,613
Less accumulated depreciation and amortization	(606)	(1,235)	(1,497)
Property and equipment, net	$1,941	$ 2,107	$ 2,116

Accrued liabilities consists of the following (in thousands):

	December 31, 2005	December 31, 2006	March 31, 2007 (Unaudited)
Accrued research and development expense	$ 4,166	$ 5,119	$ 4,499
Accrued compensation	3,329	4,322	2,950
Accrued sales and marketing expense	2,231	783	2,071
Accrued general and administrative expense	365	1,440	1,397
Other	1,030	1,279	2,180
Total accrued liabilities	$11,121	$12,943	$ 13,097

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.

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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
Total fair value of assets acquired, net of liabilities assumed	$146,116

Liabilities of $8.0 million as shown above included $4.0 million of restructuring charges related primarily to employee severance payments and the closure of facilities, of which no amounts remained unpaid as of December 31, 2006.

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

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

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

In January 2005, Orphan Medical submitted a supplemental New Drug Application, or sNDA, to the FDA seeking an expanded label indication for Xyrem for the treatment of excessive daytime sleepiness in patients with narcolepsy. At the time of the acquisition, the FDA had not yet approved the sNDA. The Company used a

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

discount rate of 26% to calculate the fair value of the expanded label indication for Xyrem and accounted for $15.2 million associated with the expanded label indication as in-process research and development expense. The sNDA was approved by the FDA in November 2005. At the time of acquisition, Orphan Medical was also conducting a Phase II clinical trial to evaluate the use of sodium oxybate, the active pharmaceutical ingredient in Xyrem, to treat fibromyalgia syndrome. The Company used a 50% discount rate to calculate the fair value associated with this development project and accounted for $5.9 million associated with the project as in-process research and development. In August 2006, the Company initiated a Phase III clinical trial of sodium oxybate for the treatment of fibromyalgia syndrome. In addition, at the time of acquisition, Orphan Medical was conducting initial research into new dosage forms of Xyrem. The Company used a 50% discount rate to calculate the fair value of these research efforts and accounted for $200,000 associated with this research as in-process research and development expense.

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

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):

	Year Ended December 31,	
	2004	2005
Revenues	$ 23,768	$ 37,275
Net loss	(60,318)	(77,643)
Loss per common share	$(3,769.88)	$(12,940.50)

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

6. Goodwill and Intangible Assets

The gross carrying amount and net book value of goodwill and intangible assets is as follows (in thousands):

	December 31, 2005			December 31, 2006			March 31, 2007		
	Gross Carrying Amount	Accumulated Amortization	Net Book Value	Gross Carrying Amount	Accumulated Amortization	Net Book Value	Gross Carrying Amount	Accumulated Amortization (Unaudited)	Net Book Value
Developed technology—Xyrem	$ 39,700	$2,155	$37,545	$ 39,700	$ 6,327	$33,373	$ 39,700	$ 7,370	$32,330
Developed technology—Antizol	31,100	1,688	29,412	31,100	4,956	26,144	31,100	5,773	25,327
Developed technology—Cystadane	4,300	234	4,066	4,300	687	3,613	—	—	—
Agreements not to compete	5,600	696	4,904	5,600	2,042	3,558	5,600	2,379	3,221
Trademarks	2,600	141	2,459	2,600	414	2,186	2,600	483	2,117
Other	400	46	354	400	134	266	400	156	244
Amortizable intangible assets	83,700	4,960	78,740	83,700	14,560	69,140	79,400	16,161	63,239
Goodwill	38,883			38,213			38,213		
Total	$122,583			$121,913			$117,613		

Future amortization costs per year for the Company's existing intangible assets other than goodwill as of December 31, 2006 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

In March 2007, as discussed more fully in note 19, the Company sold its rights to the Cystadane product and as a result reduced the gross carrying amount and accumulated amortization of this intangible asset by $4.3 million and $761,000, respectively.

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 and March 31, 2007, $2.2 million and $3.1 million, respectively, 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

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

785,728 shares of the Company's Series BB preferred stock exercisable at $20.36 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%, 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 and March 31, 2007, 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 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 March 31, 2007 and is reflected as long-term restricted cash and investments on the Company's consolidated balance sheet. The notes contain customary covenants including limitations on the Company's ability to pay dividends, make investments or other restricted payments, incur debt, grant liens, sell assets and enter into sale-leaseback transactions. Upon the occurrence of certain events of default under the notes, including a default by the Company in payment of principal or interest on the notes, a bankruptcy filing by the Company, or a change in control of the Company, the Company may be required to repay the notes at a premium. The repayment premium was 30.0% and 28.3% of the principal amount of the notes as of December 31, 2006 and March 31, 2007, respectively, 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, $1.1 million and $599,000 during the years ended December 31, 2005 and 2006 and the three months ended March 31, 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

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

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 and March 31, 2007. No assurances can be given that the covering insurers will not attempt to dispute the validity, applicability, or amount of coverage without expensive litigation against these insurers, in which case the Company may incur substantial liabilities as a result of these indemnification obligations.

Lease and Other Commitments

In June 2004, the Company entered into a noncancelable operating lease for an office facility in Palo Alto, California which expires in August 2008. The lease is renewable through 2017 at the Company's option. In addition to these lease payments, the Company is obligated to pay for operating expenses for the leased property. 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. Rent expense under all operating leases was $268,000 and $361,000 for the three months ended March 31, 2006 and 2007, 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
Total future minimum lease payments	$ 2,411

Future minimum lease payments under the Company's noncancelable operating leases at March 31, 2007, are as follows (unaudited) (in thousands):

Year ended December 31,	Lease Payments (Unaudited)
Remainder of 2007	$ 1,242
2008	1,338
2009	343
2010	57
Total future minimum lease payments	$ 2,980

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

The Company uses third party contract manufacturers to manufacture products. As of December 31, 2006 and March 31, 2007, the Company had $1.5 million and $1.7 million, respectively, 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' 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, with leave to amend. On March 14, 2007, the plaintiff filed an amended complaint, and the defendants responded with a motion to dismiss on March 16, 2007. 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 active pharmaceutical ingredient in JZP-4. The Company paid and recorded research and development

expense of $2.0 million upon execution of the agreement and $3.0 million in July 2006 upon achievement of a development milestone. The Company also agreed to pay up to $113.5 million upon the achievement of future development and commercial milestones and royalties at specified rates based on net sales.

The Company 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 development milestones under the terms of three agreements which have since been terminated and under which no future obligations existed at December 31, 2006. In connection with its product development activities, the Company may enter into agreements with third party technology providers, patent holders and others. Patent licenses may require upfront payments, patent prosecution and maintenance fees and royalties on sales of products covered by the patents. Agreements with technology providers often provide for upfront payments and milestone payments based upon the achievement of specified development and commercial milestones and royalties based on sales of the products the Company develops with the technology provider. The Company currently has two such agreements pursuant to which it has agreed to pay up to $8.2 million upon achievement of development 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 fibromyalgia syndrome 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 nonrefundable commercial milestone payments of $500,000 and $2.0 million in June 2006 and March 2007, respectively, 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 fibromyalgia syndrome. The Company recognized revenues of $463,000 and $252,000 related to these upfront payments during the year ended December 31, 2006 and the three months ended March 31, 2007, respectively. The remaining $14.3 million was recorded as deferred revenues as of March 31, 2007 and is being recognized ratably through 2019, the expected performance period under the agreement. There has been no change in the expected performance period since its establishment in 2006 at the time of the initial upfront payment. The amended agreement requires UCB to make additional milestone payments of up to $146.0 million, of which up to $6.0 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 fibromyalgia syndrome and up to $100.0 million relate primarily to the commercialization of JZP-6 for the treatment of fibromyalgia syndrome as well as additional sales of Xyrem for the treatment of narcolepsy.

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 785,728 shares of Series BB preferred stock at an exercise price of $20.36 per share. The warrants are exercisable, at the option of the holders, at any time until June 24, 2012, and 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

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estimated to be $7.4 million, $8.5 million and $11.6 million as of December 31, 2005, December 31, 2006 and March 31, 2007, respectively, using the following assumptions:

	December 31,		March 31, 2007
	2005	2006	(Unaudited)
Series BB preferred stock fair value	$ 16.60	$ 19.37	$ 24.79
Volatility	60%	59%	57%
Contractual term	6.5	5.5	5.2
Risk-free rate	4.3%	4.7%	4.5%
Expected dividend yield	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, and $3.1 million during the three months ended March 31, 2007, to reflect increases in the fair value of the preferred stock warrant liability. The Company recorded a benefit of $62,000 during the three months ended March 31, 2006 to reflect a decrease 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' equity (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):

	Shares Authorized	Shares Issued and Outstanding	Carrying Amount	Aggregate Liquidation Preference
Series A	1,355,380	1,355,377	$ 14,926	$ 15,000
Series B	17,096,311	4,771,048	71,549	72,000
Series B Prime	8,614,420	5,168,651	77,387	78,000
Series BB	785,728	—	—	—
Total	27,851,839	11,295,076	$ 163,862	$ 165,000

As of December 31, 2006 and March 31, 2007, 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	1,355,380	1,355,377	$ 14,926	$ 15,000
Series B	17,096,311	7,951,755	119,544	120,000
Series B Prime	8,614,420	8,614,419	129,382	130,000
Series BB	785,728	—	—	—
Total	27,851,839	17,921,551	$ 263,852	$ 265,000

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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 and March 31, 2007, the Company has reserved 8,614,420 shares of Series B preferred stock for conversion of the Series B Prime preferred stock.

In January and December 2006, the Company issued 2,319,264 and 4,307,211 shares, respectively, of Series B preferred stock and Series B Prime preferred stock at a purchase price of $15.09 per share. At the time of each of these issuances, the value of the common stock into which the Series B preferred stock and Series B Prime preferred stock is convertible had a fair value greater than the proceeds for such issuances. Accordingly, the Company recorded a deemed dividend on the Series B preferred stock and Series B Prime preferred stock of $3.5 million in January 2006 and $18.4 million in December 2006, which equals the amount by which the estimated fair value of the common stock issuable upon conversion of the issued Series B preferred stock and Series B Prime preferred stock exceeded the proceeds from such issuances.

The significant rights, privileges and preferences of the preferred stock are as follows:

Election of Directors

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.

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 for stock dividends, stock splits, subdivisions, combinations, reclassifications and similar matters affecting the common stock. 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 or March 31, 2007.

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 $11.07, $15.09, $15.09 and $20.36, 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 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.

13. Common Stock

The Company's Second Amended and Restated Certificate of Incorporation authorizes the Company to issue 22,835,080 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.

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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 and March 31, 2007 the Company had recorded a liability of $184,000, $98,000 and $77,000, respectively, associated with 216,622, 62,127 and 23,505 unvested shares, respectively. As of December 31, 2005 and 2006 and March 31, 2007, the Company had recorded $5.9 million, $8.2 million and $8.7 million as temporary equity, respectively, associated with 242,911, 392,622 and 542,336 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	As of March 31, 2007 (Unaudited)
Reserved for conversion of Series A preferred stock	1,355,380	1,355,380
Reserved for conversion of Series B, Series B Prime and Series BB preferred stock	17,882,039	17,882,039
Reserved for the Company's equity incentive plan	2,083,339	2,078,322
Total reserved shares of common stock	21,320,758	21,315,741

14. Stock-Based Compensation

2003 Equity Incentive Plan

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 2,125,042 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 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.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

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,			Three Months Ended March 31, (Unaudited)	
	2004	2005	2006	2006	2007
Weighted-average volatility	80%	60%	61%	61%	61%
Weighted-average expected term	5.0	5.0	6.0	6.0	6.5
Range of risk-free rates	3.0-4.0%	3.9-4.4%	4.6-5.1%	4.6%	4.5-4.8%
Expected dividend yield	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 and the three months ended March 31, 2006 and 2007 was $8.96, $8.66, $10.68, $10.05 and $12.07, 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 and the three months ended March 31, 2007, 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.

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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's board of directors directed management to perform an in-depth contemporaneous valuation of its common stock. In conducting this valuation, the Company 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 its 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 the "income approach" to estimate enterprise value. This enterprise value was then validated utilizing the "market approach." The income approach involved projecting future cash flows, discounting them to present value using a discount rate of 15% based upon a risk adjusted weighted average cost of capital of comparable companies, and applying probabilities for success of its product candidates to the resulting discounted cash flows. The projection of future cash flows, the determination of an appropriate discount rate and the estimates of probability for success of its product candidates each involved a significant degree of judgment. For product candidates other than JZP-6 and an alternative dosage form of Xyrem, the probabilities for success ranged from five percent to 30%. For JZP-6, a project for which the Company was preparing to commence Phase III clinical trials, the probability of success ranged from 60% to 70% and for an alternative dosage form of Xyrem, probabilities of success ranged from 50% to 100%. The present value of projected future cash flows after application of the discount rate and, for product candidates, the Company's probabilities of success, ranged from $113.5 million to $124.1 million for its existing products, $112.8 to $156.1 million for JZP-6 and $66.7 million to $142.8 million for its other product candidates, including an alternative dosage form of Xyrem, resulting in a range of enterprise values from $293.0 million to $423.0 million. The market approach used to validate the determination of enterprise value involved selecting a range of possible valuations by comparing a group of 14 publicly-traded specialty pharmaceutical and biotechnology companies with products and product candidates in similar stages of development. The range of enterprise values derived through application of the market approach method was $300.0 million to $350.0 million. As these values fell within the range of enterprise values suggested by application of the income approach, the Company determined that the market approach provided an appropriate validation of its estimated enterprise value.

In order to allocate the enterprise value to the various securities that comprise the Company's capital structure, the option-pricing method was used. For purposes of applying the option-pricing method, the Company estimated its stock price volatility to be 60% and its time to liquidity to be one year. A 10% discount was then applied to account for a lack of marketability of its common stock based upon the assumed time to liquidity. The contemporaneous valuation of its common stock suggested a range of probable fair values from $12.17 per share to $17.26 per share. On June 28, 2006, the Company's board of directors made a determination that the fair market value of its common stock was $16.60 per share, after taking into consideration the contemporaneous valuation as well as other factors including its financial performance, the development status of its product candidates and research and development efforts and the likelihood of achieving a liquidity event for the shares of common stock underlying stock options, such as an initial public offering or sale of the Company, given prevailing market conditions.

In December 2006, the Company's board of directors directed management to perform a second in-depth contemporaneous valuation with an effective date of December 31, 2006. In conducting this valuation, the Company used the same methodology and assumptions as in the prior contemporaneous valuation for determining enterprise value, with the exception of adjustments in its estimated future cash flows for certain of its existing products and product candidates and the Company's estimated probabilities of success for certain of its product candidates for purposes of the income approach. The Company also made modifications to the comparison group of companies utilized for the market approach to reflect business developments at comparable

companies and to achieve an appropriate sample size. The present value of projected future cash flows after application of the discount rate and, for product candidates, the Company's probabilities of success ranged from $83.6 million to $93.2 million for its existing products, $138.5 to $186.0 million for JZP-6 and $94.9 million to $184.8 million for its other product candidates, including an alternative dosage form of Xyrem, resulting in a range of enterprise values from $317.0 million to $464.0 million. A number of companies included in the comparison group for purposes of the market approach in the June 28, 2006 contemporaneous valuation were not included in the comparison group as of December 31, 2006 as a result of material adverse events associated with significant development projects at those companies that the Company believed made their market values incomparable to its own. Appropriate specialty pharmaceutical and biotechnology companies were added to the comparison group for purposes of the December 31, 2006 contemporaneous valuation to provide an appropriate sample size of 13 comparable companies. The range of enterprise values derived through the application of the market approach method was $350.0 million to $425.0 million. As these values fell within the range of enterprise values suggested by application of the income approach, the Company determined that the market approach provided an appropriate validation of its estimated enterprise value.

For purposes of allocating enterprise value to the Company's common stock, time to liquidity assumed in the option pricing method was reduced to six months and the discount for marketability was consequently reduced to five percent. In addition to the option-pricing method, the Company also considered the probability weighted expected return method. The application of this method yielded a result within the range of probable fair values suggested by the option pricing method. For purposes of applying the probability-weighted expected return method the Company considered six potential liquidity scenarios. Two potential scenarios were each given a probability of five percent and involved the distressed sale or liquidation of the company at alternative valuations of $10.0 million and $100.0 million. Two other potential scenarios were each given a probability of 7.5% and involved the sale of the company following the failure to achieve positive clinical trial results for certain of the Company's product candidates at alternative valuations of $200.0 million and $270.0 million. The remaining potential scenarios involved the successful sale of the Company or an initial public offering of the Company's common stock at alternative valuations of $500.0 million and $800.0 million, which were given probabilities of 70% and five percent, respectively. The contemporaneous valuation of the Company's common stock suggested a range of probable fair values from $13.94 per share to $21.36 per share. On February 13, 2007, the Company's board of directors made a determination that the fair market value of its common stock was $19.37 per share after taking into consideration the contemporaneous valuation as well as other factors, including its financial performance, the development status of its product candidates and research and development efforts, the likelihood of achieving a liquidity event for the shares of common stock underlying stock options, such as an initial public offering or sale of the Company, given prevailing market conditions and initial estimates of the potential initial public offering price of its common stock based on initial valuation discussions by and between management and the proposed underwriters for the Company's initial public offering. This determination was confirmed by the compensation committee of the Company's board of directors as of February 27, 2007, the last date in the three month period ended March 31, 2007 that the Company granted stock options.

In connection with the preparation of the Company's financial statements for the year ended December 31, 2006, it reassessed the fair value of its common stock at option grant dates from June 28, 2006 through December 31, 2006 by reviewing its corporate developments from June 28, 2006 through February 13, 2007. In undertaking this assessment, the Company determined that the increase in value from June 28, 2006 to December 31, 2006 was attributable to a decrease in expected timing to liquidity and general progress in the development status of the Company's product candidates and not the achievement of any particular business milestones which would reasonably be expected to significantly change the relative timing or likelihood of expected future net cash flows. The Company also determined that no such milestones had been achieved during the period from December 31, 2006 to February 13, 2007. As a result, the Company concluded that a ratable

increase to the estimated fair value of its common stock from $16.60 to $19.37 over the period from June 28, 2006 to December 31, 2006 for purposes of calculating stock-based compensation expense associated with its stock option grants under SFAS 123R was appropriate. In connection with the grant of stock options on February 27, 2007, the compensation committee of the Company's board of directors confirmed that the fair market value of our common stock was $19.37 on the basis that we had not achieved any particular business milestone that would reasonably be expected to significantly change the relative timing or likelihood of expected future net cash flows in the period from February 13, 2007 to February 27, 2007. Therefore, the Company determined that no reassessment of the fair value of our common stock as of February 27, 2007 was appropriate.

On February 28, 2007, Solvay informed the Company that the FDA had issued an approvable letter to Solvay for Luvox and Luvox CR dated February 27, 2007. In April 2007, the audit committee of the Company's board of directors determined that as of March 31, 2007, the fair value of the Company's common stock was $24.79 per share after taking into account the contemporaneous valuation conducted in December 2006, the achievement of a significant business milestone associated with the issuance of the approvable letter for Luvox and Luvox CR to Solvay, the likelihood of achieving a liquidity event for the shares of common stock underlying stock options, such as an initial public offering or sale of the company, given prevailing market conditions, and further estimates of the potential initial public offering price of the Company's common stock based on valuation discussions by and between management and the proposed underwriters for the offering. The Company did not perform a contemporaneous valuation of its enterprise value or common stock using the income approach or market approach as of March 31, 2007. The fair market value determination made by the Company's board of directors as of March 31, 2007 was based on the midpoint of the valuation range then suggested by the Company's proposed underwriters in connection with the contemplated initial public offering.

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 1,133,862 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 $267.71 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. During the three months ended March 31, 2007, the Company recognized $940,000 of stock-based compensation expense, of which $4,000, $201,000 and $735,000 were charged to cost of product sales, research and development and selling, general and administrative expense, respectively. During the three months ended March 31, 2006, the Company recognized $820,000 of stock-based compensation expense, of which $1,000, $144,000 and $675,000 were charged to cost of product sales, research and development and selling, general and administrative expense, respectively.

JAZZ PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

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.

The total compensation cost related to unvested stock option grants not yet recognized as of March 31, 2007 was $7.2 million and the weighted-average period over which these grants are expected to vest is 2.7 years.

Certain information regarding employee stock option grants during the 12 months prior to March 31, 2007 is as follows:

Grant Date	Shares Underlying Option Grants	Exercise Price Per Share	Fair Value Per Share for Accounting Purposes	Black-Scholes Fair Value Per Share
April 2006	22,680	$ 16.60	$ 16.60	$ 10.12
June 2006	6,146	$ 16.60	$ 16.60	$ 10.15
August 2006	49,922	$ 16.60	$ 17.49	$ 10.80
October 2006	21,279	$ 16.60	$ 18.48	$ 11.61
December 2006	16,807	$ 16.60	$ 19.37	$ 12.38
February 2007 (unaudited)	100,259	$ 19.37	$ 19.37	$ 11.84
February 2007 (unaudited)	180,719	$ 19.37	$ 19.37	$ 12.19

The following table summarizes activity under the Company's stock option plans from January 1, 2004 through March 31, 2007:

	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	—	33,658	$ 1.11		
Shares authorized through Plan amendment	2,061,566	—			
Options granted	(1,249,254)	1,249,254	23.31		
Options exercised	—	(5,873)	1.11		
Outstanding at December 31, 2004	812,312	1,277,039	22.83		
Options granted	(209,509)	209,509	15.79		
Options forfeited	27,426	(27,426)	13.50		
Options expired	1,807	(1,807)	1.11		
Outstanding at December 31, 2005	632,036	1,457,315	22.02		
Options granted	(177,432)	177,432	16.60		
Options exercised	—	(6,012)	1.63		
Options forfeited	30,482	(30,482)	15.28		
Options expired	919	(919)	15.29		
Outstanding at December 31, 2006	486,005	1,597,334	21.62	7.5	$ 4,722
Options granted (unaudited)	(280,978)	280,978	19.37		
Options exercised (unaudited)	—	(5,017)	15.14		
Options forfeited (unaudited)	1,510	(1,510)	16.33		
Options expired (unaudited)	9,255	(9,255)	15.09		
Outstanding at March 31, 2007 (unaudited)	215,792	1,862,530	21.34	7.7	$ 12,297
Vested and expected to vest at March 31, 2007 (unaudited)		1,763,688	21.53	7.6	$ 11,625
Exercisable at March 31, 2007 (unaudited)		1,042,158	22.57	7.0	$ 6,856

JAZZ PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

At December 31, 2006 options to purchase 1,552,592 shares with a weighted-average exercise price of $21.78 per share, a weighted-average remaining contractual term of 7.5 years and aggregate intrinsic value of $4.6 million were vested or expected to vest. At December 31, 2006 options to purchase 956,073 shares with a weighted-average exercise price of $22.55 per share, a weighted-average remaining contractual term of 7.2 years and aggregate intrinsic value of $2.9 million were exercisable.

Aggregate intrinsic value shown is equal to the difference between the exercise price of the underlying stock options and the fair value of the Company's common stock for stock options that were in the money.

During 2004, stock options exercised had no intrinsic value. No options were exercised during 2005. The aggregate intrinsic value of options exercised during 2006 and the three months ended March 31, 2007 was $90,000 and $8,000, respectively.

The following table summarizes information about stock options outstanding as of December 31, 2006:

	Options Outstanding		Options Exercisable
Exercise Price	Number of Shares	Weighted-Average Remaining Contractual Life (Years)	Number of Shares
$ 1.11	15,586	6.6	15,586
15.09	871,585	7.2	585,463
16.60	256,617	9.1	33,742
30.18	226,773	7.1	160,641
45.27	226,773	7.1	160,641
	1,597,334	7.5	956,073

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

	Options Outstanding		Options Exercisable
Exercise Price	Number of Shares	Weighted-Average Remaining Contractual Life (Years) (Unaudited)	Number of Shares
$ 1.11	15,586	6.3	15,586
15.09	857,217	7.1	624,643
16.60	255,203	9.0	52,315
19.37	280,978	9.9	—
30.18	226,773	6.9	174,807
45.27	226,773	6.9	174,807
	1,862,530	7.7	1,042,158

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.

JAZZ PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Accounting and Disclosures Under APB 25 and SFAS 123

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

	Year Ended December 31,	
	2004	2005
	(In thousands except per share data)	
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	$(1,550.25)	$(14,192.67)
Pro forma	$(1,695.56)	$(14,681.67)

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 $15.09 and $15.79 during the years ended December 31, 2004 and 2005, respectively. The Company granted options to purchase 453,546 shares with exercise prices greater than fair value per share with a weighted-average exercise price per share of $37.73 and weighted-average fair value per share of $15.09 during the year ended December 31, 2004.

15. Income Taxes

The Company has a history of losses and therefore has made no provision for income taxes. All of the Company’s losses result from domestic operations.

Deferred income taxes reflect the tax effects of net operating loss and tax credit carryforwards and the net temporary differences between the carrying amounts of assets and liabilities for financial reporting and the amounts used for income tax purposes.

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	December 31, 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
Total deferred tax assets	63,224	80,323
Deferred tax liabilities:		
Acquired intangible assets	(27,559)	(24,328)
Other	—	(457)
Total deferred tax liabilities	(27,559)	(24,785)
Valuation allowance	(35,665)	(55,538)
Net deferred tax assets	$ —	$ —

Realization of the deferred tax assets is dependent upon the generation of future taxable income, if any, the amount and timing of which are uncertain. Based on available objective evidence, management believes it more likely than not that the Company's deferred tax assets are not recognizable. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by $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.

The Company adopted Financial Accounting Standards Board Interpretation No. 48 *Accounting for Uncertainties in Income Taxes—an interpretation of FASB Statement No. 109 ("FIN 48")* effective January 1, 2007. FIN 48 requires that the Company recognize the financial statement effects of a tax position when it is more likely than not, based on the technical merits, that the position will be sustained upon examination. No cumulative adjustment to the Company's accumulated deficit was required upon our adoption of FIN 48.

As of January 1, 2007, the Company had approximately $1.5 million of unrecognized tax benefits, substantially all of which would, if recognized, affect our tax expense. We do not anticipate that the amount of existing unrecognized tax benefits will significantly increase or decrease within the next 12 months. Because of net operating loss carryforwards, substantially all of the Company's tax years remain open to tax federal

JAZZ PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

examination. We file income tax returns in the United States and various states, which typically have three tax years open at any point in time.

16. Related Party Transactions

In June 2005, the Company issued senior secured notes in the aggregate principal amount of $80.0 million with interest payable on the notes at the rate of 15% per year, payable quarterly in arrears. The notes are due and payable on June 24, 2011. As of both December 31, 2006 and March 31, 2007, 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 years ended December 31, 2005 and 2006 was $2.1 million and $4.0 million, respectively, and $1.0 million during each of the three months ended March 31, 2006 and 2007. The interest expense recognized with respect to notes held by LB I Group during the fiscal years ended December 31, 2005 and 2006 was $2.5 million and $5.0 million, respectively, and $1.2 million during each of the three months ended March 31, 2006 and 2007. No payments of principal were made in either of these periods. As of December 31, 2006 and March 31, 2007, warrants to purchase 245,540 and 304,469 shares of our Series BB preferred stock were owned by 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):

	Year Ended December 31,		Three Months Ended March 31,	
	2005	2006	2006	2007
			(Unaudited)	
Xyrem	$ 11,200	$ 29,049	$ 6,153	$ 8,624
Antizol	6,782	12,813	3,131	2,636
Cystadane	814	1,437	487	365
Total	$ 18,796	$ 43,299	$ 9,771	$ 11,625

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.

JAZZ PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

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

	Year Ended December 31,		Three Months Ended March 31,	
	2005	2006	2006	2007
			(Unaudited)	
United States	$ 18,305	$ 42,326	$ 9,350	$11,513
Europe	3,020	1,757	231	2,524
All other	117	773	256	51
Total	$ 21,442	$ 44,856	$ 9,837	$14,088

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

	Year Ended December 31,		Three Months Ended March 31,	
	2005	2006	2006	2007
			(Unaudited)	
Express Scripts	51%	65%	63%	61%
Cardinal Health	*	12%	15%	*
Amerisource Bergen	15%	*	*	*
UCB	12%	*	*	17%
McKesson Corporation	*	*	11%	*

* 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 development 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. As the initial $2.0 million payment has no alternative future use, the Company has expensed this amount as research and development expense in the three months ended March 31, 2007. 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 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 recorded a gain of approximately $5.1 million on the sale of the rights to Cystadane in the first quarter of 2007.

Legal Proceedings

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

The Company and Orphan Medical have been in discussions regarding a possible settlement with the United States, acting through the Department of Justice, the U.S. Attorney's Office for the Eastern District of New York and other federal agencies, including the Office of Inspector General, U.S. Department of Health and Human Services, relating to this matter. If the Company completes a settlement on the terms that the Company is currently discussing, Orphan Medical would plead guilty to one felony count of introducing a misbranded drug into interstate commerce and would pay a total of approximately $20.5 million in civil and criminal payments over the next several years in connection with this matter, with approximately $1.5 million payable in 2007, $2.0 million payable in 2008, $2.5 million payable in 2009, $3.0 million payable in 2010, $3.0 million payable in 2011 and $8.5 million payable in 2012. The Company would guarantee payment of these amounts by Orphan Medical.

If the Company completes a settlement on the terms that the Company is currently discussing, the U.S. Attorney has indicated that the Company would not be prosecuted. As part of the settlement, the Company would enter into a corporate integrity agreement with the Office of Inspector General, U.S. Department of Health and Human Services, which would require the Company to maintain a comprehensive compliance program. The Company would have additional ongoing compliance-related operating costs related to this compliance program, which the Company does not expect to be material, as a result of the corporate integrity agreement.

The settlement terms described above are subject to the negotiation and execution of definitive agreements. Even if the Company reaches a settlement agreement with the U.S. Attorney's Office, the Company might still be subject to regulatory and/or enforcement action by federal agencies that are not parties to the settlement, private insurers and states' attorneys general with respect to activities covered by the settlement. If the Company does not reach a settlement, the Company could be required to spend significant amounts to defend itself and Orphan Medical, and the investigation could involve criminal charges, as well as criminal and/ or civil fines and penalties, against the Company, Orphan Medical, or both. If the Company is unable to complete the settlement described above, 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, and such an outcome could have a material adverse effect on the Company's financial position, liquidity and results of operations. 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.

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

ORPHAN MEDICAL, INC.

STATEMENT OF OPERATIONS
(In thousands, except per share amounts)

	Period from January 1, 2005 to June 24, 2005
Revenues:	
Product sales, net	$ 12,966
Royalties, net	71
Contract revenues	1,806
Total revenues	14,843
Operating expenses:	
Cost of product sales	1,975
Research and development	4,212
Selling, general and administrative	12,155
Total operating expenses	18,342
Loss from operations	(3,499)
Interest income	111
Interest expense	(13)
Net loss	(3,401)
Less: Preferred stock dividends	491
Loss attributable to common stockholders	$ (3,892)

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

ORPHAN MEDICAL, INC.

STATEMENT OF CASH FLOWS
(In thousands)

	Period from January 1, 2005 to June 24, 2005
Operating activities	
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:	
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	(8,704)
Investing activities	
Purchases of property and equipment	(5)
Restricted cash	(1)
Net cash used in investing activities	(6)
Financing activities	
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.

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 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

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. 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

ORPHAN MEDICAL, INC.

NOTES TO FINANCIAL STATEMENTS—(Continued)

studies, fees paid to third parties for development candidates, allocated expenses, such as facilities and 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.

	Period from January 1, 2005 to June 24, 2005
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)

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:

	Period from January 1, 2005 to June 24, 2005
Expected dividend yield	0%
Expected stock price volatility	65%
Risk-free interest rate	4%
Expected life of option (in years)	8

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 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):

	Period from January 1, 2005 to June 24, 2005
Xyrem	$ 8,034
Antizol	4,267
Cystadane	665
Total	$ 12,966

ORPHAN MEDICAL, INC.

NOTES TO FINANCIAL STATEMENTS—(Continued)

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

	Period from January 1, 2005 to June 24, 2005
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:

	Period from January 1, 2005 to June 24, 2005
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 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. On March 14, 2007, the plaintiff filed an amended complaint, and the defendants responded with a motion to dismiss on March 16, 2007. 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.


Jazz Pharmaceuticals™
Innovation that performs

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.

	Amount to be Paid
SEC registration fee	$ 5,508
NASD filing fee	18,400
NASDAQ Global Market initial listing fee	120,000
Blue sky qualification fees and expenses	15,000
Printing and engraving expenses	125,000
Legal fees and expenses	950,000
Accounting fees and expenses	950,000
Transfer agent and registrar fees and expenses	20,000
Miscellaneous expenses	96,052
Total	$ 2,300,000

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 to above, the corporation must indemnify him or her against the expenses that such officer or director has actually and reasonably incurred. Our fourth 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.

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 fourth 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, Momtazee and Patel 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.

Item 15. Recent Sales of Unregistered Securities.

The following list sets forth information regarding all unregistered securities sold by us since our inception through March 31, 2007.

(1) Since our inception through March 31, 2007, we had granted options under our 2003 Equity Incentive Plan to purchase 1,980,649 shares of common stock to employees and directors, having exercise prices ranging from $1.11 to $45.27 per share. Of these, options to purchase 46,720 shares of common stock had been exercised for aggregate consideration of $125,333, at exercise prices ranging from $1.11 to $16.60 per share. As of March 31, 2007, we had cancelled options to purchase 71,399 shares of common stock.

(2) On March 20, 2003, we issued and sold an aggregate of 357,819 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 73,642 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 27,107 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 29,818 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 194,268 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 451,792 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 59,637 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 21,008 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 709,317 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 1,563,829 shares of Series B preferred stock to a total of thirty-one accredited investors for aggregate consideration of $23,599,999.74.

(12) On February 18, 2004, we issued and sold an aggregate of 1,722,883 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 26,505 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 13,252 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 3,180,714 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 3,445,768 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 785,728 shares of Series BB preferred stock to a total of eight accredited investors. Pursuant to the terms of

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 1,113,245 shares of Series B preferred stock to a total of thirty-two accredited investors for aggregate consideration of $16,799,996.53.

(19) On January 26, 2006, we issued and sold an aggregate of 1,206,019 shares of Series B Prime preferred stock to a total of two accredited investors for aggregate consideration of $18,200,000.56.

(20) On December 14, 2006, we issued and sold an aggregate of 2,067,462 shares of Series B preferred stock to a total of thirty-two institutional and accredited investors for aggregate consideration of $31,199,983.44.

(21) On December 14, 2006, we issued and sold an aggregate of 2,239,749 shares of Series B Prime preferred stock to a total of two institutional and accredited investors for aggregate consideration of $33,799,997.74.

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

The offers, sales, and issuances of the securities described in Items 15(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 Number	Description of Document
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*	Third Amended and Restated Certificate of Incorporation of the Registrant, currently in effect.
3.2*	Form of Fourth 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.

Exhibit Number	Description of Document
4.3.1+*	Second Amended and Restated Investor Rights Agreement, dated as of June 24, 2005, by and between the Registrant and the other parties named therein.
4.3.2+*	Form of Third Amended and Restated Investor Rights Agreement, by and between the Registrant and the other parties named therein, to be effective upon the closing of this offering.
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.
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.

Exhibit Number	Description of Document
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 Option Exercise and Stock Purchase Agreement and Forms of Grant Notices 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, by and between Orphan Medical, Inc. and Lonza, Inc.
10.32	Amendment No. 1 to Sodium Gamma Hydroxybutyrate Development and Supply Agreement, dated as of February 7, 2005, by and between Orphan Medical, Inc. and Lonza, Inc.
10.33#*	Amended and Restated Services Agreement, dated as of May 31, 2005, by and between Orphan Medical, Inc. and Express Scripts Specialty Distribution Services, Inc.
10.34#*	Consent and Addendum to Amended and Restated Master Services Agreement, dated as of June 1, 2006, by and between the Registrant and Express Scripts Specialty Distribution Services, Inc.
10.35#*	Addendum No. 2 to Amended and Restated Master Services Agreement, dated as of June 22, 2006, by and between the Registrant and Express Scripts Specialty Distribution Services, Inc.
10.36#*	Addendum No. 3 to Amended and Restated Master Services Agreement, dated as of August 17, 2006, by and between the Registrant and Express Scripts Specialty Distribution Services, Inc.
10.37	Xyrem Supply Agreement, dated as of June 30, 2000, by and between Orphan Medical, Inc. and Catalytica Pharmaceuticals, Inc.
10.38	Letter Amendment No. 1, dated as of November 9, 2000, by and between Orphan Medical, Inc. and Catalytica Pharmaceuticals, Inc.
10.39	Amendment No. 2 to the Xyrem Supply Agreement, dated as of August 19, 2002, by and between Orphan Medical, Inc. and DSM Pharmaceuticals, Inc. (formerly Catalytica Pharmaceuticals, Inc.).
10.40	Amendment No. 3 to the Xyrem Supply Agreement, dated as of March 21, 2005, by and between Orphan Medical, Inc. and DSM Pharmaceuticals, Inc. (formerly Catalytica Pharmaceuticals, Inc.).
10.41#*	Amended and Restated Xyrem License and Distribution Agreement, dated as of June 30, 2006, by and between the Registrant and UCB Pharma Limited.

Exhibit Number	Description of Document
10.42#*	License Agreement, dated as of January 31, 2007, by and between the Registrant and Solvay Pharmaceuticals, Inc.
10.43	Supply Agreement, dated as of January 31, 2007, by and between the Registrant and Solvay Pharmaceuticals, Inc.
10.44	Trademark License Agreement, dated as of January 31, 2007, by and between the Registrant and Solvay Pharmaceuticals, Inc.
10.45*	Assignment, Assumption and Consent, dated as of January 31, 2007, by and among the Registrant, Solvay Pharmaceuticals, Inc and Elan Pharma International Limited.
10.46#*	License Agreement, dated as of December 22, 1997, by and between Solvay Pharmaceuticals, Inc and Elan Corporation plc.
10.47#*	Amendment to License Agreement, dated as of March 1, 1999, by and between Solvay Pharmaceuticals, Inc and Elan Corporation plc.
10.48#*	Letter Amendment No. 2 to License Agreement, dated April 13, 2000, by and between Solvay Pharmaceuticals, Inc and Elan Pharmaceutical Technologies.
10.49#*	Amendment Agreement No. 3 to License Agreement, dated as of November 7, 2006, by and between Solvay Pharmaceuticals, Inc. and Elan Corporation plc.
10.50#*	Xyrem Manufacturing Services and Supply Agreement, dated as of March 13, 2007, by and between the Registrant and Patheon Pharmaceuticals, Inc.
10.51#*	Quality Agreement, dated as of March 13, 2007, by and between the Registrant and Patheon Pharmaceuticals, Inc.
10.52*	Commercial Lease, dated as of June 2, 2004, by and between the Registrant and The Board of Trustees of the Leland Stanford Junior University.
10.53*	Sublease Agreement, dated as of February 25, 2007, by and between Xerox Corporation and the Registrant.
10.54	Amendment No. 2 to Sodium Gamma Hydroxybutyrate Development and Supply Agreement, dated as of March 30, 2007, by and between Registrant and Lonza, Inc.
10.55+*	Directors Deferred Compensation Plan.
10.56+*	Non-Employee Director Compensation Arrangements.
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 the Registration Statement on Form S-1 (File No. 333-141164) filed with the SEC on March 9, 2007).
24.2*	Power of Attorney of Jaimin R. Patel.

* Previously filed.
\+ Indicates management contract or compensatory plan.
\# Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

(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.

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

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.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the Registrant has duly caused this Amendment No. 4 to the Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Palo Alto, State of California, on the 24th day of May, 2007.

JAZZ PHARMACEUTICALS, INC.

By: /s/ Matthew K. Fust

Matthew K. Fust
Senior Vice President and
Chief Financial Officer

Pursuant to the requirements of the Securities Act of 1933, this Amendment No. 4 to the 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. **Samuel R. Saks, M.D.**	Chief Executive Officer and Member of the Board of Directors (*Principal Executive Officer*)	May 24, 2007
/s/ MATTHEW K. FUST **Matthew K. Fust**	Senior Vice President and Chief Financial Officer (*Principal Accounting and Financial Officer*)	May 24, 2007
* **Adam H. Clammer**	Director	May 24, 2007
* **Samuel D. Colella**	Director	May 24, 2007
* **Bruce C. Cozadd**	Director	May 24, 2007
* **Bryan C. Cressey**	Director	May 24, 2007
* **Michael W. Michelson**	Director	May 24, 2007
* **James C. Momtazee**	Director	May 24, 2007
* **Kenneth W. O'Keefe**	Director	May 24, 2007
* **Jaimin R. Patel**	Director	May 24, 2007
* **Alan M. Sebulsky**	Director	May 24, 2007
* **James B. Tananbaum, M.D.**	Director	May 24, 2007

*By: /s/ CAROL A. GAMBLE
Carol A. Gamble
Attorney-in-Fact

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Index to Financial Statements

EXHIBIT INDEX

Exhibit Number	Description of Document
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*	Third Amended and Restated Certificate of Incorporation of the Registrant, currently in effect.
3.2*	Form of Fourth 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.
4.3.1+*	Second Amended and Restated Investor Rights Agreement, dated as of June 24, 2005, by and between the Registrant and the other parties named therein.
4.3.2+*	Form of Third Amended and Restated Investor Rights Agreement, by and between the Registrant and the other parties named therein, to be effective upon the closing of this offering.
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.
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.

Exhibit Number	Description of Document
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 Option Exercise and Stock Purchase Agreement and Forms of Grant Notices 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, by and between Orphan Medical, Inc. and Lonza, Inc.
10.32	Amendment No. 1 to Sodium Gamma Hydroxybutyrate Development and Supply Agreement, dated as of February 7, 2005, by and between Orphan Medical, Inc. and Lonza, Inc.
10.33#*	Amended and Restated Services Agreement, dated as of May 31, 2005, by and between Orphan Medical, Inc. and Express Scripts Specialty Distribution Services, Inc.
10.34#*	Consent and Addendum to Amended and Restated Master Services Agreement, dated as of June 1, 2006, by and between the Registrant and Express Scripts Specialty Distribution Services, Inc.
10.35#*	Addendum No. 2 to Amended and Restated Master Services Agreement, dated as of June 22, 2006, by and between the Registrant and Express Scripts Specialty Distribution Services, Inc.
10.36#*	Addendum No. 3 to Amended and Restated Master Services Agreement, dated as of August 17, 2006, by and between the Registrant and Express Scripts Specialty Distribution Services, Inc.
10.37	Xyrem Supply Agreement, dated as of June 30, 2000, by and between Orphan Medical, Inc. and Catalytica Pharmaceuticals, Inc.
10.38	Letter Amendment No. 1, dated as of November 9, 2000, by and between Orphan Medical, Inc. and Catalytica Pharmaceuticals, Inc.

Exhibit Number	Description of Document
10.39	Amendment No. 2 to the Xyrem Supply Agreement, dated as of August 19, 2002, by and between Orphan Medical, Inc. and DSM Pharmaceuticals, Inc. (formerly Catalytica Pharmaceuticals, Inc.).
10.40	Amendment No. 3 to the Xyrem Supply Agreement, dated as of March 21, 2005, by and between Orphan Medical, Inc. and DSM Pharmaceuticals, Inc. (formerly Catalytica Pharmaceuticals, Inc.).
10.41#*	Amended and Restated Xyrem License and Distribution Agreement, dated as of June 30, 2006, by and between the Registrant and UCB Pharma Limited.
10.42#*	License Agreement, dated as of January 31, 2007, by and between the Registrant and Solvay Pharmaceuticals, Inc.
10.43	Supply Agreement, dated as of January 31, 2007, by and between the Registrant and Solvay Pharmaceuticals, Inc.
10.44	Trademark License Agreement, dated as of January 31, 2007, by and between the Registrant and Solvay Pharmaceuticals, Inc.
10.45*	Assignment, Assumption and Consent, dated as of January 31, 2007, by and among the Registrant, Solvay Pharmaceuticals, Inc and Elan Pharma International Limited.
10.46#*	License Agreement, dated as of December 22, 1997, by and between Solvay Pharmaceuticals, Inc and Elan Corporation plc.
10.47#*	Amendment to License Agreement, dated as of March 1, 1999, by and between Solvay Pharmaceuticals, Inc and Elan Corporation plc.
10.48#*	Letter Amendment No. 2 to License Agreement, dated April 13, 2000, by and between Solvay Pharmaceuticals, Inc and Elan Pharmaceutical Technologies.
10.49#*	Amendment Agreement No. 3 to License Agreement, dated as of November 7, 2006, by and between Solvay Pharmaceuticals, Inc. and Elan Corporation, plc.
10.50#*	Xyrem Manufacturing Services and Supply Agreement, dated as of March 13, 2007, by and between the Registrant and Patheon Pharmaceuticals, Inc.
10.51#*	Quality Agreement, dated as of March 13, 2007, by and between the Registrant and Patheon Pharmaceuticals, Inc.
10.52*	Commercial Lease, dated as of June 2, 2004, by and between the Registrant and The Board of Trustees of the Leland Stanford Junior University.
10.53*	Sublease Agreement, dated as of February 25, 2007, by and between Xerox Corporation and the Registrant.
10.54	Amendment No. 2 to Sodium Gamma Hydroxybutyrate Development and Supply Agreement, dated as of March 30, 2007, by and between Registrant and Lonza, Inc.
10.55+*	Directors Deferred Compensation Plan.
10.56+*	Non-Employee Director Compensation Arrangements.
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 the Registration Statement on Form S-1 (File No. 333-141164) filed with the SEC on March 9, 2007).
24.2*	Power of Attorney of Jaimin R. Patel.

* Previously filed.
\+ Indicates management contract or compensatory plan.
\# Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

Exhibit 5.1

Cooley
GODWARD KRONISH LLP

May 24, 2007

Jazz Pharmaceuticals, Inc.
3180 Porter Drive
Palo Alto, CA 94304

Ladies and Gentlemen:

You have requested our opinion with respect to certain matters in connection with the filing by Jazz Pharmaceuticals, Inc., a Delaware corporation (the "Company"), of a Registration Statement on Form S-1 (the "Registration Statement") with the U.S. Securities and Exchange Commission covering an underwritten public offering of up to 6,900,000 shares of common stock, par value $.0001, including 900,000 shares of common stock for which the underwriters have been granted an over-allotment option (the "Shares"). All of the Shares are to be sold by the Company as described in the Registration Statement and the Prospectus.

In connection with this opinion, we have examined and relied upon (a) the Registration Statement and related Prospectus, (b) the Company's Third Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws, as currently in effect, (c) the form of the Company's Fourth Amended and Restated Certificate of Incorporation, filed as Exhibit 3.2 to the Registration Statement (the "Restated Charter"), to be filed with the Secretary of State of the State of Delaware immediately upon the closing of the offering contemplated by the Registration Statement, (d) the form of the Company's Amended and Restated Bylaws, filed as Exhibit 3.4 to the Registration Statement, to be effective immediately upon the closing of the offering contemplated by the Registration Statement, and (e) the originals or copies certified to our satisfaction of such records, documents, certificates, memoranda and other instruments as in our judgment are necessary or appropriate to enable us to render the opinion expressed below. As to certain factual matters, we have relied upon a certificate of officers of the Company and have not sought to independently verify such matters. Our opinion is expressed only with respect to the general corporation laws of the State of Delaware.

On the basis of the foregoing, and in reliance thereon, we are of the opinion that upon the filing of the Restated Charter with the Secretary of State of the State of Delaware, the Shares, when sold and issued in accordance with the Registration Statement and related Prospectus, will be validly issued, fully paid and non-assessable.

We consent to the reference to our firm under the caption "Legal Matters" in the Prospectus included in the Registration Statement and to the filing of this opinion as an exhibit to the Registration Statement.

Sincerely,

Cooley Godward Kronish LLP

By: /s/ John M. Geschke
John M. Geschke

Exhibit 10.24

Jazz Pharmaceuticals, Inc.
ID:
3180 PORTER DR
PALO ALTO, CA 94304

Notice of Grant of Stock Options
and Option Agreement

[Name]
[Address]

Option Number:
Plan: **2007**
ID:

Effective [date], you have been granted a(n) [Incentive][Nonstatutory] Stock Option to buy [number] shares of Jazz Pharmaceuticals, Inc. (the Company) stock at $[price] per share.

The total option price of the shares granted is $[price].

Shares in each period will become fully vested on the date shown.

Shares	Vest Type	Full Vest	Expiration
[number of shares]	[schedule of vesting]	[fully-vested date]	[expiration date]

By your signature and the Company's signature below, you and the Company agree that these options are granted under and governed by the terms and conditions of the Company's 2007 Equity Incentive Plan as amended and the Option Agreement, all of which are attached and made a part of this document.

Jazz Pharmaceuticals, Inc. — Date

[Name] — Date

Date:
Time:

JAZZ PHARMACEUTICALS, INC.
2007 EQUITY INCENTIVE PLAN

OPTION AGREEMENT
(INCENTIVE STOCK OPTION OR NONSTATUTORY STOCK OPTION)

Pursuant to your Option Grant Notice ("***Grant Notice***") and this Option Agreement, Jazz Pharmaceuticals, Inc. (the "***Company***") has granted you an option under its 2007 Equity Incentive Plan (the "***Plan***") to purchase the number of shares of the Company's Common Stock indicated in your Grant Notice at the exercise price indicated in your Grant Notice. Defined terms not explicitly defined in this Option Agreement but defined in the Plan shall have the same definitions as in the Plan.

The details of your option are as follows:

1. VESTING. Subject to the limitations contained herein, your option will vest as provided in your Grant Notice, provided that vesting will cease upon the termination of your Continuous Service.

2. NUMBER OF SHARES AND EXERCISE PRICE. The number of shares of Common Stock subject to your option and your exercise price per share referenced in your Grant Notice may be adjusted from time to time for Capitalization Adjustments.

3. EXERCISE RESTRICTION FOR NON-EXEMPT EMPLOYEES. In the event that you are an Employee eligible for overtime compensation under the Fair Labor Standards Act of 1938, as amended (*i.e.*, a "***Non-Exempt Employee***"), you may not exercise your option until you have completed at least six (6) months of Continuous Service measured from the Date of Grant specified in your Grant Notice, notwithstanding any other provision of your option.

4. METHOD OF PAYMENT. Payment of the exercise price is due in full upon exercise of all or any part of your option. You may elect to make payment of the exercise price in cash or by check or in one or more of the following manners:

(a) Provided that at the time of exercise the Common Stock is publicly traded and quoted regularly in *The Wall Street Journal*, pursuant to a program developed under Regulation T as promulgated by the Federal Reserve Board that, prior to the issuance of Common Stock, results in either the receipt of cash (or check) by the Company or the receipt of irrevocable instructions to pay the aggregate exercise price to the Company from the sales proceeds.

(b) Provided that at the time of exercise the Common Stock is publicly traded and quoted regularly in *The Wall Street Journal*, by delivery to the Company (either by actual delivery or attestation) of already-owned shares of Common Stock that are owned free and clear of any liens, claims, encumbrances or security interests, and that are valued at Fair Market Value on the date of exercise. "Delivery" for these purposes, in the sole discretion of the Company at the time you exercise your option, shall include delivery to the Company of your attestation of

ownership of such shares of Common Stock in a form approved by the Company. Notwithstanding the foregoing, you may not exercise your option by tender to the Company of Common Stock to the extent such tender would violate the provisions of any law, regulation or agreement restricting the redemption of the Company's stock.

5. WHOLE SHARES. You may exercise your option only for whole shares of Common Stock.

6. SECURITIES LAW COMPLIANCE. Notwithstanding anything to the contrary contained herein, you may not exercise your option unless the shares of Common Stock issuable upon such exercise are then registered under the Securities Act or, if such shares of Common Stock are not then so registered, the Company has determined that such exercise and issuance would be exempt from the registration requirements of the Securities Act. The exercise of your option also must comply with other applicable laws and regulations governing your option, and you may not exercise your option if the Company determines that such exercise would not be in material compliance with such laws and regulations.

7. TERM. You may not exercise your option before the commencement or after the expiration of its term. The term of your option commences on the Date of Grant and expires upon the earliest of the following:

(a) three (3) months after the termination of your Continuous Service for any reason other than your Disability or death; *provided*, *however*, that (i) if during any part of such three (3) month period your option is not exercisable solely because of the condition set forth in Section 6, your option shall not expire until the earlier of the Expiration Date or until it shall have been exercisable for an aggregate period of three (3) months after the termination of your Continuous Service and (ii) if (x) you are a Non-Exempt Employee, (y) you terminate your Continuous Service within six (6) months after the Date of Grant specified in your Grant Notice, and (z) you have vested in a portion of your option at the time of your termination of Continuous Service, your option shall not expire until the earlier of (A) the later of the date that is seven (7) months after the Date of Grant specified in your Grant Notice or the date that is three (3) months after the termination of your Continuous Service, or (B) the Expiration Date;

(b) twelve (12) months after the termination of your Continuous Service due to your Disability;

(c) eighteen (18) months after your death if you die either during your Continuous Service or within three (3) months after your Continuous Service terminates;

(d) the Expiration Date indicated in your Grant Notice; or

(e) the day before the tenth (10th) anniversary of the Date of Grant.

If your option is an Incentive Stock Option, note that to obtain the federal income tax advantages associated with an Incentive Stock Option, the Code requires that at all times beginning on the date of grant of your option and ending on the day three (3) months before the date of your option's exercise, you must be an employee of the Company or an Affiliate, except in the event of your death or Disability. The Company has provided for extended exercisability

of your option under certain circumstances for your benefit but cannot guarantee that your option will necessarily be treated as an Incentive Stock Option if you continue to provide services to the Company or an Affiliate as a Consultant or Director after your employment terminates or if you otherwise exercise your option more than three (3) months after the date your employment with the Company or an Affiliate terminates.

8. EXERCISE.

(a) You may exercise the vested portion of your option during its term by delivering a Notice of Exercise (in a form designated by the Company) together with the exercise price to the Secretary of the Company, or to such other person as the Company may designate, during regular business hours, together with such additional documents as the Company may then require.

(b) By exercising your option you agree that, as a condition to any exercise of your option, the Company may require you to enter into an arrangement providing for the payment by you to the Company of any tax withholding obligation of the Company arising by reason of (i) the exercise of your option, or (ii) the disposition of shares of Common Stock acquired upon such exercise.

(c) If your option is an Incentive Stock Option, by exercising your option you agree that you will notify the Company in writing within fifteen (15) days after the date of any disposition of any of the shares of the Common Stock issued upon exercise of your option that occurs within two (2) years after the date of your option grant or within one (1) year after such shares of Common Stock are transferred upon exercise of your option.

9. CHANGE IN CONTROL.

(a) If your Continuous Service terminates either within twelve (12) months following or one (1) month prior to the effective date of a Change in Control due to an Involuntary Termination Without Cause, the vesting and exercisability of your option shall be accelerated in full.

(b) "***Involuntary Termination Without Cause***" means the involuntary termination of your Continuous Service for reasons other than death, Disability, or Cause. For this purpose, "Cause" means that, in the reasonable determination of the Company, you have (i) committed an intentional act or acted with gross negligence that has materially injured the business of the Company; (ii) intentionally refused or failed to follow lawful and reasonable directions of the Board or the appropriate individual to whom you report; (iii) willfully and habitually neglected your duties for the Company; or (iv) been convicted of a felony involving moral turpitude that is likely to inflict or has inflicted material injury on the business of the Company. Notwithstanding the foregoing, Cause shall not exist based on conduct described in clause (ii) or (iii) unless the conduct described in such clause has not been cured within fifteen (15) days following your receipt of written notice from the Company specifying the particulars of the conduct constituting Cause. Any determination by the Company that your Continuous Service was terminated by reason of dismissal without Cause for the purposes of this Option Agreement shall have no effect upon any determination of the rights or obligations of you or the Company for any other purpose.

10. PARACHUTE PAYMENTS

(a) If any payment or benefit you would receive in connection with a Change in Control from the Company or otherwise ("***Payment***") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "***Excise Tax***"), then the Company shall cause to be determined, before any amounts of the Payment are paid to you, which of the following two alternative forms of payment would maximize your after-tax proceeds: (i) payment in full of the entire amount of the Payment (a "***Full Payment***"), or (ii) payment of only a part of the Payment so that you receive the largest payment possible without the imposition of the Excise Tax (a "***Reduced Payment***"), whichever amount results in your receipt, on an after-tax basis, of the greater amount of the Payment notwithstanding that all or some portion of the Payment may be subject to the Excise Tax. For purposes of determining whether to make a Full Payment or a Reduced Payment, the Company shall cause to be taken into account all applicable federal, state and local income and employment taxes and the Excise Tax (all computed at the highest applicable marginal rate, net of the maximum reduction in federal income taxes which could be obtained from a deduction of such state and local taxes).

(b) If a Reduced Payment is made, (i) the Payment shall be paid only to the extent permitted under the Reduced Payment alternative, and you shall have no rights to any additional payments and/or benefits constituting the Payment, and (ii) reduction in payments and/or benefits shall occur in the following order unless you elect in writing a different order (provided, however, that such election shall be subject to Company approval if made on or after the date on which the event that triggers the Payment occurs): (1) reduction of cash payments; (2) cancellation of accelerated vesting of equity awards other than stock options; (3) cancellation of accelerated vesting of stock options; and (4) reduction of other benefits paid to you. In the event that acceleration of compensation from your equity awards is to be reduced, such acceleration of vesting shall be canceled in the reverse order of the date of grant (*i.e.*, earliest granted Stock Award cancelled last) unless you elect in writing a different order for cancellation.

(c) The accounting firm engaged by the Company for general tax purposes as of the day prior to the effective date of the Change in Control shall perform the foregoing calculations. If the accounting firm so engaged by the Company is serving as accountant or auditor for the individual, entity or group effecting the Change in Control, the Company shall appoint a nationally recognized accounting firm to make the determinations required hereunder. The Company shall bear all expenses with respect to the determinations by such accounting firm required to be made hereunder.

(d) The accounting firm engaged to make the determinations hereunder shall provide its calculations, together with detailed supporting documentation, to you and the Company within fifteen (15) calendar days after the date on which your right to a Payment is triggered (if requested at that time by you or the Company) or such other time as requested by you or the Company. If the accounting firm determines that no Excise Tax is payable with respect to a Payment, either before or after the application of the Reduced Amount, it shall

furnish you and the Company with an opinion reasonably acceptable to you that no Excise Tax will be imposed with respect to such Payment. Any good faith determinations of the accounting firm made hereunder shall be final, binding and conclusive upon you and the Company.

11. TRANSFERABILITY. Your option is not transferable, except by will or by the laws of descent and distribution, and is exercisable during your life only by you. Notwithstanding the foregoing, by delivering written notice to the Company, in a form satisfactory to the Company, you may designate a third party who, in the event of your death, shall thereafter be entitled to exercise your option. In addition, you may transfer your option to a trust if you are considered to be the sole beneficial owner (determined under Section 671 of the Code and applicable state law) while the option is held in the trust, provided that you and the trustee enter into transfer and other agreements required by the Company.

12. OPTION NOT A SERVICE CONTRACT. Your option is not an employment or service contract, and nothing in your option shall be deemed to create in any way whatsoever any obligation on your part to continue in the employ of the Company or an Affiliate, or of the Company or an Affiliate to continue your employment. In addition, nothing in your option shall obligate the Company or an Affiliate, their respective stockholders, Boards of Directors, Officers or Employees to continue any relationship that you might have as a Director or Consultant for the Company or an Affiliate.

13. WITHHOLDING OBLIGATIONS.

(a) At the time you exercise your option, in whole or in part, or at any time thereafter as requested by the Company, you hereby authorize withholding from payroll and any other amounts payable to you, and otherwise agree to make adequate provision for (including by means of a "cashless exercise" pursuant to a program developed under Regulation T as promulgated by the Federal Reserve Board to the extent permitted by the Company), any sums required to satisfy the federal, state, local and foreign tax withholding obligations of the Company or an Affiliate, if any, which arise in connection with the exercise of your option.

(b) Upon your request and subject to approval by the Company, in its sole discretion, and compliance with any applicable legal conditions or restrictions, the Company may withhold from fully vested shares of Common Stock otherwise issuable to you upon the exercise of your option a number of whole shares of Common Stock having a Fair Market Value, determined by the Company as of the date of exercise, not in excess of the minimum amount required to be withheld by law (or such lower amount as may be necessary to avoid classification of your option as a liability for financial accounting purposes). Any adverse consequences to you arising in connection with such share withholding procedure shall be your sole responsibility.

(c) You may not exercise your option unless the tax withholding obligations of the Company and/or any Affiliate are satisfied. Accordingly, you may not be able to exercise your option when desired even though your option is vested, and the Company shall have no obligation to issue a certificate for such shares of Common Stock or release such shares of Common Stock from any escrow provided for herein unless such obligations are satisfied.

14. NOTICES. Any notices provided for in your option or the Plan shall be given in writing and shall be deemed effectively given upon receipt or, in the case of notices delivered by mail by the Company to you, five (5) days after deposit in the United States mail, postage prepaid, addressed to you at the last address you provided to the Company.

15. GOVERNING PLAN DOCUMENT. Your option is subject to all the provisions of the Plan, the provisions of which are hereby made a part of your option, and is further subject to all interpretations, amendments, rules and regulations, which may from time to time be promulgated and adopted pursuant to the Plan. In the event of any conflict between the provisions of your option and those of the Plan, the provisions of the Plan shall control.

ORPHAN MEDICAL, INC.

SODIUM GAMMA HYDROXYBUTYRATE
DEVELOPMENT AND SUPPLY AGREEMENT

TABLE OF CONTENTS

APPENDICES

ORPHAN MEDICAL, INC.

SODIUM GAMMA HYDROXYBUTYRATE DEVELOPMENT AND SUPPLY AGREEMENT

THIS AGREEMENT ("Agreement") is made as of this 6th day of November, 1996 by and between ORPHAN MEDICAL, INC., a Minnesota corporation, having its principal offices at 13911 Ridgedale Drive, Minnetonka, Minnesota 55305 ("ORPHAN") and LONZA, INC., a New York corporation, having its principal offices at 17-17 Route 208, Fair Lawn, New Jersey 07410, ("Supplier").

RECITALS

1. Supplier develops and manufactures bulk pharmaceutical chemicals meeting the regulatory and governmental requirements for commercial use in pharmaceutical products.

2. ORPHAN develops and markets ethical Pharmaceuticals targeted to specified populations of patients.

3. ORPHAN and Supplier desire to cooperate in the transfer of the manufacture of a pharmaceutical chemical known as "Sodium Gamma Hydroxybutyrate" ("the Drug").

4. Supplier desires to manufacture the Drug exclusively for sale to ORPHAN.

5. Upon obtaining approval to market the DRUG, ORPHAN wishes to purchase all of its requirements of the Drug from Supplier and Supplier wishes to supply ORPHAN all of its requirements for the Drug in the Territory.

6. Supplier understands that the Drug will likely be scheduled by the Drug Enforcement Administration (DEA) upon approval by the FDA. While Orphan anticipates

a Schedule IV designation, Orphan cannot guarantee the level of scheduling that will be required. Supplier agrees that the Drug Price estimate is based on Schedule IV handling. Supplier also agrees to provide Drug to Orphan if a more restrictive level of scheduling is ultimately required at a price to be mutually agreed upon.

NOW, THEREFORE, in consideration of the mutual covenants hereinafter set forth and other good and valuable consideration, the receipt of which is hereby acknowledged, the parties agree as follows:

ARTICLE 1 **DEFINITIONS**

The following terms, when capitalized, shall have the following meanings in this Agreement, whether used in the singular or the plural.

1.1 “Acquisition Cost” in respect of a particular item means the actual invoiced price paid by either party to a Third Party for acquiring such item, including without limitation, shipping, insurance and handling costs and customs duties.

1.2 “Affiliate” means any corporation or non-corporate business entity which controls, is controlled by, or is under common control with a party to this Agreement. A corporation or non-corporate business entity shall be regarded as in control of another corporation if it owns or directly or indirectly controls at least forty-nine percent (49%) of the voting stock of another corporation, or (a) in the absence of the ownership of at least forty-nine percent (49%) of the voting stock of a corporation, or (b) in the case of a non corporate business entity, if it possesses, directly or indirectly, whether by virtue of an ownership interest of any kind, by contract or otherwise, the power to direct or cause the direction of the management and policies of the corporation or non-corporate business entity or to elect or cause the election of a majority of the board of directors or other governing body of such corporation or non-corporate business entity.

1.3 “Contract Year” means the twelve (12) month period beginning on the first

day of the month in which ORPHAN commercially launches the Drug or a product containing the Drug in a country of the Territory. For purposes of this Section 1.3, test marketing of the Drug or a product containing the Drug by ORPHAN shall not be deemed to be a commercial launch thereof.

1.4 “Delivery” means delivery of the Drug to a drug product manufacturer or any other ORPHAN-designated Third Party.

1.5 “Technology Transfer/Development Program” means the multi-staged Technology Transfer/Development Program further described in Appendix A which is attached hereto and made a part hereof, as well as any additional process or analytical development activities or process or analytical development modifications for the Drug to be mutually agreed upon in good faith by the parties after the date this Agreement is signed and subsequently attached hereto as a replacement for or as an addition to Appendix A.

1.6 “DMF” means a Type II Drug Master File intended for filing with the FDA.

1.7 “Dollars” or “$” means United States Dollars.

1.8 “Drug Price” means the price to ORPHAN, in Dollars per kilogram, for manufacture of the Drug.

1.9 “Drug” means bulk Sodium Gamma Hydroxybutyrate (GHB).

1.10 “Effective Date” means the date appearing at the beginning of this Agreement.

1.11 “FDA” means the US Food and Drug Administration or any successor entity.

1.12 “FD&C Act” means the US Federal Food, Drug and Cosmetic Act, together with all regulations issued thereunder, as the same may be amended from time to time.

1.13 “GMPs” means the current Good Manufacturing Practices regulations promulgated by the FDA, and any applicable amendments thereto in effect at the time of the Drug’s manufacture.

1.14 “Manufacturing Cost” means Supplier’s costs of labor (including allocable employee benefits and employment taxes), material (including without limitation raw materials, solvents, packaging, waste disposal and labeling), energy, utilities and other charges directly incurred in the manufacture of the Drug, plus normal production overhead (i.e. indirect labor, utilities, maintenance and depreciation of the manufacturing equipment and facilities and other allocable overhead of the manufacturing facility), all determined in accordance with generally accepted accounting principles applied on a consistent basis in the country of manufacture.

1.15 “NDA” means a New Drug Application filed with the FDA or any equivalent successor application or entity.

1.16 “Notification” means the date on which mailed as evidenced by the U.S. Postal Service or other carrier.

1.17 “Production Batch” means a production size batch of the Drug with a specified kilogram weight range, the size and range of which is to be established and mutually agreed upon by the parties during the Technology Transfer/Development Program. Each Production Batch is to have uniform character and quality within specified limits produced according to a single manufacturing order during the same cycle of manufacture.

1.18 “Proprietary Information” means all non-public information or data relating to the subject matter hereof first communicated by or on behalf of one party to the other, whether in writing or orally, including without limitation, all scientific, clinical, commercial, financial and business information and data, know-how, compilations, formulae,

processes, plans, technical information, new product information, compounds, formulations, methods of product delivery, test procedures, product samples, specifications and other information or data.

1.19 “Registration” means any legally required approval by the relevant government authorities in a country of or community or association of countries included in the Territory (including, where applicable, price approvals) which must be granted for the Drug or a product containing the Drug to be manufactured and/or sold in such jurisdiction.

1.20 “Specifications” means the final specifications for the Drug attached hereto as Appendix C and made a part hereof, including the final NDA specifications as approved by the FDA, as well as any revised specifications and/or additional specifications for the Drug to be mutually agreed upon in good faith by the parties after the Effective Date and subsequently attached hereto as a replacement for or as an addition to Appendix C. Such additional specifications may include, but shall not be limited to specifications for degradation, identification of drug substance and physical appearance.

1.21 “Territory” means worldwide.

1.22 “Third Party” means any entity other than Supplier or ORPHAN or their respective Affiliates.

1.23 “Validation Protocol” means the written protocol which will be mutually approved by the parties in writing prior to the manufacture of the first Validation Batch and which will set forth the tests and acceptance criteria to demonstrate that a process used by Supplier in the manufacture of the Drug does what it purports to do and yields quantities of the Drug which consistently meet the Specifications. The Validation Protocol may be amended from time to time during the term of this Agreement upon mutual agreement of the parties hereto, giving due consideration to applicable legal and regulatory requirements pertaining to the Drug.

1.24 “Validation Batches” means the first three (3) Production Batches manufactured consecutively according to the approved Validation Protocol.

ARTICLE 2 **TECHNOLOGY TRANSFER/DEVELOPMENT PROGRAM**

2.1 Supplier hereby agrees to conduct the Technology Transfer/Development Program in accordance with Appendix A, the goal of which is to transfer the current process for commercial manufacture of the Drug, develop protocols for testing the Drug, and finalize Specifications. The Technology Transfer/Development Program shall consist of two (2) main stages (individually, a “Stage” or collectively, the “Stages”). Supplier agrees to provide or purchase all materials and supplies.

In general, Supplier shall perform validations for the Drug at its Conshohocken, Pennsylvania facility, provide stability samples, prepare an environmental assessment report, and prepare the chemical manufacturing section for ORPHAN to file in an NDA with FDA. A more detailed description, including the time schedule for completion of each Stage of the Technology Transfer/Development Program, is set forth in Appendix A attached hereto and made a part hereof.

2.2 Promptly upon completion of the development activities conducted by Supplier during each Stage of the Technology Transfer/Development Program, to the extent it has not already done so, Supplier shall deliver to ORPHAN a complete written report or reports. A detailed description of such reports, as well as other reports to be provided by Supplier during the Technology Transfer/Development Program is set forth in Appendix B. Within thirty (30) working days after the delivery to ORPHAN of all reports relating to such Stage, ORPHAN shall either (a) accept such reports and notify Supplier if it intends to proceed with the Technology Transfer/Development Program or (b) send Supplier written notice of Supplier’s failure to conduct such Stage in accordance with the requirements set forth in Appendix A. Supplier agrees to take such corrective actions and to conduct such additional work required to satisfy the requirements set forth in Appendix A for completion of such Stage.

During ORPHAN'S review of each Stage completion report, Supplier and ORPHAN may mutually agree to continue execution of the Technology Transfer/Development Program based on previous verbal and written correspondence. If ORPHAN advises Supplier with a written notice to stop execution activities, Supplier will cease all program activities and bill ORPHAN on a time and material basis for work performed.

2.3 In consideration of Supplier's conduct of the Technology Transfer/Development Program, ORPHAN agrees to pay Supplier the cost for each Stage as set forth in Appendix A. ORPHAN shall only pay Supplier for Stages which are completed. A breakdown of costs for each Stage is set forth in Appendix A. Payments for each Stage will be made within 30 days of satisfactory completion, as determined by ORPHAN after review of the associated stage completion summary reports as set forth in Appendix B and any other data generated through execution of the Technology Transfer/Development Program. Supplier shall not incur any costs in excess of the amounts set forth in this paragraph without the prior written consent of ORPHAN.

2.4 Supplier and ORPHAN agree to designate one individual who will serve as a central liaison to the other at all times. The person designated will have the capability and authority to assist with coordination and resolution of any and all issues that might arise.

ARTICLE 3 **VALIDATION ACTIVITIES**

3.1 Supplier Validation Responsibilities. Supplier shall be responsible for regulatory required validations of its manufacture of the Drug and its facilities and shall take all reasonable steps to pass government inspection by the FDA or other regulatory agencies in the Territory. Supplier shall also provide reasonable assistance in preparing and updating the chemical manufacturing portion of the Registrations and all other documents required by the FDA and other regulatory agencies in the Territory for approval of the Drug. In the event non-U.S. Territory regulatory agencies require process development testing beyond that required for the U.S., Supplier agrees to provide the additional process development testing and associated documentation revisions at terms to be negotiated in good faith by the parties.

3.2 Validation of Cvtec Manufacturing Process . As provided in Appendix A, Supplier shall manufacture ORPHAN'S three (3) consecutive Production Batches of the Drug in accordance with the pre-approved Validation Protocol for validation purposes.

Supplier and ORPHAN will jointly review all process development and analytical test results, the Validation Protocol, and stability study results prior to manufacture of each Validation Batch.

3.3 Re-Validation of Larger Scale Batches. Supplier shall have the option to manufacture three additional commercial Validation Batches using larger scale equipment judged to be regulatorily appropriate by Supplier and ORPHAN, conduct appropriate validation testing, and prepare an updated Process Validation Report to improve manufacturing cost. Costs associated with efforts required for completion of such 'scale up' activities will be included in the Manufacturing Cost of the commercial quantities produced subsequent to the scaleup and within the first Contract Year thereafter.

If the larger scale Validation Batches may be sold commercially by ORPHAN and, if such Validation Batches meet the Specifications and the acceptance criteria set forth in the Validation Protocol at the time of FDA approval of a product containing the Drug, the Drug shall be sold, pursuant to the terms of this Agreement, by Supplier to ORPHAN in fulfillment of ORPHAN'S orders for the Drug.

3.4 Defective Or Deficient Validation Batches. If any of the Validation Batches do not meet the Specifications and the acceptance criteria set forth in the Validation Protocol, Supplier shall, at its own expense, for a reasonable period of time not to exceed ninety (90) days, make necessary modifications to its facilities, equipment, processes and/or procedures and, after such modifications, shall manufacture one or more additional Validation Batches which will meet the Specifications and the acceptance criteria set forth in the Validation Protocol. If ORPHAN concludes that such modifications cannot be made effectively and promptly or if the additional Validation Batches still do not

meet the Specifications and the acceptance criteria set forth in the Validation Protocol, ORPHAN may terminate this Agreement upon written Notification to Supplier in accordance with Article 15 of this Agreement.

ARTICLE 4 **MARKETING RIGHTS**

4.1 ORPHAN shall have the exclusive right, directly or through any Affiliate, to market, distribute and sell the Drug or any product containing the Drug in the Territory, if the required Registrations have been obtained and if ORPHAN determines in its business judgment to do so. Supplier shall not market, distribute, make or sell the Drug or any product containing the Drug, directly or indirectly anywhere in the Territory and, except in the performance of its duties under this agreement, Supplier shall not reference or otherwise utilize any DMF or other filing made by Supplier on ORPHAN'S behalf unless required by a governmental agency or reference or otherwise utilize any data or information contained in such filing.

ARTICLE 5 **SUPPLY OF PRODUCT**

5.1 Material Safety Data Sheets. Prior to commencement of development or manufacturing operations hereunder, ORPHAN shall provide Supplier with a Material Safety Data Sheet (MSDS) and toxicity information for the Drug and any other information reasonably available to ORPHAN which relates to the safe conduct of the manufacturing and/or packaging operations to be conducted by Supplier. When and as such information becomes available, ORPHAN shall promptly update such information pertinent to the manufacture and/or packaging of the Drug.

5.2 Manufacture and Supply. During the term of this Agreement, ORPHAN shall purchase from Supplier, and Supplier shall supply ORPHAN and its Affiliates their requirements of the Drug for sale or other distribution in the Territory. Supplier and Orphan agree to cooperate closely to ensure that the Drug meets FDA, European, and Japanese standards and specifications. The International Conference on Harmonisation (ICH) guidelines will be followed for development and manufacturing decisions.

Supplier commits to provide the following kilograms per year for the first three years and will use best efforts to provide any additional quantities that are required:

Year 1 - 75,000 kilograms

Year 2 - 150,000 kilograms

Year 3 - 250,000 kilograms

In the event Supplier is not able to provide quantities required that exceed those stated above, Supplier will no longer be the exclusive supplier in the Territory and will provide technology transfer support per the terms of 5.6 below, to a second supplier chosen by Orphan.

Supplier shall provide or purchase all materials and supplies necessary to manufacture the Drug. Supplier shall manufacture the Drug in accordance with the Specifications, the Validation Protocol and applicable cGMPs and shall package, label and/or otherwise prepare the Drug for bulk delivery to an ORPHAN-designated drug product manufacturer.

5.3 Packaging. Supplier shall furnish all packaging supplies and labels for the Drugs after such materials have been approved by ORPHAN prior to use. All such packaging and labels shall conform to applicable requirements and regulations of FDA or other regulatory authorities in the Territory. Packaging supplies and labels furnished by Supplier hereunder shall be timely approved by ORPHAN prior to use.

5.4 Qualification of Alternate Supplier Manufacturing Site. Supplier will develop a plan for qualification of an alternate Supplier site for manufacture of the Drug within one year of FDA approval of the Drug. If the plan allows for preparation to manufacture in 120 days or less, it will not be executed prior to determination of need. If the timeline for provision of the Drug from an alternate site is greater than 120 days, one year after approval of the Drug for commercial use by the FDA, Supplier agrees to take such actions as are reasonably necessary to qualify a second Supplier manufacturing site in addition to the current facility at Conshohocken, Pennsylvania. Supplier will provide regulatory documentation of processes or activities as required by each country of the Territory within which ORPHAN applies for approval of the Drug. ORPHAN will be

responsible for determining the regulatory requirements for each submission. Supplier agrees to provide any additionally required development process testing at terms to be negotiated in good faith by the parties.

5.5 Conditions Requiring Backup Manufacture. Supplier agrees to support the successful transfer of manufacturing technology as set forth in Section 5.6 to a second bulk drug manufacturer chosen by ORPHAN to make, have made, use and sell the Drug if Supplier (a) for a period of at least one hundred fifty (150) days, is unable to manufacture substantially all of ORPHAN'S orders for any reason covered by Section 16.1 hereof, or (b) if Supplier otherwise fails or refuses to meet ORPHAN'S orders for the Drug pursuant to the terms hereof.

5.6 Supplier Responsibility in Transfer of Technology to Back-Up Manufacturer. Subject to the provisions of Section 5.5, Supplier agrees to provide information and qualified personnel (five (5) days maximum) to support the successful transfer of all analytical and manufacturing development, to include know-how and patent processes (the "Background Technology") and the right to reference any DMF filed with the FDA relating to the Drug. Supplier agrees to render all reasonable technical assistance to the secured contract manufacturer and to provide, at cost if requested, sources of or supplies of raw materials necessary to manufacture the Drug. ORPHAN shall reimburse Supplier for its reasonable out-of-pocket costs incurred in rendering such technical assistance for which ORPHAN prior approval has been obtained for each day in excess of three (3) man-days. In addition, ORPHAN and Supplier will negotiate in good faith any additional time and cost for the successful transfer of manufacture to a backup supplier.

ARTICLE 6 **FORECASTS. ORDERS AND DELIVERIES**

6.1 Forecasts. ORPHAN shall provide Supplier with forecasts of ORPHAN'S anticipated quarterly requirements of the Drug for distribution and sale in the United States commencing with the twelve (12) month period that begins at the time of an FDA approval. Such forecast will be provided one year in advance of anticipated FDA approval of the NDA and ORPHAN shall update such 12-month forecast on a quarterly

basis thereafter. Once FDA approval of the Drug is received, ORPHAN will provide Supplier, prior to the beginning of each calendar quarter, with forecasts of its anticipated requirements of the Drug for the following four calendar quarters. Supplier will provide an annual anticipated schedule for manufacture and will consult with ORPHAN on schedule changes.

(a) The forecasts provided to Supplier pursuant to this Section 6.1 are for planning purposes only and do not constitute a commitment by ORPHAN to have such or any quantity of Drug manufactured by Supplier or a commitment by Supplier to manufacture any quantity of the Drug for ORPHAN during the calendar year.

(b) Supplier shall not be required, but will attempt in good faith, subject to its obligation to other customers, to manufacture during any calendar quarter up to one hundred fifty percent (150%) of the quantity of the Drug ORPHAN forecasted it would purchase from Supplier during such quarter in its most recent forecast covering such quarter. Supplier will promptly communicate with ORPHAN as to its ability to produce quantities requested.

(c) When and as ORPHAN proposes to commence its distribution and sale of the Drug outside the United States, ORPHAN shall supplement its 12-month forecast accordingly to indicate the additional requirements of the Drug for such purposes.

(d) Supplier acknowledges that accurate forecasts of requirements are inherently difficult for a new pharmaceutical product. ORPHAN acknowledges that if it orders substantially less than forecasted quantities, this can cause hardship to Supplier if it is obligated to reserve capacity needlessly for ORPHAN'S requirements and, as a consequence, foregoes other opportunities. Accordingly, if Supplier anticipates competing demands for its capacity, it will inform ORPHAN at least ninety (90) days in advance, in which case ORPHAN shall have the opportunity to deliver to Supplier a firm commitment for a six-month supply (a "Six Month Commitment"). The consequences of delivery of a Six Month Commitment are that during such six-month period (i) ORPHAN shall be required to purchase not less than

80% of the amount set forth in the Six Month Commitment and (ii) Supplier shall be required to manufacture not more than 120% of such amount. If ORPHAN does not deliver a Six Month Commitment, Supplier may accept other opportunities to use its production capacity, but will nevertheless use its best efforts to produce the Drug in accordance with ORPHAN'S purchase orders in a timely manner. It is agreed that this procedure will be used on an exception basis.

(e) If Supplier manufactures the Drug with a lead time of more than ninety (90) days, ORPHAN shall not be required to pay any additional storage, or pay for the Drug sooner than as set forth in Section 7.5 nor shall any advance manufacture lead to a violation of the warranty of expiration date set forth in Section 8.1.

6.2 Orders. ORPHAN shall order the manufacturing of the Drug by Supplier pursuant to written purchase orders, including delivery dates, with not less than ninety (90) days lead time prior to the requested delivery dates specified therein. Each purchase order for the Drug shall be in Production Batch sizes or whole multiples thereof. The terms contained in this Agreement shall govern over all purchase orders or sales orders of the Drug hereunder and shall not be varied by the terms of any ORPHAN purchase order or Supplier sales order or invoice. If ORPHAN requires manufacture of the Drug with less than ninety (90) days lead time, Supplier shall use reasonable efforts to accommodate ORPHAN'S requirements. Supplier shall not manufacture the Drug except upon receipt of an ORPHAN purchase order to ensure a supply of the Drug with the maximum expiration dating.

6.3 Late Manufacture and Delivery. When ORPHAN submits a purchase order at least ninety (90) days prior to the required delivery date, Supplier shall confirm delivery upon receipt of this order and provide Orphan with a manufacturing plan detailing timing within fifteen (15) working days. Changes in this manufacturing plan which could affect the timing of deliveries will not be made without the written agreement of ORPHAN. In the event of unexpected delays owing to manufacturing problems associated with the Drug, Supplier will inform ORPHAN immediately and action to be taken will be jointly

decided. A failure to provide supply of Drug on schedule will be considered a material breach of this Agreement and Supplier will no longer be the exclusive supplier in the Territory and will provide technology transfer support per the terms of Section 5.6 above, to a second supplier chosen by ORPHAN.

6.4 Delivery of Drug. Supplier shall arrange all shipments of the Drug F.O.B. destination to an ORPHAN designated location to be determined by ORPHAN prior to or upon regulatory approval of the Drug in accordance with reasonable commercial practices and, for shipments to be made in the United States, any applicable U.S. Department of Transportation regulations for pharmaceutical products to ensure against deterioration and damage of the Drug. ORPHAN shall approve any final shipping specifications subject to any stability findings for the Drug.

(a) Risk of loss of any shipment of the Drug shall pass to ORPHAN upon acceptance of the shipment at the approved destination.

(b) ORPHAN shall pay (or reimburse) Supplier for any freight charges, taxes, packing costs, export or import duties, and insurance costs incurred by Supplier. Supplier may invoice ORPHAN for any freight charges, taxes, packing costs, export/import duties and insurance costs relating to shipment of the Drug paid by Supplier for ORPHAN'S account immediately upon each shipment of the Drug, provided all such charges or costs fall within the terms and conditions established by ORPHAN with the carrier for such shipment.

(c) ORPHAN reserves the right to select one or more carriers for shipment of the Drug and to negotiate the terms and conditions for such shipment. Risk of loss of any shipment of the Drug would then pass to ORPHAN upon Supplier's tender of such shipment to the carrier selected by ORPHAN.

(d) The quantity of Drug in any shipment may vary from the quantity reflected in the purchase order for such shipment by up to five percent (5%) and still be deemed to be in compliance with such purchase order; provided, however, that ORPHAN shall only be invoiced and required to pay for the quantity actually shipped.

(e) All Drug shall be shipped in bulk a) using suitable packaging as provided for

in the approved NDA, or in other regulatory approvals obtained in the Territory, and b) in accordance with such other contract specifications as may be mutually agreed upon by the parties hereto.

6.5 Finished Bulk Inventory Storage. Supplier agrees to store Drug manufactured for ORPHAN, in quantities of up to 60,000 kg for no longer than three (3) months beyond the purchase order delivery date according to the requirements established through conduct of a stability study program as outlined in Appendix D at a charge included in the Drug Price. ORPHAN will be billed for storage beyond three months at a cost to be negotiated in good faith upon FDA approval. Supplier shall have no responsibility for deterioration of Drug stored in accordance with such requirements.

6.6 Certifications. For each Validation Batch and upon request for Production Batches of the Drug manufactured for ORPHAN hereunder, Supplier shall furnish to ORPHAN at the time of its delivery copies of the following records. Originals are to be retained by Supplier:

(a) representative samples of such batch for assay and other testing;

(b) batch records and quality assurance data for such batch; and

(c) a Certificate of Analysis that such batch conforms to the Specifications and a Certificate of Manufacture which confirms that the Drug was manufactured, tested, and delivered in full compliance with all applicable laws and regulations.

ARTICLE 7 **PRICES AND PAYMENTS**

7.1 First Contract Year Manufacturing Price. After completion of Stage A of the Technology Transfer/Development Program, Supplier will quote the Drug Price that ORPHAN shall pay to Supplier for any orders of the Drug manufactured during the first Contract Year (including, if applicable, Validation Batches and any quantities ordered prior to the first Contract Year) as set forth in the Validation Protocol. The Drug Price for the first Contract Year shall be no higher than the maximum Drug Price estimate set forth in Appendix H for the volume range which is appropriate unless assumptions listed in

Appendix H are no longer valid. The Drug Price for the first Contract Year will be lower than the maximum Drug Price estimate contained in Appendix H to the extent that there are improvements in the Manufacturing Cost thereof from the assumptions for Manufacturing Costs set forth in Appendix H and determined during the Technology Transfer/Development Program for the volume range appropriate.

7.2 Annual Price Adjustment Notification. At least sixty (60) days prior to the end of the first Contract Year of this Agreement and each Contract Year thereafter, Supplier shall notify ORPHAN of the proposed Drug Price for the next succeeding Contract Year provided, however, that the proposed Drug Price for each new Contract year shall be equal to the then current price increased or decreased by the percentage amount of the actual increase or decrease in the Manufacturing Cost for the Drug from the first day to the last day of the preceding twelve (12) month period; provided, however, (a) that the percentage amount of any such increase in Manufacturing Cost may not exceed the percentage increase in the Producer Price Index for Finished Goods, (PPI) issued by the Bureau of Labor Statistics, U.S. Department of Labor, or comparable successor index, during the twelve (12) month period ending with the most recent month for which published monthly statistics are available as of the first day of such new price year, and (b) that ORPHAN will receive prior notification. Any increase or decrease in Drug Price shall be applicable only to those Production Batches of the Drug for which the production process is begun after the change in cost becomes effective and shall remain in effect until another price change becomes applicable.

In the event the cost of methanol increases by more than 50% within a single contract year, the Drug Price may be adjusted by the amount of the actual increase for that year. Likewise, if the cost of methanol decreases by more than 50% within a single contract year, the Drug Price will be adjusted down by the amount of the actual decrease for that year. Any adjustments made as a result of methanol price increases or decreases are separate from and in addition to the annual price adjustments described above.

7.3 Justification of Price Increases. Supplier shall substantiate, upon ORPHAN'S request, Supplier's price increases for the Drug for any Contract Year.

Supplier shall keep full and accurate books and records of account containing all particulars that may be necessary for the purpose of calculating the Manufacturing Cost of the Drug, including Supplier's Acquisition Cost for any raw materials used in manufacturing the Drug. ORPHAN may, upon reasonable notice to Supplier and at ORPHAN'S expense, have an independent public accountant reasonably acceptable to Supplier conduct, during normal business hours, an examination of Supplier's books and records to verify the basis of such increases of the Drug Price for any Contract Year or Contract Years. If Supplier has increased Drug Price based on a claimed increase in Manufacturing Cost to ORPHAN in excess of five percent (5%) above what such independent certified public accountant finds to be justifiable for any Contract Year, or Contract Years, Supplier shall reimburse ORPHAN'S reasonable cost and expenses of such examination. In no event shall the Manufacturing Cost with respect to any period be audited more than once. The independent public accountant used to conduct such audit shall enter into a confidentiality agreement satisfactory to Supplier and shall provide ORPHAN only with its conclusions.

7.4 Cost Reductions Through Process Improvements. To encourage active and open consideration of Manufacturing Cost reductions, it is agreed that 65% of a cost reduction benefit will be provided to the party that determines how to reduce cost. After the pilot campaign, the pricing offered shall be considered applicable to the process as then practiced (the "Baseline Process"). Any subsequent improvements which lead to realized manufacturing cost reductions shall be shared by Supplier and ORPHAN according to the formula 65% to that party proposing the improvement and 35% to the other party. Proposals for improvement will be outlined in writing or communicated verbally and will detail how the improvement should be realized. In the event of improvements developed through a joint collaboration where the originator is unclear, improvements will be shared 50% to each party. This sharing of benefits will come into effect only after (i) full amortization of the capital investment (if any) made necessary to implement the cost improvement and (ii) full amortization of the associated development costs (including without limitation, laboratory and validation work, engineering costs, and any associated regulatory costs.) After realization of improvements and application of this mechanism, the Baseline Process will be redefined and. the same calculation will be applied to any subsequent Manufacturing Cost reductions.

7.5 Invoice Payment. Payment for each lot of the Drug shall be due net thirty (30) days from the date of the invoice therefor, provided that no invoice shall be dated prior to the date of actual release of the Drug reflected therein. ORPHAN will accept title to the Drug at the earlier of (a) when risk of loss passes pursuant to Section 6.4, and (b) the date of the payment of the invoice thereof. Supplier will retain liability for the safe keeping of the Drug until delivery of shipment FOB destination.

ARTICLE 8 **REPRESENTATIONS, WARRANTIES AND INSPECTIONS**

8.1 Representations and Warranties.

(a) ORPHAN represents and warrants to Supplier that:

(i) The execution of this Agreement and the performance by ORPHAN of its obligations hereunder have been duly authorized by all necessary corporate action and are within the power and authority of ORPHAN; and

(ii) The processes transferred to Supplier by ORPHAN pursuant to the Technology Transfer/Development Program do not infringe any Third Party patents, copyrights, trademarks, trade secrets or other Third Party intellectual property rights.

(b) Supplier represents and warrants to ORPHAN that:

(i) The execution of this Agreement and the performance by Supplier of its obligations hereunder have been duly authorized by all necessary corporate action and are within the power and authority of Supplier;

(ii) Subject to ORPHAN'S warranty set forth in Section 8.1 (a)(ii), Supplier warrants that no Third Party patents, copyrights, trademarks, trade secrets or other Third Party intellectual property rights will be infringed by Supplier's performance of its obligations under this Agreement;

(iii) Supplier shall not use in any capacity persons, or the services of persons that are debarred, are on the Debarment List, or that have been convicted of actions that could lead to debarment as described in Section 306(a) and (b) of the Federal Food, Drug, and Cosmetic Act;

(iv) at the time of its delivery to a designated drug product manufacturer or other ORPHAN designated location, each Production Batch of the Drug manufactured by Supplier will:

(A) have an expiration date at the time of shipment equal to that approved by the FDA, via the initial NDA submission or via extended stability study data subsequently submitted;

(B) conform to the Specifications and will be stored under proper conditions ;

(C) have been manufactured in conformance with the Validation Protocol and the DMF or NDA CMC Section on file with the FDA for manufacture of the Drug at Supplier's facilities and in compliance with all other applicable laws and regulations, including, without limitation, the then-current FDA GMP's;

(D) not to be adulterated or misbranded by Supplier within the meaning of the FD&C Act, as amended, or be an article which may not be introduced into interstate commerce under Sections 404 or 505 of such Act. This guarantee shall be continuing and shall be applicable to any Drug shipped by Supplier to a drug product manufacturer or any other ORPHAN designated location before receipt by ORPHAN of written notice of revocation thereof;

(E) be free from all liens and encumbrances of any kind provided, however, THE WARRANTIES SET FORTH HEREIN ARE EXPRESSLY IN LIEU OF AND EXCLUDE, AND SUPPLIER EXPRESSLY DISCLAIMS AND NEGATES ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, ARISING BY OPERATION OF LAW OR OTHERWISE, INCLUDING IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

8.2 ORPHAN Inspection Rights. ORPHAN shall have the following inspection rights with respect to Supplier's manufacture of the Drug:

(a) During the Technology Transfer/Development Program, upon five (5) days' prior written notice, ORPHAN'S authorized representatives may, during normal business hours, inspect Supplier's facilities at which the Technology Transfer/Development Program is being conducted to monitor the progress of the Technology Transfer/Development Program. Supplier shall provide all data and records relating to the conduct of the Technology Transfer/Development Program reasonably requested by ORPHAN'S authorized representatives.

(b) Prior to commencement of manufacture and/or packaging of the Drug and at least once during each Contract Year, upon five (5) day's prior written notice, ORPHAN'S authorized representatives may, during normal business hours, review Supplier's governmental licenses and permits relating to the facilities and operations utilized by Supplier in the manufacture and/or packaging of the Drug.

(c) ORPHAN'S authorized representatives may inspect Supplier's manufacturing facilities during each production run of the Drug and at any other time upon reasonable notice to Supplier to audit any manufacturing, packaging, storage, and testing operations that ORPHAN deems reasonably appropriate to confirm that each batch of Drug has been manufactured, handled, and stored in accordance with the terms hereof. Upon ORPHAN'S request, Supplier shall notify ORPHAN at least thirty (30) days in advance of any production run of the Drug.

(d) Supplier shall provide ORPHAN'S authorized representatives with copies of all data and records relating to (i) process validation for the Drug including, without limitation, validation of associated automated systems, information systems and any other systems associated with process control, promptly after completion thereof and, promptly thereafter, following any revalidation; and (ii) the production of the Drug, including, without limitation, raw materials, additional validations, production batch records, packaging components, stability data and quality assurance records.

(e) Supplier shall keep ORPHAN updated on Supplier's internal audit and approval process for raw material suppliers, including, without limitation, an annual review of Supplier's audit reports of suppliers for materials to be used in the manufacture of the Drug.

(f) ORPHAN shall perform assays on samples from each Production Batch of the Drug and may perform such other tests as ORPHAN deems necessary or appropriate from any production run of the Drug manufactured for ORPHAN hereunder, and, without charge, Supplier shall furnish such samples, the analytical methodology and specifications relating thereto approved by FDA or other appropriate regulatory authorities and other testing materials as ORPHAN may reasonably request for such purposes.

(g) ORPHAN'S authorized representatives who are to conduct inspection or to review any Supplier records pursuant to this Section 8.3 shall execute a nondisclosure agreement substantially in the form attached hereto as Appendix E prior to conducting such inspections or reviewing such records.

8.3 Regulatory correspondence and Inspections. Supplier shall promptly inform ORPHAN of any regulatory correspondence or inspection with respect to Supplier's manufacture of the Drug as follows:

(a) Supplier shall provide ORPHAN with copies of any correspondence and other documentation received or prepared by Supplier in connection with the manufacture and testing of the Drug in the Territory, including, but not limited to, copies of the proposed NDA (but only of those portions for which Supplier is responsible) and of the potential DMF for the Drug and of annual submissions to the FDA and other regulatory authorities in the Territory. Copies of all such correspondence or other documentation prepared by Supplier shall be reviewed and approved by ORPHAN prior to its submission.

(b) If Supplier receives any regulatory correspondence or comments from any federal, state, or local regulatory agency in connection with its manufacture of the Drug requiring a response or action by Supplier, including, without limitation, receipt of an FDA Form 483 (Inspectional Observations) or an FDA "Warning Letter", Supplier shall immediately provide ORPHAN with a copy of each such regulatory correspondence or comment and a copy of

Supplier's proposed response thereto for ORPHAN'S review and approval prior to its submission if Supplier's manufacture of additional products are not involved. In cases where Supplier's manufacture of additional products are involved, a good faith effort will be made to reach joint approval within an appropriate timeframe.

(c) If Supplier's manufacturing facility is inspected by representatives of any federal, state, or local regulatory agency in connection with Supplier's manufacture of the Drug, including, but not limited to, any pre-NDA approval inspection by the FDA, Supplier shall notify ORPHAN within one (1) working day (by telephone and, if possible, by fax or letter) upon learning of such inspection, and shall supply ORPHAN with copies of any correspondence or portions of correspondence which relate to such regulatory inspection. ORPHAN may send representatives to Supplier's manufacturing facility to observe any portion of such regulatory inspection relating to the Drug.

ARTICLE 9 **ACCEPTANCE. REJECTION. AND CLAIMS**

9.1 Acceptance and Rejection. Each shipment shall be considered to conform to the Specifications and the other warranties set forth in Section 8.1(b) unless ORPHAN gives Supplier notice in writing that it does not consider a particular shipment to conform, together with supporting documentation, within ninety (90) days of receipt of such shipment (or, in the case of nonconformity that could not be reasonably discovered by ORPHAN'S analysis within thirty (30) days of such discovery). ORPHAN will analyze (or cause to be analyzed by its designated product manufacturer) each shipment of Drug using the validated methods approved by FDA for release of Drug. Such testing will be done for acceptance or rejection of the lot. If ORPHAN gives Supplier such notice, Supplier shall thereupon be given access to the shipment in question to conduct its own analysis thereof, and the parties will endeavor to agree amicably as to whether or not the shipment does conform to the Specifications and such other warranties and, if not, whether such non-compliance was due any action or inaction on the part of Supplier.

In the event that the parties are unable to agree as to whether or not the shipment

conforms with the Specifications or other warranty, the question will be submitted to an independent quality control laboratory as the parties may mutually agree upon. Cost for the independent quality control laboratory shall be borne by the party whose results are shown by such laboratory to have been wrong. During the pendency of a dispute that requires settlement by an independent laboratory under this section, if requested to do so by ORPHAN, Supplier will replace the portion of such shipment under dispute until such dispute is resolved.

9.2 Rejected Shipments. If the nonconformity in a rejected shipment of the Drug was due to any action or inaction of ORPHAN, its carrier or its designated drug product manufacturer subsequent to delivery (F.O.B. destination) of the Drug by Supplier, Supplier shall have no liability for such rejected shipment. If the nonconformity in a rejected shipment of the Drug was due to any action or inaction of Supplier prior to shipment delivery (F.O.B. destination), Supplier at its cost shall either credit ORPHAN for the full Manufacturing Cost of such shipment or replace it with a conforming shipment within thirty (30) days of the notice of rejection. Such credit or replacement will be ORPHAN'S sole remedy for such rejected Drug provided Supplier provides replacement or credit within thirty (30) days of notice of rejection.

9.3 Disposal; Return Material Authorization. If ORPHAN expects to make a claim against Supplier with respect to a rejected shipment of the Drug, ORPHAN shall not dispose or allow the disposal of such Drug shipment without the express written authorization and instructions of Supplier. ORPHAN or any ORPHAN designated drug product manufacturer shall not return any rejected shipment of the Drug to Supplier without a Return Material Authorization ("RMA") from Supplier (Appendix F). Upon written request of ORPHAN or the ORPHAN designated drug product manufacturer, as the case may be, Supplier shall promptly issue a RMA for any rejected shipment, provided, however, appropriate samples may be retained as evidence of the basis for such rejection.

9.4 Product Recalls. Each party shall promptly notify the other party if any batch of the Drug is alleged or proven to be the subject of a recall, market withdrawal or

correction ordered by the FDA or any other regulatory authority in the Territory. The parties shall cooperate in good faith to handle and dispose of such recall, market withdrawal or correction; provided, however, that in the event of a disagreement as to any matters related to such recall, market withdrawal or correction, ORPHAN'S decision shall prevail. ORPHAN shall bear all the costs of any such recall, market withdrawal or correction unless such recall, market withdrawal or correction was the result of Supplier's breach of any of its representations and warranties set forth in Article 8 above, in which case Supplier shall bear all costs of such recall, market withdrawal, or correction. Supplier will not bear the cost for recalls made as a result of errors that could have been detected by Orphan through acceptance and rejection testing as outlined in Article 9.

ARTICLE 10 **INDEMNIFICATION**

10.1 Supplier's Indemnification to ORPHAN. Subject to Suppliers warranty and ORPHAN'S compliance with its obligations in Section 10.3 hereof, Supplier hereby indemnifies, defends, and holds ORPHAN and its directors, officers, employees, agents, and Affiliates harmless against any and all losses, damages, expenses, reasonable attorneys' fees (regardless of outcome), settlement costs and judgments arising out of or resulting from Supplier's material breach of any of its representations or warranties under Article 8 above, including, but not limited to, development, manufacture, testing, shipping, storage, delivery and/or other handling or processing of the Drug, except to the extent that such losses, damages, expenses, fees, settlement costs and judgments result from the material breach by ORPHAN of its covenants or warranties under this Agreement or the negligence or willful misconduct of ORPHAN, its employees or agents. Supplier shall defend and indemnify ORPHAN for any injuries or claims of injuries which may arise during manufacturing of the Product.

10.2 ORPHAN Indemnification of Supplier. Except as provided in Section 10.1 above, and subject to Supplier's compliance with its obligations in Section 10.3 hereof, ORPHAN hereby indemnifies, defends, and holds Supplier and its directors, officers, employees, agents and Affiliates harmless against any and all claims, losses, damages, expenses, reasonable attorneys' fees (regardless of outcome), settlement costs and

judgments (a) to which Supplier may be subject with respect to the Drug, except those which arise under facts and circumstances pursuant to which Supplier would be required to indemnify ORPHAN under the provisions of Section 10.1, or (b) arising out of or resulting from any subsequent formulation, repackaging, distribution or other use of the Drug supplied hereunder, including third party liability claims relating thereto.

10.3 Indemnification Procedures. A party (the "Indemnitee") which intends to claim indemnification under this Article 10 shall promptly notify the other party (the "Indemnitor") in writing of any action, claim or other matter in respect of which the Indemnitee or any of its directors, officers, employees, agents or Affiliates intend to claim such indemnification. The Indemnitee shall permit, and shall cause its directors, officers, employees, agents and Affiliates to permit, the Indemnitor, at its discretion, upon providing the Indemnitee with a written acknowledgment of full and complete responsibility for the indemnification of the Indemnitee with respect to any such action, claim or other matter, to settle any such action, claim or other matter; and to complete control of such defense or settlement by the Indemnitor; provided, however, that such settlement shall not adversely affect the Indemnitee's rights hereunder or impose any obligations on the Indemnitee in addition to those set forth herein in order for it to exercise such rights. No such action, claim or other matter shall be settled without the prior written consent of the Indemnitor, and the Indemnitor shall not be responsible for any legal fees or other costs incurred other than as provided herein. The Indemnitee, its directors, officers, employees, agents and Affiliates at the Indemnitor's expense shall cooperate with the Indemnitor and its legal representatives in the investigation and defense of any action, claim or other matter covered by this indemnification. The Indemnitee shall have the right, but not the obligation, to be represented by counsel of its own selection and at its own expense.

ARTICLE 11 INVENTIONS AND PATENTS

11.1 Inventions by Supplier. Supplier hereby assigns, releases, and transfers to ORPHAN its entire right, title and interest in and to any invention, discovery or

improvement relating to the Drug (whether patentable or not) made or conceived by Supplier employees or contractors, including, without limitation, manufacturing, manufacturing processes and procedures, analytical process, procedure or method, analytical results, and any route(s) of synthesis provided, however, ORPHAN hereby grants to Supplier a paid-up, worldwide, nonexclusive, nontransferable license to use patented inventions, discoveries, or improvements (a) for purposes of this Agreement, (b) for Supplier's and internal research and development purposes, (c) for Supplier's non pharmaceutical commercial purposes and (d) with other non-competitive pharmaceutical compounds used in different therapeutic classes.

11.2 Inventions by ORPHAN. ORPHAN shall own all right, title and interest in and to any invention, discovery or improvement relating to the Drug (whether patentable or not) made or conceived solely by ORPHAN employees or by any ORPHAN contractor other than Supplier, including, without limitation, any manufacturing or analytical process, procedure or method or any source of synthesis given to Supplier.

11.3 Supplier shall promptly disclose to ORPHAN any and all inventions, discoveries and improvements relating to the Drug (collectively "Inventions"), by Supplier's employees or contractors, either alone or together with ORPHAN'S employees or contractors, and shall assign all its interests to ORPHAN or its designee in accordance with Section 11.1. Supplier shall execute at ORPHAN'S expense any assignments, applications or other instruments or documents reasonably requested by ORPHAN in accordance with this Article 11 and, at ORPHAN'S expense, give testimony which shall be deemed necessary to apply for and obtain Letters Patent of the United States or of any other country and otherwise to perfect ORPHAN'S interest therein. Supplier's and ORPHAN'S obligations hereunder shall survive termination of this Agreement. All data obtained in the Technology Transfer/Development Program and the stability program described in Appendix D—Requirements for Stability Studies, are the property of ORPHAN and cannot be used without its consent except for the performance by Supplier of its obligations hereunder.

ARTICLE 12 **TRADEMARKS**

12.1 ORPHAN Trademarks. ORPHAN may originate, select and apply to register one or more trademarks ("ORPHAN Trademarks") under which the Drug will be sold and distributed by ORPHAN or its Affiliates and distributors. ORPHAN shall own all right, title, and interest in the ORPHAN Trademarks, subject to the limited license granted to Supplier in this Article 12. ORPHAN shall be solely responsible for all prosecution, defense, maintenance and costs relating to the ORPHAN Trademarks.

12.2 Limited Trademark License. ORPHAN hereby grants Supplier a paid-up, worldwide, nonexclusive, nontransferable license to the ORPHAN Trademarks solely for purposes of manufacturing and distributing the Drug under this Agreement. Supplier shall comply with ORPHAN'S standard policies and procedures for the use of the ORPHAN Trademarks and shall furnish ORPHAN with copies of any packaging, or other materials incorporating the ORPHAN Trademarks for ORPHAN'S review and approval prior to any use thereof. Supplier shall make any changes or additions reasonably requested by ORPHAN to comply with ORPHAN'S standard policies and procedures for the use of the ORPHAN Trademarks. Upon termination of this Agreement, Supplier shall promptly cease any use of the ORPHAN Trademarks.

12.3 Limitations. Supplier shall not use, or assert any claims to, any of the ORPHAN Trademarks or any trademark confusingly similar to any ORPHAN Trademarks, provided that ORPHAN shall not choose a trademark which is the same as, or confusingly similar to, a trademark previously used by Supplier.

12.4 Infringement. Supplier shall promptly notify ORPHAN if Supplier knows or reasonably suspects that a Third Party is infringing any ORPHAN Trademark and shall provide ORPHAN with any evidence thereof. At ORPHAN'S expense, Supplier shall reasonably cooperate in any investigation or other legal action with regard to such infringement.

ARTICLE 13 **CONFIDENTIALITY**

13.1 Proprietary Information. During the term hereof and for a period of five (5) years thereafter, any Proprietary Information disclosed by the one party (the "Disclosing Party"), directly or indirectly, to the other party (the "Receiving Party") under this Agreement shall be deemed confidential and trade secret information, whether so designated or not, and shall not be disclosed by the Receiving Party to any Third Party, except as set forth below. Access to such Proprietary Information will be limited to employees, agents, consultants or contractors of the Receiving Party who reasonably require such Proprietary Information for purposes of performing the Receiving Party's obligations hereunder and who are bound to the Receiving Party by similar obligations in respect of confidentiality and use. Such employees, agents, consultants or contractors will be advised of the nature and existence of the undertakings in respect of such Proprietary Information pursuant to this Agreement and of the applicability of such undertakings to them. The Receiving Party will use such Proprietary Information only to carry out its obligations or to exercise its rights hereunder and will not use such Proprietary Information for its own benefit or for the benefit of others or in any way inconsistent with this Agreement.

13.2 Exceptions. Information shall not be deemed Proprietary Information which:

(a) at the time of disclosure, is already in the public domain or thereafter becomes part of the public domain by publication or otherwise through no fault or act of the Receiving Party;

(b) was demonstrably in the possession of the Receiving Party prior to the time of the disclosure to it and was not acquired, directly or indirectly, from the Disclosing Party;

(c) is independently disclosed to the Receiving Party by a third party who has not violated any confidential obligation owed to the Disclosing Party;

(d) was independently developed by the Receiving Party without any use of or reliance on any Proprietary Information of the Disclosing Party;

(e) is required to be disclosed by legal process; provided that, in each case the

party so disclosing information timely informs the other and uses its best efforts to limit the disclosure and maintain confidentiality to the extent possible and permits the other party to attempt by appropriate legal means to limit such disclosure;

(f) is information which is required to be included in patent applications filed hereunder or required to be provided to the FDA or any other regulatory authority in the Territory in order for ORPHAN or Supplier to obtain Registrations for the Drug or otherwise to comply with applicable regulatory requirements, or for Supplier to manufacture the Drug for ORPHAN hereunder; provided, however, that no Proprietary Information of ORPHAN or Supplier will be disclosed in any such patent application without the prior written consent of the other Disclosing Party, which consent will not be unreasonably withheld; or

(g) is information which is required to be disclosed to customers, users, and prescribers of the Product or which is reasonably necessary to disclose in connection with the ethical marketing of the Product, if applicable.

13.3 Disclosure by the Receiving Party to a Third Party shall be made only to the extent necessary to enable the Receiving Party to comply with its contractual obligations to the disclosing party.

13.4 Each Third Party to which Proprietary Information is disclosed other than a governmental agency will agree in writing prior to such disclosure to keep the Proprietary Information in strict confidence and to comply with the terms of this Article 13.

13.5 Both parties agree to limit access of Proprietary Information to those of its officers, directors, or employees, or any Third Party who must have Proprietary Information to carry out the terms of any agreement made between the parties.

13.6 Neither party shall utilize the Proprietary Information disclosed to it by the Disclosing Party after the completion of the Agreement between the parties, either in its own development work or for commercial purposes, without advance written consent of the Disclosing Party.

13.7 The party receiving Proprietary Information will obtain no right or license of any kind under any patent applications, patent or otherwise by reason of this Agreement and all Proprietary Information will remain the sole property of the Disclosing Party unless provided otherwise in this Agreement.

13.8 Except as otherwise required by law, applicable regulations or the terms of this Agreement or mutually agreed upon by the parties hereto, each party shall treat as confidential the terms, conditions, and existence of this Agreement.

13.9 Prior Confidentiality Agreement. The Confidentiality Agreement between the parties hereto dated February 27, 1996, is hereby superseded and terminated. Any disclosure of Proprietary Information by either party pursuant to such Confidentiality Agreement shall be deemed to have been made hereunder and shall be subject to this Article 13.

13.10 Terms of Agreement; Press Releases. Except as otherwise required by law or the rules and regulations of any stock exchange on which a party's securities may be publicly traded or in disclosures made in confidence to a party's professional or financial advisors, applicable regulations or the terms of this Agreement or mutually agreed upon by the parties hereto, each party shall treat the terms, conditions and existence of this Agreement as Proprietary Information. The parties shall cooperate in good faith in the preparation of any press releases or other public disclosures of their business relationship, and neither party shall issue any such press release or other disclosure without the prior approval of the other party, which approval shall not be unreasonably held.

ARTICLE 14 **TERM OF AGREEMENT**

14.1 Unless sooner terminated pursuant to Article 15 below, the initial term of this Agreement shall commence on the Effective Date and end upon expiration of the third (3rd) Contract Year. Supplier and ORPHAN may mutually agree to extend this Agreement on a for one or more additional three year terms. Supplier or ORPHAN must

provide a written notice of intent to terminate the Agreement at least eighteen (18) months prior to the expiration of the initial or any extended term. All references herein to "term of this Agreement" shall be deemed to include both the initial and any extended terms.

ARTICLE 15 **TERMINATION**

15.1 Termination by Either Party. In addition to any other legal or equitable remedies it may have, either party may terminate this Agreement prior to the expiration of the term of this Agreement upon ten (10) days' written notice to the other party:

(a) If the other party breaches any material term or condition of this Agreement, including any term or condition in any appendix attached hereto, provided such other party has not cured such breach within thirty (30) days of written notice thereof; provided, further, that if at the end of such thirty (30) day period the party in breach is making a good faith effort to cure, a reasonable time thereafter (not to exceed an additional thirty (30) days) shall be allowed for such cure.

(b) If the other party is declared bankrupt or insolvent, or makes an assignment for the benefit of its creditors, or if a receiver is appointed or any proceedings are commenced, voluntary or involuntary, by or against either party under any bankruptcy or similar law, and such status is not cured within thirty (30) days from its occurrence.

(c) If an event of force majeure continues for more than six (6) months, either party, at its option, may elect to treat such continued suspension of performance as a material breach and may terminate this Agreement.

15.2 Termination by ORPHAN. In addition to any other legal or equitable remedies it may have, ORPHAN may terminate this Agreement upon thirty (30) days' written notice to Supplier:

(a) If the minimum requirements for the Drug or the timeframes for performance set forth in Appendix A hereto are not met by Supplier and no amendment thereof is acceptable to ORPHAN; or

(b) If ORPHAN determines, in its sole discretion, not to proceed further with the investigation of the Drug for the treatment of narcolepsy or any other indication.

15.3 Termination by Supplier. In addition to any other legal or equitable remedies it may have. Supplier may terminate this Agreement upon thirty (30) days' written notice to ORPHAN if in the course of performing Stage A, Supplier determines that solely, in order to manufacture the Drug under the terms of this Agreement, it will have to make a capital investment in excess of $100,000. Replacement of machinery as a result of ordinary wear and tear is excluded from this amount.

15.4 Effects of Expiration or Termination. Upon expiration or termination of this Agreement for any reason:

(a) Supplier shall manufacture and ship, and ORPHAN shall purchase, Production Batches of the Drug ordered by ORPHAN prior to the effective date of such expiration or termination.

(b) Supplier shall continue to provide manufacturing and quality assurance support and support of the stability studies for the Drug until the expiration date of the last production Batch of the Drug purchased by ORPHAN hereunder or the date required by any applicable law or regulation in the Territory, whichever is later, provided, however, if ORPHAN terminates this Agreement, ORPHAN shall reimburse Supplier for the actual costs of any required support of the stability studies.

(c) Supplier shall take all steps reasonably requested by ORPHAN to confirm the assignment to ORPHAN all of Supplier's right, title and interest in the Inventions, including, without limitation, to execute or cause its employees or contractors to execute such documents as may be reasonably requested by ORPHAN to vest all such right, title and interest in such Inventions in ORPHAN, provided ORPHAN shall pay all reasonable expenses, including any of time and travel of Supplier's employees, in connection with steps.

(d) Each party shall return to the other party any Proprietary Information of the other party except for one (1) archival copy as may be required for purposes of compliance with any FDA regulation or other applicable law or regulation in the Territory.

15.5 Survival. The provisions of Articles 4 (Marketing Rights), 7 (Prices and Payments), 8 (Representations, Warranties, and Inspections), 9 (Acceptance, Rejection and Claims), 10 (Indemnification), 11 (Inventions and Patents), 12 (Trademarks), 13 (Confidentiality), 14 (Term of Agreement), 15 (Termination), 16 (Force Majeure), 17 (Dispute Resolution) and 18 (Miscellaneous) shall survive the expiration or termination of this Agreement and shall remain in full force and effect in accordance with the terms thereof.

ARTICLE 16 **FORCE MAJEURE**

16.1 Events of Force Majeure. Either party shall be excused from the performance of its obligations in the event such performance is prevented by a cause beyond the reasonable control of such party, including, without limitation, any act of God; regulation or law of any government or an agency thereof; war; insurrection or civil commotion; earthquake, tornado, fire, flood or storm; epidemic; or failure of suppliers, public utilities or common carriers. Such excuse shall continue as long as the condition preventing the performance continues. Upon cessation of such condition, such party shall promptly resume performance hereunder.

16.2 Notice. A party affected by an event of force majeure shall give the other party prompt written notice of the occurrence of any event of force majeure and the nature and duration thereof. An affected party shall use all reasonable efforts to resume performance as quickly as possible and to give the other party prompt written notice when it is again fully able to perform such obligations. If Supplier is the affected party, such notice of resumption of performance shall state the quantities of Drug manufactured but not shipped by Supplier due to any event of force majeure and the expiration dates thereof.

16.3 Cover. During any suspension of performance by Supplier under Section 16.1 above, ORPHAN may, at its option, purchase elsewhere the quantities of the Drug ORPHAN has ordered which Supplier is unable to deliver.

16.4 Short Supply Allocation. If Supplier is unable to supply all of ORPHAN'S orders for the Drug hereunder in a timely manner, Supplier shall equitably allocate its available resources and production capacity among ORPHAN and Supplier's other customers and internal needs, taking into consideration the respective requirements of each of the parties during a reasonable time period prior to allocation and their requirements during the allocation period.

ARTICLE 17 **DISPUTE RESOLUTION**

17.1 Negotiation. The parties intend that any dispute, controversy or claim arising out of or relating to this Agreement, or any breach thereof, shall be resolved under the procedures set forth in this Section, including, as a final method of resolution, binding arbitration. The amount involved in any such dispute, controversy, or claim shall be conclusively determined for the sole purpose of determining whether such dispute, controversy, or claim is subject to the provisions of this Article 17, by the amount set forth in an initial letter from the party making the claim to the other party.

17.2 Mediation. If attempts to resolve the dispute pursuant to Section 17.1 are unsuccessful, before commencing arbitration, mediation shall be conducted by a single mediator appointed by mutual agreement of the parties. The mediator shall not have the power to bind the parties to the resolution. The mediation session shall take place in New York, New York , on two (2) consecutive business days and shall be attended by a representative of each party with full authority to settle the matter, along with any other representatives reasonably necessary to discuss and address the issues involved in the Dispute. On the first day of mediation, each party shall be allotted a maximum of four (4) hours with other representatives necessary to discuss and address the issues involved in the Dispute to state its views of the Dispute to the mediator and to the other party. On the second day of mediation, the parties shall attempt to resolve the Dispute with the aid of the mediator in a format agreed to by the parties or imposed by the mediator. If the

parties cannot agree upon a mutually acceptable mediator within ten (10) days of the end of the 30-day negotiation period in Section 17.1 or if the Dispute is not resolved by mediation within ten (10) days after completion of the mediation session, either party may give notice in writing that the Dispute shall be decided by final and binding arbitration.

17.3 Arbitration. Final and binding arbitration of any Dispute shall be conducted in Minneapolis, Minnesota, before three (3) arbitrators selected by mutual agreement of the parties or, if no such agreement is possible, appointed by the American Arbitration Association ("AAA"). The arbitration shall be conducted in accordance with the AAA Commercial Arbitration Rules then in effect, subject to the modifications set forth below, and judgment upon the award may be entered in any court of competent jurisdiction. At least one arbitrator shall have experience in the pharmaceutical industry, and at least one arbitrator shall be an attorney with experience in pharmaceutical industry licensing and contractual matters. The arbitration shall be closed to any Third Party. Notwithstanding any provision to the contrary in the AAA's Commercial Arbitration Rules, the parties hereby stipulate that any arbitration hereunder shall be subject to the following special rules:

(a) Each party shall have the right to request from the arbitrators, and the arbitrators shall order upon good cause shown, reasonable and limited pre-hearing discovery as permitted in civil matters in the courts of Minnesota, , including (i) exchange of witness lists, (ii) depositions under oath of named witnesses, (iii) written interrogatories, and (iv) document requests;

(b) If a party is asked to reveal material in the arbitration which the party considers to be Proprietary Information, the party shall bring the matter to the attention of the arbitrators, who shall make such protective orders as are reasonable and necessary;

(c) Upon conclusion of the pre-hearing discovery, the arbitrators shall promptly hold a hearing upon the evidence to be presented by the parties and shall promptly render a written opinion and award but in no event later than sixty (60) days after the conclusion of the hearing.

(d) The arbitrators shall not add to, detract from, or alter the provisions of the Agreement of any applicable law or rule of civil procedure;

(e) The arbitrators my not award or assess punitive damages against either party;

(f) The arbitrators may require either party to specifically perform its obligations under this Agreement; and

(g) Each party shall bear its own costs and expenses of the arbitration and one-half (1/2) of the fees and costs of the arbitrators, subject to the power of the arbitrators, in their sole discretion, to award all such reasonable costs, expenses and fees, including, without limitation, attorney's fees, to the prevailing party.

ARTICLE 18 **MISCELLANEOUS**

18.1 Choice of Law. This Agreement shall be governed by and interpreted in accordance with the laws of Minnesota, without regard to its conflict of laws provisions and the courts of Minnesota shall have exclusive jurisdiction over all matters arising out of this agreement.

18.2 Notices. Any and all notices provided for shall be sent to the respective parties at the following addresses by certified or registered mail or sent by a national courier service with proof of delivery, by personal delivery or by facsimile with an electronic and verbal confirmation of receipt:

If to Supplier: General Manager
Special Fine Chemicals
Lonza Inc.
Corporate Headquarters
17-17 Route 208
Fairlawn, New Jersey 07410-2821
Fax: (201)794-2695

If to ORPHAN: Harry Cook

Orphan Medical, Inc. 3911

Ridgedale Drive Minnetonka,

Minnesota 55305

Fax: (612)541-9209

with a copy to each President's office, or to such other addresses as may be subsequently furnished by one party to the other in writing. Any such notice shall be deemed effective three (3) days after mailing or upon receipt if sent by courier service, personal delivery or facsimile.

18.3 Severabilitv. If any term or condition of this Agreement is found by a court of competent jurisdiction in a final unappealed or unappealable order to violate the provisions of any applicable statute, law or regulation, the remainder of this Agreement shall remain in full force and effect. The parties shall then negotiate in good faith to modify this Agreement, but only to the extent necessary to make the affected term or condition of this Agreement valid and enforceable, having full regard for applicable laws and the intent and purposes of the parties entering into this Agreement.

18.4 Integration; Amendment. This Agreement and all appendices hereto constitute the entire agreement between the parties relating to the subject matter of this Agreement and supersedes all prior agreements, representations, and understandings. This Agreement may not be amended, modified, or varied except in writing signed by a duly authorized representative of each party. In the event of a conflict between the terms of this Agreement, and any appendix hereto, the terms of this Agreement shall control.

18.5 Assignment. Neither party may assign this Agreement without the prior written consent of the other party except that either ORPHAN or Supplier may assign this Agreement (a) to an Affiliate or (b) in connection with the sale or transfer of all or substantially all of the assets of such party or the division of such party manufacturing or marketing of the Drug, as the case may be, provided, however, any permitted assignee shall assume all obligations of its assignor under this Agreement. Any purported assignment in violation of the foregoing sentence shall be null and void. No assignment

shall relieve either party of responsibility for the performance of any accrued obligation under this agreement. Subject to the foregoing, this Agreement shall be binding upon and inure to the benefit of the permitted successors or permitted assigns of Supplier and ORPHAN respectively.

18.6 Waiver. No course of dealing between Supplier and ORPHAN or delay or failure to exercise any rights hereunder shall operate as a waiver of such rights or preclude the exercise of any other rights hereunder.

18.7 Relationship. Each of the parties hereto is an independent contractor and nothing herein shall be deemed to constitute the relationship of partners, joint venturers, nor of principal and agent between the parties hereto.

18.8 Captions. The captions to the several Articles hereof are not a part of this Agreement, but are merely guides or labels to assist in locating and reading the several Articles hereof and shall not affect the meaning or interpretation hereof.

18.9 Counterparts. Two (2) or more counterparts of this Agreement may be signed by the parties, each of which shall be an original, but all of which together shall constitute the same instrument.

18.10 Diligence. Each party agrees to use due diligence in preparing full disclosure of relevant information, in reviewing information when available, and in committing decisions necessary to enable completion of Stages within target timeframes.

IN WITNESS WHEREOF, the parties have caused this Agreement to be entered into by their duly authorized representatives as of the Effective Date.

SUPPLIER

By: /s/ Peter Pollak
Print: Peter Pollak
Its: VP/GM Fine Chemicals
Date: November 8, 1996

ORPHAN MEDICAL, INC.

By: /s/ Bert Spilker
Print: Bert Spilker
Its: President
Date: November 6, 1996

APPENDIX A

GHB TECHNOLOGY TRANSFER/DEVELOPMENT PROGRAM

Stage A, Part I: Technology Transfer/Development	Cost/Timeline
1. Review available data associated with previous development, testing and manufacture.	
2. Identification & Qualification of intermediate suppliers, order and test for release raw materials.!*)	
3. Evaluation of quality of GBL required for production of GHB with defined specifications.	
4. Cross-Validation of analytical methods will be completed using the current Lonza standard operating procedure for cross-validation of analytical methods.	
5. Make recommendations and conduct development testing to determine if improvements can be made in yield, waste reduction, etc. and prepare a Process Development Report	
6. Complete IQ, OQ & PQ. Prepare validation protocol and confirm manufacturing method (through production of one lot, prep, of Process Validation Report.(2)	
7. Comparability of the impurity profile and specifications for Batch 1 to the drug manufactured by Cytec Industries, Inc. The purpose is to ensure that the toxicology clinical data collected through use of Cytec manufactured drug are not jeopardized. Reconfirm solid state drug substance form through DSC, X-ray, particle size and range of variation, hygroscopicity and clarity in solution.	
8. Write Stage A, Part I Completion Report. (See Appendix B, “Reporting)	
Stage A, Part II	$150,000
9. Manufacture 2 additional lots per the Validation Protocol, update the Process Validation Report and reconfirm solid state drug substance form as in 6 above.	$ 35,000 5 to 6 months
10. Write Environmental Assessment Report	
11. Assist in the preparation of the Drug Substance NDA CMC Section and/or DMF as requested by Orphan. Lonza will document efforts/data from this Technology Transfer/Development Program in a format acceptable for NDA submission.	
12. Write Stage A, Part II Completion Report (See Appendix B, “Reporting”)	
TOTAL This price is cost without profit to Lonza. The price is a fixed sum and is a cost cap as will be defined in the contract being negotiated.	

1) **Raw Material Specifications and Acceptance Criteria**—Transfer and document acceptance testing methods and specifications for ORPHAN review and approval. Evaluate currently approved vendors. If supplier of critical raw materials are not previously audited, conduct audits. Audit reports on vendors of critical raw materials will be provided to ORPHAN for review. DMF Reference Authorization letters from suppliers of any commercial combination excipients and activities must be obtained and included in the submission. Certificates of Analysis and batch numbers for raw materials will be maintained.

2) **Process Validation Protocol**—The Validation Protocol must be mutually approved. ORPHAN will be notified two weeks in advance of the dates for manufacture of any validation batch in order that an ORPHAN representative can be present. The Drug will be manufactured in compliance with cGMPs and applicable regulatory standards for manufacturing drugs for use as clinical trial material or for commercial use. Three Validation Batches will be manufactured in a mutually approved reactor. The final decision regarding the timing for manufacture of the three validation batches and their intended use will be mutually decided.

A pharmaceutically acceptable batch record will be developed for production of the ORPHAN bulk pharmaceutical compound that meets or exceeds current pharmaceutical industry and cGMP standards and copy said batch record will be provided to ORPHAN for its approval prior to use.

ORPHAN will be notified two (2) weeks in advance of the dates for manufacture of validation batches in order that an ORPHAN representative can be present for the manufacture, if desired.

3) ORPHAN will provide GHB reference standard material for use in the Development Program.

4) The scope of this Development Program does not include new analytical methods development. Supplier agrees to accept the Cytec analytical methods for GHB and impurity testing for cross- validation. Methods will be provided for all required tests unless mutual agreement is otherwise reached.

Stage B Final Process Re-validation at Larger Scale for Commercial Use

1. Manufacture additional re-validation lots and write final Process Validation Report, and final Cleaning Report (re-validation efforts may be required in transferring production to larger scale reactors)

2. Demonstrated clean out of operating vessels to cGMP standards (pre and post), write Cleaning Validation report.

3. Prepare NDA CMC update to include stability report.

4. Prepare for FDA pre-approval inspection.

5. Provide responses to FDA NDA CMC questions.

6. Write a Stage B Completion Report.

APPENDIX B

REPORTING REQUIREMENTS

The following items represent minimum content requirements. Actual reports should include all information that is relevant in assessing the status of the development program and in completing documentation that is required by regulatory agencies. Any documentation that is required for preparation of the CMC Section, Process Certification Report, Process Validation Report, etc. should not be rewritten as part of a stage completion report.

Progress reports on development will be discussed with ORPHAN on an agreed upon schedule depending on the level of activity at any point in time. Decisions, issues, and significant findings will be documented for review and concurrence. Reasonable efforts will be used to take corrective actions and conduct such additional work as is necessary to achieve the Required Specifications as outlined in Appendix C. The parties will mutually agree upon the time impact of any changes. Additional resources will be committed to conduct of the GHB Technology Transfer/Development Program if necessary to ensure completion of the project as close to the overall time frame specified as possible.

STAGE A: Technology Transfer/Development
COMPLETION REPORT

A “Stage A Completion Report” will contain the data and analytical results from all processing and testing conducted to include the manufacture of one (1) Validation Batch. This report will also include a copy of the following for ORPHAN review and approval if approval has not already been obtained:

1) Manufacturing Validation Protocol and Report

   a) Process range

   - Temperature, atmospheric pressure definitions
   - Charge definitions
   - Time definitions (include allow, holding time)
   - Yields, purity
   - Solvents, reagents
   - Concentration
   - Centrifigation/Isolation
   - Equip validation as req (IQ, PQ, OQ)
   - Cleaning documentation
   - Packaging Procedures
   - Raw Materials (Names and amounts of all substances used, including tests and specifications, precautions for storage, U.S. pharmacopeia specifications)
   - Alternative process description, if available

   b) Allowable process parameters

2) Re-validation of analytical methods, tests and specifications (to include validation documentation to support all analytical methods)

   - Identity tests
   - Impurities testing
   - % moisture
   - Heavy metals
   - Sodium
   - Volatiles
   - Assay
   - Identity versus standard

3) Additional Testing
    - pH
    - Bulk density
    - Dissolution rate
    - Solubility
    - Other (residual solvents, etc.)
4) Raw Material Vendor and Specs, and Final Product Specifications and Methods Manual
5) Copies of executed Batch Record(s) and Certificate(s) of Analysis
6) Stability Report (See—‘Requirements For Stability Studies’)
7) Description of manufacturing facilities, personnel, Standard Operating Procedures, and appropriate supporting validation documentation as required for the NDA.
    - Training
    - Util and Support Systems
    - Environmental Standards
    - Process Conditions
8) Update estimates for cost of goods

STAGE B: Final Process Validation and Preparation for Commercial Launch

COMPLETION REPORT

1) Mutually approved Bulk Drug Manufacturer Contract Release Specifications (ID, Assay, Impurity, Appearance, and Quantitative Component Assessment. Labels, packaging batch records and certificates of analysis will be verified prior to release.).

2) Subsequent to FDA approval, ORPHAN will be notified for prior approval of any updates made through standard operating “Change Control” procedures. Changes requiring notification for approval will include and not be limited to the following:

   A) Changes in raw material supplies and suppliers

   B) Process changes

   C) Equipment changes

   D) Packaging component changes

APPENDIX C

REQUIRED DRUG SPECIFICATIONS

Expiration Storage	36 months at 25°C with 60% RH (60 months desired)	
Conditions	25°C with 60% RH - double polypropylene bags in a fiberpak (dessicants required and not to be in contact with Drug)	
Appearance	White free flowing powder	
Heavy Metals	20 ppm maximum {By USP} {PP} {BS}	
Moisture	0.05% maximum (GHB's hygroscopic and must be kept as dry as possible)	
Residual Methanol	400 ppm maximum	
Identity Impurity	Match FT/IR of reference {PP} {BS}	
Profile {PP} {BS}		
	No unknown impurity greater than 0.05%	{over %}
	Succinic Acid	<0.05% {% wt}
	Succinic Anhydride	<0.05% {% wt}
	Succinic Acid, Sodium Salt	<0.05% {% wt}
	Methyl-gamma hydroxy-butyric acid	<0.05% {% wt}
	1,4-butanediol	<0.05% {% wt}
	gamma-Butyrolactone	<0.05% {% wt}
	Sodium hydroxide	<0.05% {% wt}
	Sodium carbonate	<0.05% {% wt}
	Total of known impurities not to exceed	0.5% {% wt}
Particle Size	To be mutually established	
Contractual Release Specifications:	Some specification requirements for release of the Drug will be more restrictive than those approved via the NDA to ensure Drug adequacy upon analytical retesting or anticipated degradation over time. Release specifications will be mutually agreed upon based on the findings of the "Technology Transfer/Development Program" and upon the FDA approved specifications.	
Assay	99-102% {wt % }{PP} {BS}	

APPENDIX D

REQUIREMENTS FOR STABILITY STUDIES

REQUIREMENTS FOR DEVELOPMENT PROGRAM STABILITY STUDIES

I. Stability Protocol

A proposed stability study matrix and protocol(s) will be provided for joint review to ensure development of the best stability study strategy. Stability study protocols will be approved by ORPHAN. The stability study program will:

A) meet requirements of the 'Stability Testing of New Drug Substances and Products' endorsed by the ICH Steering Committee.

B) meet stability requirements for support to Stage II, III and IV clinical studies and requirements for support to on-going commercial production of bulk drug for pharmaceutical purposes.

II. Reporting

Written stability study reports will be provided which include, but are not limited to, the following information for all Drug batches used for stability.

A) Certificate of analysis (include batch size, date of manufacture)

B) Batch numbers

C) Stability study results until there are two (2) consecutive failures including both initial and data at the designated time points for analysis with references to analytical procedures used. (Additionally, tests will be conducted immediately before the NDA filing.)

Additionally, the following information will be provided upon request for all Drug batches placed on stability prior to FDA approval.

D) Raw material listing for all batches and a description of differences, if any

E) Lot number(s) of raw materials used in each batch

F) Sampling plan

G) Manufacturing process

H) Use of Batches

Other stability requirements in the Technology Transfer/Development Program.

I) Stability study results

a) Suitability and specificity of stability indicating assay methods

b) Degradation products and pathways—Identification and quantitation of degradents. (If the degradants become regulatorily significant, Supplier agrees to negotiate time and cost, isolation, and preparation of samples for toxicity testing which will be conducted by ORPHAN. Descriptions of any known toxicological properties associated with identified degradents will be provided.)

c) Details on storage containers

d) Discussion of stability results

J) Solubility profiles in an aqueous medium

K) Reports on stability indicating parameter(s).

L) Samples to be retained from stability batches until 1 year past expiration (Note: Retention of samples from clinical trial batches will meet the more rigorous requirements of FDA.) Adequate samples to be retained to enable full compendial testing.

III. Packaging and Storage Conditions

A stability study matrix will be mutually developed which includes study of the following factors:

A) Samples will be placed on storage in mutually agreed upon packaging. Double ply bags to be of same composition as those used by Cytec Industries (possibly thicker) with dessicant between bags.

B) Storage conditions for solid drug will include the environments and testing frequences noted on the Proposed Development Program Stability Plan.

(C) Three (3) lots of GHB bulk drug substance will be packaged in five (5) gram aliquots and stored in double ply bags of the same composition as used by Cytec which have been or exceed Class 100 requirements.

The samples will be twist-tied and placed in a fiber box with a fiber cover.

IV. Extent of Studies and Methods of Testing

A) There are 3 lots of Drug to be tested.

B) Cytec developed methods will be used for analytical testing.

C) The method for moisture analysis will be a validated potentiometric Karl Fischer.

D) Interval data will be provided within fifteen (15) working days of the sample pull date, and a stability report will be provided to support the NDA submission and a final stability report will be provided.

REQUIREMENTS FOR PRODUCTION STABILITY STUDIES

I. A Production Stability Protocol to be jointly approved. The protocol will meet requirements of the “Stability Testing of New Drug Substances and Products’ endorsed by the ICH Steering Committee.

II. Reporting

Written stability study reports will be provided which include, but are not limited to, the following information for all Drug batches used for stability.

A) Certificate of analysis (include batch size, date of manufacture)

B) Batch numbers

C) Stability study results past two (2) consecutive failures or to 60 months, whichever is shortest, including both initial and data at the designated time points for analysis with references to analytical procedures used.

PROPOSED DEVELOPMENT PROGRAM STABILITY PLAN

REQUIRED TESTS, STORAGE CONDITIONS AND FREQUENCY

STRENGTH NA

PRODUCT:Gamma Hydroxybutyrate Bulk

LOT#_____ Stability start date____

CONTAINER TYPE & PART # Representative of Bulk Storage
CLOSURE TYPE & PART # Representative of Bulk Storage
Batch Size _____
Date of Manufacture _____

Required Tests/ Method	Specifications	Storage Condition	0	1	2	3	4	5	6	7	8	9	10	11	12	18	24	36	48	60.
Appearance	white to off-white	CRT(25±2°/60%±5RH)	X	XC	XC	X			X			X			X	X	X	X	X	X
Visual	free-flowing powder	(40°/C75%RH± 5%RH)	X	X	X	X			X											
Assay	98.0% to 102.0%	CRT(25±2°/60%±5RH)	X	XC	XC	X			X			X			X	X	X	X	X	X
Potentiometric Titration		(40°/C75%RH+ 5%RH)	X	X	X	X			X											
Melting Point	146-147°C	CRT(25±2°/60%+5RH)	X	XC	XC	X			X			X			X	X	X	X	X	X
		(40°/C75%RH± 5%RH)	X	X	X	X			X											
Moisture	TBD Report Value	CRT(25±2°/60%+5RH)	X	XC	XC	X			X			X			X	X	X	X	X	X
Karl Fischer		(40°/C75%RH± 5%RH)	X	X	X	X			X											
Degradation	TBD Report Value	CRT(25±2°/60%±5RH)	X	XC	XC	X			X			X			X	X	X	X	X	X
Products		(40°/C75%RH± 5%RH)	X	X	X	X			X											
Cytec Methods																				

NOTE:

- **Samples will be packed for storage using two package configurations. The secondary package configuration for greater moisture vapor transmission rate barrier will be noted as contingency 2 (C2).**
- **The primary package configuration noted as X will be tested at all indicated timepoints. Timepoints noted with XC1 are primary package contingency test samples for analysis only if the corresponding X sample fails stability.**

PRODUCTION STABILITY STUDY PLAN

STORAGE CONDITION	TIME IN MONTHS						BATCHES
	0	12	24	36	48	60	Description
25°C±2°C/60%RH±5%	X	X	X	X	X	X	Production stability as required by FDA.

Container: Double polypropylene bags in fiberpak. Desiccants may be required. Final specifications to be determined.

Stability studies will be initiated for 1 batch per campaign.

APPENDIX E

CONFIDENTIAL DISCLOSURE AGREEMENT FOR INFORMATION EXCHANGED
BETWEEN LONZA AND AN EXTERNAL SOURCE

This Agreement is made and entered into this day ____ of _____ 19__, by and between Lonza Inc., a company _____ located in Fair Lawn, New Jersey ("LONZA") and _____ a company (the "POTENTIAL-COLLABORATOR") located in_____.

A. LONZA and the "POTENTIAL-COLLABORATOR" have entered into certain discussions the purpose of which is to explore and consider the possibilities of a business relationship between, or other transaction involving, LONZA and the "POTENTIAL-COLLABORATOR".

B. In this connection with and in furtherance of this possible business relationship, it is anticipated that both of the undersigned parties (i.e. LONZA and the POTENTIAL-COLLABORATOR) at various times will disclose (the "DISCLOSING PARTY") and receive (the "RECEIVING PARTY") certain information with each other which the undersigned parties consider proprietary and confidential.

The undersigned RECEIVING PARTY in consideration for the use of certain information, knowledge, software, data and/or know-how (hereinafter called "INFORMATION") related to the possible contract manufacturing of Sodium Gamma Hydroxybutyric Acid made available to it by DISCLOSING PARTY hereby agrees as follows:

1. RECEIVING PARTY agrees to keep in confidence and not to use the INFORMATION for its commercial benefit (except for technical and economic evaluation) for a period of five (5) years from the date hereof.
2. RECEIVING PARTY further agrees that it shall keep in confidence and not disclose any part of INFORMATION to a third party for a period of five (5) years from the date hereof.
3. Obligations of RECEIVING PARTY shall not apply to any information, knowledge, software, data and/or know-how which:
   (a) is or hereafter becomes a part of the public domain other than through a breach of this Agreement by RECEIVING PARTY;
   (b) RECEIVING PARTY can demonstrate was in its possession prior to the time of disclosure by DISCLOSING PARTY or can demonstrate was received by it from a third party who shall not have received same from DISCLOSING PARTY
   (c) is required by a court or other governmental authority with competent jurisdiction to be disclosed in a non-confidential manner.
4. Each party warrants and represents that the terms of this Agreement are not inconsistent with other contractual or legal obligations it may have, or with the policies or rules of any institution or company with which it is associated.
5. Each party agrees that, without the other party's prior written consent, it will not disclose the existence of this Agreement or the fact that each party is evaluating the Information.
6. RECEIVING PARTY agrees to obligate its employees who shall have access to any portion of INFORMATION to protect the confidential and proprietary nature of INFORMATION. If either or both parties are not interested in proceeding with the establishment of a manufacturing contract, or if a commercial arrangement is not entered into, each party shall return the Information of the other party to the other party, subject to retention of one copy for archival purposes.
7. This Agreement shall be governed by and interpreted in accordance with the laws of the State of Minnesota.

Accepted and Agreed by Both Parties Lonza, Inc.	Third Party
Signature: _____	Authorized Signature: _____
Name (Print): _____	Name (Print): _____
Title: _____	Title: _____
Date: _____	Date: _____

Return Material Authorization (RMA)

For material return, Lonza operates a paperless, computer-supported system. The following procedure will be followed:

1. Orphan can request return authorization by calling Lonza at 1-800-777-1875 and requesting the “Customer Service Department”.

2. Lonza will issue material return authorization number generated by its quality performance database according to standard work practices in effect within Lonza at that time.

3. Lonza will organize transport of material through coordination with Orphan. The appropriate contact will be given by Orphan at the time of request for return of material.

4. Upon receipt of returned material, Lonza will send a confirmation of this to the designated contact at Orphan.

PROCEDURE FOR RETURNED MATERIALS

1.0 This procedure is to describe the system for accepting customer returned goods or return of material for salvaging.

2.0 Customer return calls for regulated products will be forwarded to the Quality Control Department either through direct customer contact or through communications with Shipping, Receiving, or the Manufacturing Department.

2.1 The Quality Control then reviews verbal return policy and forwards a preprinted Notice of Authorization to Return Form to the customer.

2.2 The customer will fill in the required information and forward the form to the Quality Control Department. The Quality Control Department will circulate the return goods form to Shipping & Receiving, Manufacturing, Purchasing, Accounting, and the Warehouse for information on return.

2.3 Upon receipt of the returned goods form, the material is authorized for return. The GMP Department will communicate authorization to customer approving the return.

2.4 Once the material is physically returned it shall be labeled *"Hold Pending Investigation"* by the Quality Control Department

2.5 The disposition of the returned goods will be indicated on a Returned Goods Form by the Quality Control Department.

2.6 A Returned Goods Form will be circulated for approval by the Plant Manager, Project Engineer, and Quality Control Manager, indicating disposition of material.

2.7 Salvaging or rework shall be within the GMP guidelines and meet DMF and/or NDA considerations.

Approved:

Production Manager _____ Date _____

Quality Control _____ Date _____

Plant Manager _____ Date _____

APPENDIX G

CHANGE CONTROL REQUEST

Change Control Number _____

Date of Request: _____

Name and address of person making request:

Requested by: _____
Company Name: _____
Company address: _____
_____
_____
_____
_____

Product/Process Affected: _____
Requested change: _____
_____
_____
_____
_____
_____

Reason for change:
_____
_____
_____
_____

☐ Change Request approved

☐ Change Request not approved

Approved Signatures:

_____ _____
Orphan Medical Regulatory Affairs Date

_____ _____
Orphan Medical QA Date

_____ _____
Orphan Medical Director of New Medicine Date

_____ _____
Contract Vendor Date

APPENDIX H

MAXIMUM DRUG PRICE ESTIMATES
according to Section 7.4

	Annual Requirement 100.000 kg and above	**Annual Requirements 50.000-99.999 kg**	**Annual Requirements 10,000 kq-49.999 kg**
Max. price of compound:	$ 25/kg	$ 30-40/kg	$ 45-55/kg

Assumptions:

50,000 kg minimum manufactured in a single campaign
Vessel size 1500 gallon
Cycle time 18 hours or less (including drying)
Material purchased within 30 days of release
Yield >=60%

Raw material quality to be same as that of Cytec (Supplier agrees to conduct development testing to confirm that a lower electronic grade of GBL will yield Drug meeting the specifications listed in Appendix •)

At least 2 industrial campaigns completed prior to this volume manufacture to allow optimization DEA classification 4

There is a remaining uncertainty of approx. $2/kg due to unknown waste treatment costs. If waste treatment costs do not exceed $1/kg, the $25/kg figure would apply. This will be clear after the trial production run.

This price includes:

All raw materials, processing, depreciation, overheads, profit, packaging
Scale up from intermediate size reactors for launch quantities to 1500 gallon or larger vessels
DMF (or equivalent) modifications required
Delivery to US destination
Reasonable regulatory support to Orphan
Ongoing process improvement efforts with benefit sharing with Orphan

Note:

The price ranges noted above will be reduced if improvements are made to the process to achieve above the current 60% yield.

“Within range” price variation partially depends upon reduction in waste stream treatment costs, allocation of validation work, and degree of process work completed.

Price for development batches includes use of GBL which meet current Cytec specifications for GBL.

The price ranges make the assumption that butyrolactone is:

(i) readily available at a quality sufficiently pure to meet specifications of the final product

(ii) the price of this quality does not exceed that of the electronics grade butyrolactone. Current butyrolactone electronics grade is estimated to cost $4/kg.

Amendment No. 1
to
Sodium Gamma Hydroxybutyrate
Development and Supply Agreement

Amendment No. 1, dated February 7, 2005 (this "Amendment"), between Orphan Medical, Inc., a Delaware corporation ("Orphan"), and Lonza, Inc., a New York corporation ("Supplier").

Recitals

1. Orphan and Supplier are parties to a Sodium Gamma Hydroxybutyrate Development and Supply Agreement, dated November 6, 1996 (the "Agreement").

2. Orphan and Supplier wish to extend the term of the Agreement and to amend certain provisions of the Agreement.

3. Each capitalized term used in this Amendment and not defined herein shall have the meaning ascribed to it in the Agreement.

NOW, THEREFORE, for good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, Orphan and Supplier agree as follows:

1. Acknowledgments. Orphan and Supplier acknowledge and agree that the initial Contract Year of the Agreement commenced as of August 1, 2002, and that each Contract Year consists of the twelve-month period commencing on August 1 and extending through the following July 31.

2. Amendments to the Agreement. Effective as of the date of this Amendment, the Agreement shall be amended and modified as follows:

a. Section 14.1 of the Agreement shall be amended in its entirety and shall hereafter read as follows:

14.1. Unless terminated pursuant to Article 15, the initial term of this Agreement shall commence on the Effective Date and end upon expiration of the third (3rd) Contract Year. Following the expiration of the initial term and any renewal terms, this Agreement shall be automatically extended for an additional term of three (3) Contract Years unless either party delivers a written notice of termination at least eighteen (18) months prior to the expiration of the initial or any renewal term. All references herein to the "term of the Agreement" shall be deemed to include both the initial and any renewal terms.

b. Appendix C {Required Drug Specifications} of the Agreement shall be amended in its entirety and shall be replaced by the Appendix C attached to this Amendment.

c. Section 18.2 of the Agreement is amended to replace the address for Orphan set forth in Section 18.2 with the following address:

Orphan Medical, Inc.
13911 Ridgedale Drive
Suite 250
Minnetonka, MN 55305
Attn: Vice President of Regulatory Affairs

d. Appendix H {Quality Agreement}. The Quality Agreement herein attached is incorporated within the overall Development and Supply Agreement.

3. Ratification. As modified by this Amendment, the Agreement is hereby ratified and confirmed in all respects.

IN WITNESS WHEREOF, each of Orphan and Supplier has caused this Amendment to be executed by a duly authorized representative as of the date set forth in the first paragraph.

LONZA, INC.	ORPHAN MEDICAL, INC.
/s/ Simon Edwards Feb 7, 2005	/s/ John Howell Bullion
By *(print)*: Simon Edwards	By: John Howell Bullion
Its VP Sales & Business Development	Its Chief Executive Officer

APPENDIX C

Orphan Medical, Inc.
Bulk Drug Substance Specification

Specification: BDS-XYR-0400 Rev 13
Effective Date: 02/16/05
Supersede Date: 09/10/03

Bulk Drug Substance: Sodium Oxybate Powder

RetestDate*: 56 months

Storage Conditions: 15-30°C in packaging specified as follows

Packaging Requirements:

Closure:	Electrogalvanized Steel Lock Ring Cover: 24 Gauge Varnish/Precoated
Chime Bands:	Electrogalvanized Steel Top and Bottom
Gasket:	Urethane
Supplier:	Grief Brothers or Berenfield Containers
Container:	Polyethylene Bag Semi-Transparent Plastic Film EF603GU LDPE (95%), 100323 Anti-Stat (5%) 0.004” thick, 36”wX68”L (± 1”) Stock #595131
Supplier:	Target Industries
Container:	Foil-lined Al-Fi 44 gallons Leverpak, M4400-E7K3
Supplier:	Grief Brothers, Lombard, IL
Desiccant:	Desiccant Bag (Activated Clay) 3767 Dessipak, 2 x 132 g Absorption Capacity: 16.00 wt/wt Residual Moisture : 3.00 wt/wt
Supplier:	Sud-Chemie Performance Packaging, Belen, NM

Each drum should be packaged with approximately 75 kg of Sodium Oxybate with a minimum of two desiccant bags placed between the polyethylene bags and labeled with an approved label.

APPENDIX C

Sampling:

Follow SOP-QA-0095 for sampling process. The sample is divided into a testing sample and a lOOg retain sample.

* Denotes Minimum Retest Requirements

Test	Specification	Method
***Appearance**	White to off-white powder	Lonza-1006542
***Assay - HPLC**	98.0-102.0% (anhydrous basis)	Lonza-SXB-F002
***Impurities - Total**	NMT 1.0%	Lonza-SXB-F003 (HPLC)
***Impurities - Specified**	NMT 0.05%	Lonza-SXB-F003 (HPLC)
GBL-RRT1.6 GHBB-RRT4.3	NMT 0.05%	
***Impurities - Unspecified**	md. Impurities NMT 0.05%	Lonza-SXB-F003 (HPLC)
***Water Content**	NMT 0.5% (w/w)	Lonza-1006542 USP<921>
Residual Solvents - GC	Methanol NMT 1000 ppm	Lonza-SXB-FOOl
Identification (HPLC)	0.95-1.05 RT of Reference Standard	Lonza-SXB-F002
Identification (IR)	Matches Reference Spectrum	Lonza-1006542 USP<197M>
Heavy Metals	NMT 20 ppm	Lonza-1006542, USP<231> Method E

Contractual Release Specifications:

APPENDIX C

Some specification requirements for release of the bulk drug substance will be more restrictive than those approved in the NDA to ensure drug adequacy upon analytical retesting or anticipated degradation over time. Sodium Oxybate Powder must meet BP/EP/EC/Japan standards. Orphan Medical Quality Assurance will issue a certificate of analysis as the final release for the bulk drug substance.

Approval:
Original Signatures on File

Regulatory Affairs: Lisa Ylitalo 02/16/05

Quality Assurance: Kristine Goman 02/16/05
Vendor Code: 17

APPENDIX H

QUALITY AGREEMENT
BY AND BETWEEN

ORPHAN MEDICAL, INC.
13911 Ridgedale Drive, Suite 250
Minnetonka, Minnesota 55305
(hereafter called "ORPHAN")

Approved by: **Orphan Medical, Inc.**

By: Illegible

Date: April 25, 2005

And

LONZA, INC.
900 River Road
Conshohocken, PA 19428
(hereafter called "LONZA")

Approved by: **Lonza, Inc.**

By: Illegible

Date: April

APPENDIX H

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APPENDIX H

1. QUALITY AGREEMENT

1.1 Purpose

1.1.1 This agreement (this "Agreement") defines the roles and responsibilities for the Quality Assurance and Regulatory Affairs Department ("Quality Assurance") of Lonza (LONZA) when providing services for Orphan Medical, Inc. ("ORPHAN").

1.1.2 This Agreement also defines how ORPHAN Quality Assurance and the LONZA Quality Department will interact with each other.

1.2 Relationship to Supply Agreement

1.2.1 This Agreement shall be incorporated within and constitute a part of the Supply Agreement by and between LONZA and ORPHAN.

1.2.2 In the event of a conflict between any of the provisions of this Quality Agreement and the Supply Agreement, the provisions of this Quality Agreement shall govern.

2. PRODUCT

The PRODUCT prepared for ORPHAN by LONZA are described in **Appendix I.**

3. ADMINISTRATIVE INFORMATION

3.1 ORPHAN Contact Names

See **Appendix II.**

3.2 LONZA Contact Names

See **Appendix II.**

4. TERM OF AGREEMENT

This Quality Agreement will expire with termination of the Supply Agreement (except for quality issues that may extend past the Supply Agreement; i.e. complaints). This Agreement can be modified as needed with the written approval of both parties.

5. MANUFACTURING GMP COMPLIANCE

5.1 General

The manufacturing operations for the PRODUCT to be performed by LONZA are defined in the Supply Agreement.

5.2 Premises

5.2.1 LONZA will perform required operations for manufacturing activities at approved sites.

5.2.2 The premises and equipment used to manufacture the PRODUCT will be maintained according to current regulatory requirements and in accordance with the controlled documentation approved by ORPHAN.

5.2.3 The manufacture of the PRODUCT will be conducted in a suitably controlled environment and such facilities will be regularly monitored for parameters critical to the process to demonstrate compliance with (i) applicable GMP guidelines and (ii) any conditions registered in the manufacturing authorization (NDA or investigational application).

5.2.4 LONZA will maintain controlled access to the premises. All visitors must sign in and are escorted during any visit to the areas of the premise.

5.3 GMP Guidelines

The principles detailed in the US Current Good Manufacturing Practices (21 CFR 210 and 211) that govern the standards of manufacture for active pharmaceutical ingredients, as well as the product Guidance for Industry “Q7A Good Manufacturing Practice, Guidance for Active Pharmaceutical Ingredients”, will govern (i) the standards of manufacture of the PRODUCT, (ii) the product specifications, (iii) any applicable product license, and (iv) the NDA/ANDA application, pharmacopoeia or formulatory requirements.

5.4 Materials

5.4.1 LONZA will use only chemical materials, packaging, and labeling components approved by ORPHAN and tested and approved in accordance with the documentation reviewed and approved by ORPHAN.

5.4.2 Prior to commercial use, all materials used in the PRODUCT shall meet ORPHAN'S requirements for production use.

5.5 Materials procured by LONZA

5.5.1 LONZA is responsible for auditing and qualifying vendors of actives and raw materials used in PRODUCT and will provide ORPHAN with a Certificate of Conformance statement for such vendors when requested. LONZA shall audit raw material vendors/suppliers at regular intervals according to a defined program; and the documentation of the vendors/suppliers audited and date of audit shall be available for review by ORPHAN upon request.

5.5.2 LONZA is responsible for ensuring that all materials and components procured by LONZA for use in the PRODUCT are in full compliance with the specifications listed in documentation reviewed and approved by ORPHAN. Raw Materials are given a repeat test date upon the satisfactory completion of all initial testing. Repeat testing will be performed at defined time intervals to ensure the chemical and physical stability of the raw materials unless ORPHAN provides an official expiration date.

5.5.3 LONZA is responsible for ensuring that all materials are labeled (for ID and current status) and stored properly, used correctly, appropriately tested upon receipt, and traceable to the relevant Certificate of Analysis for the materials.

5.6 Materials Provided by ORPHAN for LONZA

ORPHAN is responsible for ensuring that all materials and components provided by ORPHAN for use in the PRODUCT are in full compliance with the specifications registered, ORPHAN will provide LONZA with a Certificate of Compliance statement for the vendors that ORPHAN is responsible for qualifying.

5.7 Master Production Records

LONZA may transcribe the manufacturing information (i.e., bulk manufacturing) into its own fonnat and will obtain written approval from ORPHAN for major changes to the process before manufacturing. Additionally Lonza will provide Orphan with all changes to process documentation, analytical methods, and specifications. Agreed upon changes to documentation will be handled as outlined by Change Management (see Section 10) of this agreement.

5.8 Standard Operating Procedures

LONZA is responsible for writing and approval of any SOPs required to manufacture, test, and store the PRODUCT in accordance with applicable GMP guidelines.

5.9 Methods Validation

5.9.1 ORPHAN is responsible for providing to LONZA approved copies of the most current and complete filed analytical methods relating to the PRODUCT for receipt of API and raw materials, in-process product testing, product lot release, and drug and product stability and cleaning validation.

5.9.2 ORPHAN is responsible for providing to LONZA a Certification of Methods Validation for all critical methods practiced by LONZA (raw materials testing, in-process product testing, product lot release, and drug and product stability) . The certifications should state, *"The methods are appropriate for the intended purpose, are validated per relevant regulatory guidelines, and are readily available in case of a regulatory inspection."*

5.10 Batch Numbers

5.10.1 The convention for LONZA "Batch Identification Number" (BIN) is as follows:

- 1-4 SXB
- The first digit is the batch number sequence within a campaign.
- The second digit is year the batch was produced.
- The three letters of the BIN are the product designator (SXB: Sodium Oxybate).

5.11 Dates of Manufacture and Expiration

5.11.1 Date of Manufacture: LONZA will allocate the Date of Manufacture based on the date that drying is complete for the PRODUCT.

5.11.2 Expiration Date: LONZA will calculate the expiry date from the Date of Manufacture using the currently approved expiry period. The expiration date will be the last day of the month assigned. Changes to the expiration date will be handled by Change Management (see Section 10).

5.12 Manufacturing and Equipment Data

LONZA is responsible for keeping records of equipment usage (previous PRODUCT produced in non-dedicated equipment), cleaning, and any maintenance/calibration performed.

5.13 Storage and Shipment

5.13.1 Storage: LONZA will store the PRODUCT under conditions approved by ORPHAN. LONZA will ensure that during storage before shipping of the PRODUCT, appropriate controls are in place to insure that there is no interference, theft, product contamination, or mixture with any other product or materials. ORPHAN will provide details of any labeling requirements and storage and shipping conditions for the PRODUCT.

5.13.2 Packaging and Labeling for Transit: The PRODUCT will be labeled and packaged for transit pursuant to instructions timely provided to LONZA in writing by ORPHAN and complying with cGMP.

5.13.3 Segregation of PRODUCT: LONZA will maintain proper segregation of the PRODUCT according to systems reviewed and approved by ORPHAN. Different lots of a single product or different types of product will not be mixed on a pallet.

5.13.4 Shipment of Product to ORPHAN: Only approved, finished (unless required by ORPHAN), labeled PRODUCT will be shipped by LONZA to ORPHAN. LONZA will not ship any product that is unapproved or under quarantine without prior written approval from Orphan Medical, Inc.

6. QUALITY CONTROL

6.1 General

The testing of the PRODUCT is to be performed by LONZA as defined in the PRODUCT Specification, see Appendix I. Following LONZA's release of the PRODUCT to ORPHAN, the ORPHAN Quality Control Unit shall be responsible for approving or rejecting drug product manufactured, processed, or packed by LONZA.

6.2 In-Process and Finished Product Testing

6.2.1 A method transfer of any validated test method developed by ORPHAN will be completed prior to product release by LONZA.

6.2.2 LONZA will perform all in-process and finished product testing using approved specifications and methods of analysis. Laboratory notebook pages and representative sample chromatograms can be reviewed on LONZA's site by ORPHAN.

6.2.3 A LONZA Qualified Person/QA Representative will sign a Certificate of Conformity confirming that the lots produced in a campaign have been manufactured, packaged, tested, and meets the requirements of the Master Batch Record and Drug Product Specification. The current release documentation information can be found in Appendix III.

6.2.4 Any reference standards that are supplied by ORPHAN or its Affliates must be accompanied by a COA listing the expiration date and any correction factors that need to be applied.

6.2.5 ORPHAN may perform testing to confirm the LONZA data. ORPHAN may perform confirmatory testing during the initial term of this Agreement to validate the LONZA data. Periodically thereafter, ORPHAN may test material to confirm the LONZA data. Dispute resolutions in conflicting test data will be handled according to the provisions of Section 9.

6.2.6 ORPHAN may perform release testing at a contract laboratory. Copies of all related documentation will be provided to LONZA upon request to support final disposition by LONZA.

6.3 Retain Samples

6.3.1 LONZA will retain samples of the active ingredients for a minimum of five (5) years beyond the ingredient date manufactured. LONZA will retain samples of raw materials for a minimum of two (2) years. The amount of sample retained will be twice the quantity required to carry out all of the tests required to determine if the material meets its specifications, with the exception of sterility and pyrogen testing (CFR 211.170a).

6.4 Routine Stability Program

6.4.1 ORPHAN is responsible for maintaining a Stability Program and will request samples from Drug Product lots to be placed on stability as required.

6.5 Out-of-Specification (OOS) Investigations

LONZA is responsible for investigating any testing performed that fails to meet specifications. Each investigation will be reviewed by LONZA's Quality Assurance designee, and will follow internal procedures that are in accordance with regulatory guidelines. LONZA will inform ORPHAN of OOS results and any subsequent retest results.

6.6 Contract QC Laboratories

ORPHAN is responsible for ensuring the compliance and documented qualification of any QC lab contracted to perform testing of the Raw Materials and PRODUCT used in the manufacture of the finished PRODUCT through an appropriate laboratory audit for compliance.

7. QUALITY ASSURANCE

7.1 Deviations and Investigations

7.1.1 Deviations: Any deviation from the process during manufacture or OOS result must be carefully documented and approved by LONZA Quality Assurance and appropriate area management. ORPHAN will be informed at the time of all Pharmaceutical Process/Formulation Exception Reports (PFERs) and reserves the right to participate in the investigation. A copy of the final investigation report will be included in the Release Documentation package provided to ORPHAN.

7.1.2 LONZA will notify ORPHAN of the disposition of any rejected PRODUCT within 5 working days.

7.1.3 LONZA will notify ORPHAN immediately, in writing, if any problems are discovered that may impact PRODUCT lots previously shipped to ORPHAN.

7.1.4 Some investigations may require additional testing, stability, or validation to be conducted. This work will be performed by LONZA as agreed by both parties.

7.2 Lot Disposition

For each lot, LONZA will provide the release documentation required in **Appendix III.**

7.3 Quality Assurance Certificate of Compliance/Analysis

7.3.1 LONZA will provide a standard Certificate of Analysis indicating the test results of each test performed as well as a signed Certificate of Compliance for the campaign confirming that the PRODUCT has been manufactured, tested, and stored according to the requirements of the Master Production Record.

7.3.2 LONZA will provide complete copies to ORPHAN of the lot documentation (Executed batch record and analytical data). Shipment of the lots will require written prior authorization by ORPHAN.

7.4 Product Release

7.4.1 Shipment of the PRODUCT, once dispositioned as "Approved" by LONZA, is the absolute responsibility of ORPHAN'S quality department. ORPHAN'S approval will be undertaken by ORPHAN, based on ORPHAN'S internal procedures, the full document package provided by LONZA, and completion of any release testing required by ORPHAN Quality Control for their internal release criteria.

7.4.2 Any problem discovered by ORPHAN likely to cause rejection of the PRODUCT will be communicated to LONZA within thirty (30) days from receipt of the full release documentation package (see Appendix III).

7.5 Product Complaints and Recalls

7.5.1 Product Complaints: ORPHAN is responsible for receiving and initially investigating any PRODUCT complaints. ORPHAN will notify LONZA of any problems thought to be due to manufacture which are found during the distribution of the PRODUCT. When LONZA receives notice of manfuacturing problems from ORPHAN, LONZA will promptly perform investigations for alleged problems. Investigation reports will be forwarded to ORPHAN within thirty (30) days from the receipt of the compliant by LONZA. ORPHAN is responsible for reporting any complaint to the appropriate regulatory authority including adverse drug events reports. Any PRODUCT complaint received by LONZA will be immediately forwarded to ORPHAN.

7.5.2 Product Recall: ORPHAN, with data and assistance provided by LONZA, is responsible for filing Field Alerts and initiating PRODUCT recalls due to any defect considered sufficiently serious. ORPHAN will provide LONZA with a copy of any regulatory correspondence related to field alerts or recalls. ORPHAN will notify LONZA of any recall. LONZA will provide a rapid initial response and a full report within ten (10) working days and will provide recommendations for recall as needed.

7.6 Records Retention

7.6.1 LONZA will retain, at a minimum, lot production records for the PRODUCT and materials for seven (7) years from manufacture of lots. Validation records may need to be held for longer than seven (7) years.

7.6.2 LONZA will retain lot records for the expiry date of the Clinical Trial Materials for a minimum of three (3) years unless notified of a shorter retention period by ORPHAN, but at a minimum of one (1) year past the stop use date.

7.7 Quality Assurance Presence in the Manufacturing Facility

7.7.1 LONZA will maintain adequate Quality Assurance presence in the manufacturing facility during the manufacture of the PRODUCT to ensure compliance with GMPs.

7.7.2 LONZA will permit ORPHAN'S presence in the manufacturing facility during the manufacture of the PRODUCT if requested by ORPHAN'S quality group.

8. REGULATORY COMPLIANCE

8.1 Regulatory Inspections

8.1.1 LONZA will immediately inform ORPHAN of any regulatory inspections that may involve the PRODUCT and permit a representative from ORPHAN Quality to be present, if required by ORPHAN.

8.1.2 LONZA will secure ORPHAN'S agreement prior to making any commitment to a regulatory agency regarding ORPHAN'S PRODUCT.

8.1.3 Additionally, LONZA will immediately forward to ORPHAN any regulatory correspondence on the PRODUCT or on other system related issues that support manufacturing, packaging, or testing for ORPHAN'S PRODUCT.

8.1.4 ORPHAN will immediately inform LONZA in writing of any regulatory issue that impacts LONZA's ability to manufacture the PRODUCT.

8.2 Regulatory Actions

8.2.1 ORPHAN will notify LONZA of any regulatory actions on the PRODUCT that may impact LONZA.

8.2.2 LONZA is responsible for supporting all lot record investigations associated with regulatory actions.

8.2.3 LONZA agrees to supply ORPHAN with any manufacturing, testing, or storage data within 48 hours, if requested, as the result of a regulatory inspection, or a potential regulatory exposure such as a recall or significant product complaint.

8.3 Regulatory Affairs

8.3.1 ORPHAN is responsible for ensuring all appropriate regulatory filings and import/export documentation are filed with regulatory agencies prior to shipment/human administration.

8.3.2 LONZA Quality Assurance will act as the point of contact between ORPHAN'S regulatory affairs staff or consultant regarding issues that impact the CMC registration information for the drug substances and/or drug product.

8.3.3 LONZA Quality Assurance will perform a technical/regulatory review of all documentation provided to ORPHAN to support regulatory submission.

8.3.4 ORPHAN will be responsible for making final decisions regarding CMC regulatory strategy.

8.3.5 ORPHAN will provide a copy of final regulatory submissions to LONZA Quality Assurance for reference during inspections.

8.3.6 LONZA will provide support for ORPHAN with respect to proposing appropriate CMC regulatory strategies and identifying potential regulatory consequences for issues involving drug substance.

8.4 Right to Audit

8.4.1 LONZA will allow representatives from ORPHAN Quality to have access to their manufacturing, warehousing, laboratory premises, and records for audit purposes pursuant to this Section 8.4. ORPHAN representatives will be escorted at all times by LONZA personnel.

8.4.2 ORPHAN will provide a thirty (30) days notification for all planned audits.

8.4.3 LONZA will permit ORPHAN Quality to conduct preparatory audits either for initiation of GMP manufacture of the PRODUCT or for pre-approval inspections (PAI).

8.4.4 LONZA will permit ORPHAN Quality to conduct audits to address significant product quality or safety problems.

8.4.5 LONZA will permit ORPHAN Quality to perform one standard GMP compliance audit per year not to exceed three working days and two groups of two auditors each. This includes audits required by ORPHAN'S commercial partners.

8.5 Audit Closeout

8.5.1 An exit meeting will be held with representatives from LONZA and ORPHAN to discuss significant audit observations.

8.5.2 ORPHAN will provide a written report of all observations within thirty (30) days to LONZA. Within thirty (30) days of the audit report receipt, LONZA will provide a written response to all findings that details corrective action to be implemented. LONZA will follow up to ensure that all corrective actions are implemented.

9. DISPUTE RESOLUTION

9.1 Non-Conformity Dispute

In the event that a dispute arises between LONZA and ORPHAN in the nonconformity of a lot of the PRODUCT, the supervisors of the Quality departments from both companies shall in good faith promptly attempt to reach an agreement. ORPHAN may only dispute a lot of PRODUCT which has been dispositioned and released by LONZA. Whatever the outcome, ORPHAN Quality retains the absolute right to determine product release status. Financial liability shall be determined according to the Supply Agreement.

9.2 Other Disputes

Other disputes shall be resolved in accordance with the Supply Agreement.

10. CHANGE MANAGEMENT

10.1 Technical & cGMP Impact Assessment

10.1.1 All changes shall proceed through a technical and cGMP impact assessment by the LONZA expert groups coordinated by LONZA's Quality Assurance change management personnel. The documents that contain ORPHAN'S intellectual property or changes that may affect (i) ORPHAN'S regulatory submissions or (ii) the support system that has a direct impact on the quality systems that will affect ORPHAN'S product, will also go through ORPHAN'S assessment for regulatory advice and implementation requirements, as per the agreements between ORPHAN and LONZA.

10.1.2 Any changes to documentation will be coordinated with ORPHAN by the responsible project scientist or project leader.

10.1.3 The scope of such a Change Management process includes Chemical Manufacturing, Pharmaceutical Manufacturing and Packaging processes. The associated changes may relate to: the Master Production Control Records (e.g. Master Formulas, Filling Work Orders, Packaging Work Orders); Bills of Materials; Analytical Standards and Test Methods (for Raw Materials and Finished Product); Stability Protocols; Purchase Specifications (for Raw Materials and Packaging Components); and ORPHAN specific Validated Equipment, Facilities, Utilities or Computer Systems.

10.1.3.1 All manufacturing, testing, and storage operations performed by LONZA for the PRODUCT will have ORPHAN Quality review and written approval within five business days of notification. ORPHAN'S Quality review and approval signifies the conformance of LONZA documents to ORPHAN'S CMC regulatory submissions.

10.1.3.2 Any significant changes will be mutually agreed upon in writing prior to implementation. All required regulatory approvals will be obtained prior to implementation.

10.1.3.3 Changes to the controlled documents or to validated equipment and systems specific to the PRODUCT must have ORPHAN Quality written approval, prior to implementation.

10.1.3.4 Administration changes to the controlled documents (e.g., typo corrections, formatting) do not require ORPHAN Quality written approval prior to implementation, but these changes must be submitted to ORPHAN Quality in a timely manner for review and approval.

11. PRODUCT AND PROCESS VALIDATION

11.1 Process Validation

LONZA is responsible for ensuring that the manufacturing process is validated. The validation should ensure that the process is capable of consistently achieving the PRODUCT acceptance specification.

11.2 Cleaning Verification/Validation

LONZA is responsible for ensuring that adequate cleaning is carried out between lots of different product to prevent contamination. Data should be available to support the campaign of lots of the same product and the type of cleaning that will be performed in between manufacturing of the same product. ORPHAN will provide information (i.e. LD50, toxicity, solubility, lot size, fill volume, product min dose/70Kg patient) to establish cleaning limits. The cleaning procedure and analytical methodology will be reviewed before the first product lots are made.

11.3 Equipment, Computer, Facility, and Utilities Qualification

LONZA is responsible for all equipment, computer, facility, and utility qualification activities associated with the PRODUCT.

11.4 Laboratory Qualification

LONZA is responsible for ensuring that all laboratories are in compliance with applicable cGMP’s guidelines. If analytical work is performed at LONZA then ORPHAN will also provide any existing analytical documentation to assist in methods transfer or methods validation. In addition, if analytical work is not performed at the Conshohocken, Pennsylvania site, LONZA may elect to perform an audit on vendors to be used for analytical testing. LONZA will be responsible for insuring that the vendor is practicing within cGMP compliance.

12. ANNUAL PRODUCT REVIEW, ANNUAL REPORT AND DRUG LISTING

12.1 Annual Product Review

12.1.1 LONZA will perform an Annual Product Review for the PRODUCT and will issue a report to ORPHAN. This report will cover all manufacturing, testing, and storage activities performed by LONZA. It will be a review of any changes at LONZA in the manufacturing, testing, storage or validation of the PRODUCT in the previous calendar year and a summary of lots made, released, and rejected. Also, control charting or trend analysis of key product parameters will be performed. Any abnormalities will be explained in the annual review.

12.1.2 ORPHAN is responsible for preparing any Annual Report as required by applicable regulations, including 21 CFR 314.70, 314.81, and/or 601.12. At least ninety (90) calendar days before the Annual Report due date, ORPHAN shall request in writing from LONZA the chemistry, manufacturing, and controls data required for submission of the Annual Report. LONZA will provide the requested information to ORPHAN within thirty (30) days.

12.2 Drug Listing

12.2.1 LONZA is responsible for drug listing as the manufacturer of the PRODUCT for ORPHAN, while ORPHAN is responsible for drug listing as the distributor of the PRODUCT. ORPHAN will provide LONZA with all required information needed to register the PRODUCT. ORPHAN will notify LONZA of the scheduled PRODUCT launch.

{Appendices are attached}

APPENDIX I: PRODUCT - SODIUM OXYBATE Specification

Bulk Drug Substance: Sodium Oxybate Powder

Retest Date*: 56 months

Storage Conditions: 15-30°C in packaging specified as follows

Packaging Requirements:

Closure: Electrogalvanized Steel Lock Ring
Cover: 24 Gauge Varnish/Precoated
Chime Bands: Electrogalvanized Steel Top and Bottom
Gasket: Urethane

Supplier: Grief Brothers or Berenfield Containers

Container: Polyethylene Bag
Semi-Transparent Plastic Film EF603GU
LDPE (95%), 100323 Anti-Stat (5%)
0.004" thick, 36"wX68"L (± 1") Stock #595131

Supplier: Target Industries

Container: Foil-lined Al-FiDrum
44 gallons Leverpak, M4400-E7K3

Supplier: Grief Brothers, Lombard, IL Berenfield Containers, Inc.
Easton, Pa. 18045

Desiccant: Desiccant Bag (Activated Clay)3767 Dessipak, 2 x 132 g
Absorption Capacity: 16.00 wt/wt
Residual Moisture : 3.00 wt/wt

Supplier: Sud-Chemie Performance Packaging, Belen, NM

Each drum should be packaged with approximately 75 kg of Sodium Oxybate with a minimum of two desiccant bags placed between the polyethylene bags and labeled with an approved label.

APPENDIX H

Sampling:

Follow SOP (QA-095) for sampling process. The sample is divided into a testing sample and a lOOg retain sample.

* Denotes Minimum Retest Requirements

Test	Specification	Method
***Appearance**	White to off white powder	Lonza-1006542
***Assay - HPLC**	98.0-102.0%(anhydrousbasis)	Lonza-SXB-F002
***Impurities - Total**	NMT1.0%	Lonza-SXB-F003 (HPLC)
***Impurities - Specified**	NMTO.05%	Lonza-SXB-F003 (HPLC)
GBL-RRT1.6 GHBB-RRT4.3	NMT 0.05%	
***Impurities - Unspecified**	Ind. Impurities NMT 0.05%	Lonza-SXB-F003 (HPLC)
***Water Content**	NMT 0.5% (w/w)	Lonza-1006542 USP<921>
Residual Solvents - GC	Methanol NMT 1000 ppm	Lonza-SXB-FOOl
Identification (HPLC)	0.95 - 1.05 RT of Reference Standard	Lonza-SXB-F002
Identification (IR)	Matches Reference Spectrum	Lonza-1006542 USP<197M>
Heavy Metals	NMT 20 ppm	Lonza-1006542, USP<231> Method II

APPENDIX H

Contractual Release Specifications:

Some specification requirements for release of the bulk drug substance will be more restrictive than those approved in the NDA to ensure drug adequacy upon analytical retesting or anticipated degradation over time. Sodium Oxybate Powder must meet BP/EP/EC/Japan standards. Orphan Medical Quality Assurance will issue a certificate of analysis as the final release for the bulk drug substance.

APPENDIX II: LIST OF QUALITY CONTACTS

ISSUE	ORPHAN	LONZA
Product Release	Kristine Goman Associate Manager Quality Assuance (952)513-6978 kgoman@orphan.com	Thomas M. Harvey QA Documentation Supervisor (610)-292-4395
QC Testing	Kristine Goman Associate Manager Quality Assuance (952)513-6978 kgoman@orphan. com	Qun Jiang Senior Analytical Chemist (610)-292-4435
Investigations	Kristine Goman Associate Manager Quality Assuance (952)513-6978 kgoman@orphan.com	Thomas M. Harvey QA Documentation Supervisor (610)-292-4395
Regulatory Affairs	Dayton Reardan Ph.D V.P.Regulatory Affairs (952)513-6969 dreardan@orphan.com	Susan Mijares QA/QC Manager (610)-292-4306
Validation	Kristine Goman Associate Manager Quality Assuance (952)513-6978 kgoman@orphan.com	*Garrett Burch Product Manager (610)-292-4313
Compliance Audits	Kristine Goman Associate Manager Quality Assuance (952)513-6978 kgoman@orphan.com	Thomas M. Harvey QA Documentation Supervisor (610)-292-4395
Product Complaints	Kristine Goman Associate Manager Quality Assuance (952)513-6978 kgoman@orphan.com	Thomas M. Harvey QA Documentation Supervisor (610)-292-4395
Change Management	Christy Frantzeskakis QA Documentation Specialist (952)513-6976 Cfrantzeskakis@orphan.com	Thomas M. Harvey QA Documentation Supervisor (610)-292-4395

Note: *Garrett Burch, as the Product Manager for SXB is the backup for all contacts.

APPENDIX III: RELEASE DOCUMENTATION

The lot release document package will include copies of the batch record prior to release, analytical test data, a-Certificate of Analysis (“CO A”) and a campaign Certificate of Compliance (“COC”) and any deviations (manufacturing or laboratory).

Certificate of Analysis: A COA which is automatically generated by LONZA Quality Assurance will be provided and will include the name of the PRODUCT, lot number, date of manufacture, retest date, and analytical specifications. The COA will list the release tests performed by LONZA laboratories and actual test results.

Certificate of Compliance: The COC will attest to the fact that the PRODUCT lots produced during a campaign was performed in accordance with all applicable regulations, licenses, and company policies.

ORPHAN MEDICAL, INC.

AND CATALYTICA PHARMACEUTICALS, INC.

XYREM

SUPPLY AGREEMENT

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XYREM SUPPLY AGREEMENT

THIS AGREEMENT ("Agreement") is made as of this 30th day of June, 2000 by and between ORPHAN MEDICAL, INC., a Minnesota corporation, having its principal offices at 13911 Ridgedale Drive, Minnetonka, Minnesota 55305 ("ORPHAN") and Catalytica Pharmaceuticals, Inc., a Delaware corporation, having its principal offices at Intersection US 13/NC11 and US 264, Greenville, North Carolina 27834 ("Catalytica").

RECITALS

1. Catalytica manufactures pharmaceuticals meeting regulatory and governmental requirements for commercial use.

2. ORPHAN develops and markets ethical pharmaceuticals targeted to specified populations of patients.

3. ORPHAN and Catalytica desire to cooperate in the transfer of the manufacture of an oral pharmaceutical product, Xyrem® (sodium oxybate) Oral Solution, containing the active ingredient sodium gamma hydroxybutyrate.

4. In anticipation of the above-referenced transfer, ORPHAN and Catalytica entered into a Technical Services Agreement, dated November 20, 1999, pursuant to which Catalytica would undertake certain technical services in order to prepare its facilities for performance of this Agreement.

5. Catalytica desires to manufacture the Product exclusively for sale to ORPHAN.

6. Upon obtaining approval to market the Product, ORPHAN wishes to purchase all of its requirements for the Product in the United States from Catalytica and Catalytica wishes to supply ORPHAN all of its requirements for the Product in the United States.

7. Catalytica understands that Public Law 106-172 has designated that Product

will be scheduled by the Drug Enforcement Administration (DEA) upon approval by the FDA, as Schedule III, and that ARCOS reporting will be required. ORPHAN and Catalytica agree that the Product Price estimate is based on Schedule III security requirements. Catalytica shall have no obligation to supply the Product pursuant to this Agreement if Schedule I security requirements are required. Orphan reserves the right to review Catalytica's SOPs regarding handling of Controlled Substances and company policies related to employees who handle controlled substances.

NOW, THEREFORE, in consideration of the mutual covenants hereinafter set forth and other good and valuable consideration, the receipt of which is hereby acknowledged, the parties agree as follows:

ARTICLE 1 DEFINITIONS

The following terms, when capitalized, shall have the following meanings in this Agreement, whether used in the singular or the plural.

1.1 "Acquisition Cost" in respect of a particular item means the actual invoiced price paid by either party to a Third Party for acquiring such item, including without limitation, shipping and handling costs, insurance and customs duties.

1.2 "Active Ingredient" means sodium gamma hydroxybutyrate in bulk form.

1.3 "Affiliate" means any corporation or non-corporate business entity which directly or indirectly controls, is controlled by, or is under common control with a party to this Agreement. A corporation or non-corporate business entity shall be regarded as in control of another corporation if it owns or directly or indirectly controls at least fifty (50%) of the voting stock of another corporation, or (a) in the absence of the ownership of at least fifty (50%) of the voting stock of a corporation, or (b) in the case of a non-corporate business entity, if it possesses, directly or indirectly, whether by virtue of an ownership interest of any kind, by contract or otherwise, the power to direct or cause the direction of

the management and policies of the corporation or non-corporate business entity or to elect or cause the election of a majority of the board of directors or other governing body of such corporation or non-corporate business entity.

1.4 “Contract Year” means the twelve (12) month period beginning on the first day of the month in which ORPHAN makes the first commercial sale, following NDA approval, of the Product or a product containing the Active Ingredient in a country of the Territory, and each successive twelve (12) month period thereafter.

1.6 “Services” means the Services as defined and further described in the Technical Services Agreement which is attached hereto as Appendix A and made a part hereof, as well as any additional process or analytical development activities or process or analytical development modifications for the Product to be mutually agreed upon in good faith by the parties after the Effective Date and subsequently attached hereto. Such modifications will include timing and cost factors.

1.7 “DMF” means a Type II Product Master File intended for filing with the FDA.

1.8 “Dollars” or “$” means United States Dollars.

1.9 “Product Price” means the price to ORPHAN, in Dollars per unit (for purposes of this Agreement, a “unit” is a 200 mL bottle), for manufacture of the Product as such price may be amended from time to time during the term of, and pursuant to, this Agreement.

1.10 “Product” means Xyrem, an oral liquid pharmaceutical product containing the Active Ingredient packaged in 200 mL bottles or such other package sizes as may be mutually agreed by the parties from time to time.

1.11 “Effective Date” means the date appearing at the beginning of this Agreement.

1.12 “FDA” means the US Food and Drug Administration or any successor entity.

1.13 “FD&C Act” means the US Federal Food, Drug and Cosmetic Act, together with all regulations issued thereunder, as the same may be amended from time to time.

1.14 “cGMPs” means the current Good Manufacturing Practices regulations promulgated by the FDA, and any applicable amendments thereto in effect at the time of the Product’s manufacture.

1.15 “Manufacturing Price” means Catalytica’s costs of labor (including allocable employee benefits and employment taxes), material (including without limitation raw materials, solvents, packaging, waste disposal and labeling, energy, utilities and other charges directly incurred in the manufacture of the Product), plus normal production overhead (i.e. indirect labor, utilities, maintenance and depreciation of the manufacturing equipment and facilities and other allocable overhead of the manufacturing facility), all determined in accordance with generally accepted accounting principles applied on a consistent basis .

1.16 “NDA” means a New Drug Application filed with the FDA or any equivalent successor application or entity relating to the formulation of the Product.

1.17 “Notification” shall have the meaning prescribed in Section 19.2 hereof.

1.18 “Production Batch” means a production size batch of the Product with a specified number of units, the size and range of which is to be established and mutually agreed upon by the parties. Each Production Batch is to have uniform character and quality within specified limits produced according to a single manufacturing order during the same cycle of manufacture.

1.19 “Proprietary Information” means all information or data relating to the subject matter hereof first communicated by or on behalf of one party (the “Disclosing Party”) to the other (the “Receiving Party”), whether in writing, orally, or otherwise,

including without limitation, all scientific, clinical, commercial, financial and business information and data, know-how, compilations, formulae, processes, plans, technical information, new product information, compounds, formulations, methods of product delivery, test procedures, product samples, specifications and other information or data. Information shall not be deemed Proprietary Information which: (a) at the time of disclosure, is already in the public domain or thereafter becomes part of the public domain by publication or otherwise through no fault or act of the Receiving Party; (b) was demonstrably in the possession of the Receiving Party prior to the time of the disclosure to it and was not acquired, directly or indirectly, from the Disclosing Party; (c) is independently disclosed to the Receiving Party by a Third Party who has not violated any confidential obligation owed to the Disclosing Party or any Third Party; (d) was independently developed by the Receiving Party without any use of or reliance on any Proprietary Information of the Disclosing Party as shown by competent evidence; (e) is required to be disclosed by legal process; provided that, in each case the party so disclosing information timely informs the other and uses its best efforts to limit the disclosure and maintain confidentiality to the extent possible and permits the other party to attempt by appropriate legal means to limit such disclosure; or (f) is information which is required to be included in patent applications filed hereunder or required to be provided to the FDA or any other regulatory authority in the Territory in order for ORPHAN to obtain registrations for the Product or otherwise to comply with applicable regulatory requirements, or for Catalytica to manufacture the Product for ORPHAN hereunder; provided, however, that no Proprietary Information of ORPHAN or Catalytica will be disclosed in any such patent application without the prior written consent of the other Disclosing Party, which consent will not be unreasonably withheld. Written Proprietary Information shall be identified by the Disclosing Party as being confidential by stamping the cover pages of such information “Confidential.” Proprietary Information disclosed orally, visually and/or in another tangible form shall be identified by the Disclosing Party to the Receiving Party as confidential at the time of such disclosure and confirmed to the Receiving Party within thirty (30) days after such disclosure in a writing marked “Confidential.”

1.20 “Specifications” means the final specifications for the Product attached

hereto as Appendix B and made a part hereof, including the final NDA specifications as approved by the FDA, packaging specifications, as well as any revised and/or additional specifications for the Product to be developed and mutually agreed to by the parties after the Effective Date and subsequently attached hereto as a replacement for or as an addition to Appendix B.

1.21 “Territory” means worldwide. Catalytica will be granted manufacturing exclusivity for US.

1.22 “Third Party” means any entity other than Catalytica or ORPHAN or their respective Affiliates.

1.23 “Quality Agreement” shall mean the Quality Agreement, as further defined in Section 8.5, which shall be substantially in the form of Exhibit F hereto.

1.24 “CMC” means Chemistry Manufacturing and Control.

1.25 “Orphan Product Exclusivity” shall refer to any period of exclusivity (including but not limited to manufacturing, marketing and advertising exclusivity) provided by the FDA. As of the date of this Agreement, ORPHAN has applied for an “ORPHAN drug” designation from the FDA, which, if approved, will entitle ORPHAN to a period of seven (7) years exclusivity on the Product, calculated from the date of Product approval.

1.26 “Lonza” refers to LONZA Group.

ARTICLE 2 VALIDATION ACTIVITIES

2.1 Catalytica’s Validation Responsibilities. Catalytica shall be responsible for regulatory required validations of its manufacture of the Product and its facilities and shall take all reasonable steps to pass inspections by the FDA and DEA or other regulatory agencies in the Territory. In the event non-U.S. Territory regulatory agencies require process development testing beyond that required in the U.S., Catalytica agrees to provide the additional process development testing per mutually approved protocols at terms to be negotiated in good faith by the parties.

ARTICLE 3 EXCLUSIVITY

3.1 ORPHAN, as between Catalytica and ORPHAN, shall have the exclusive right, directly or through any Affiliate, to apply for registrations and to market, distribute and sell the Product or any product containing the Active Ingredient in the Territory, if ORPHAN determines in its business judgment to do so. Catalytica shall not market, distribute, make or sell the Product or any product containing the Active Ingredient, directly or indirectly anywhere in the Territory, except to ORPHAN, during the term of this Agreement, or within the period of Orphan Product Exclusivity, whichever is longer.

ARTICLE 4 SUPPLY OF PRODUCT

4.1 Information Provided by ORPHAN. Prior to commencement of manufacturing operations hereunder, ORPHAN shall provide Catalytica with a Material Safety Data Sheet ("MSDS"), toxicity information for the Product, any other information reasonably available to ORPHAN which relates to the safe conduct of the manufacturing and/or packaging operations to be conducted by Catalytica, and any other documents necessary for Catalytica to manufacture the Product. When and as such information becomes available, ORPHAN shall promptly update such information pertinent to the manufacture and/or packaging of the Product.

4.2 Manufacture and Supply.

During each Contract Year of this Agreement, and subject to the provisions of Section 7.2 hereof as well as other provisions herein, ORPHAN agrees to purchase all of its requirements for the Product in the United States from Catalytica, but no less than the minimum quantities of Product indicated below:

Contract Year	Orphan's Minimum Purchase of Units
Year 1	0 bottles (200 mL)
Year 2	90,000 bottles (200 mL)
Year 3	90,000 bottles (200 mL)
Year 4	90,000 bottles (200 mL)
Year 5	90,000 bottles (200 mL)
Year 6	90,000 bottles (200 mL)
Year 7	90,000 bottles (200 mL)

Catalytica shall be the exclusive supplier of Product in the United States to ORPHAN. Subject to Section 6.1, Catalytica shall provide or purchase all materials and supplies necessary to manufacture the Product. Catalytica shall manufacture the Product in accordance with the Specifications and applicable cGMPs and shall package, label and/or otherwise prepare the Product for bulk delivery to an ORPHAN-designated distribution site.

4.3 Packaging. Catalytica shall furnish the packaging supplies and labels for the Products, which shall meet the Specifications, as specified in Appendix D and as required by ORPHAN at a mutually agreed to price. All such packaging and labels shall conform to applicable requirements and regulations of FDA or other regulatory authorities in the Territory.

4.4 Artwork. At least ninety (90) days prior to (a) the date for which delivery of Product is stated in the first purchase order or (b) any modification to the artwork for the Product, as applicable, and from time to time thereafter with respect to the Product, as needed, ORPHAN shall provide at no cost to Catalytica, in a format acceptable to Catalytica and in a timely manner, digital artwork for all packaging components to be used in the manufacture of the Product, which artwork shall meet the Specifications. In addition, Catalytica may develop such artwork at a mutually agreed cost.

4.5 Conditions Requiring Backup Manufacture. Catalytica agrees to support the successful transfer of manufacturing technology to a second Product manufacturer chosen by ORPHAN to make, have made, use and sell the Product if Catalytica breaches this Agreement and fails to cure as provided in Section 16.1 (a).

ARTICLE 5 FORECASTS, ORDERS AND DELIVERIES

5.1 Forecasts. ORPHAN shall provide Catalytica with forecasts of ORPHAN'S

anticipated quarterly requirements of the Product for distribution and sale in the United States commencing with the twelve (12) month period that begins at the time of FDA approval of the Product. Such forecast will be provided six (6) months in advance of anticipated FDA approval of the NDA and ORPHAN shall update such 12-month forecast on a quarterly basis thereafter. Once FDA approval of the Product is received, ORPHAN will provide Catalytica, prior to the beginning of each calendar quarter, with forecasts of its anticipated requirements of the Product for the following four (4) calendar quarters and the forecast for the first calendar quarter shall be firm and binding on ORPHAN. Catalytica will provide an annual anticipated schedule for manufacture and will consult with ORPHAN on schedule changes.

(a) Catalytica shall not be required, but will make best efforts, subject to its obligation to other customers, to manufacture during any calendar quarter up to one hundred twenty-five percent (125%) of the quantity of the Product ORPHAN forecasted it would purchase from Catalytica during such quarter in its most recent forecast covering such quarter. Catalytica will promptly communicate with ORPHAN as to its ability to produce quantities requested.

(b) When and as ORPHAN proposes to commence its distribution and sale of the Product outside the United States, ORPHAN shall supplement its 12-month forecast accordingly to indicate the additional requirements of the Product for such purposes.

(c) If Catalytica manufactures the Product with a lead time of more than ninety (90) days, ORPHAN shall not be required to pay any additional storage, or pay for the Product sooner than as set forth in Section 7.7 nor shall any advance manufacture lead to a violation of the warranty of expiration date set forth in Section 8.1.

5.2 Orders. ORPHAN shall order the manufacturing of the Product by Catalytica pursuant to written purchase orders, including delivery dates, with not less than

ninety (90) days “lead time” prior to the requested delivery dates specified therein. Each purchase order for the Product shall be in Production Batch sizes or whole multiples thereof and shall be for not less than three (3) batches totaling not less than 45,000 units. The terms contained in this Agreement shall govern over all purchase orders or sales orders of the Product hereunder and shall not be varied by the terms of any ORPHAN purchase order or Catalytica sales order or invoice. If ORPHAN requires manufacture of the Product with less than ninety (90) days lead time, Catalytica shall use reasonable efforts , but shall not otherwise be obligated, to accommodate ORPHAN’S requirements. Catalytica shall not manufacture the Product except upon receipt of an ORPHAN purchase order to ensure a supply of the Product with the maximum expiration dating.

5.3 Late Manufacture and Delivery. When ORPHAN submits a purchase order at least ninety (90) days prior to the required delivery date, or 105 days in the event the Product is to be shipped, used or sold outside the United States, Catalytica shall confirm receipt of this order. In the event of unexpected delays owing to manufacturing problems associated with the Product, Catalytica will inform ORPHAN promptly and action to be taken will be jointly decided.

5.4 Delivery Terms. The terms of delivery for (a) any Active Ingredients delivered by or on behalf of ORPHAN to Catalytica hereunder and (b) the Product shall be F.O.B. Catalytica’s Greenville, North Carolina plant, freight collect with regard to the Product. At its written request, ORPHAN may delay delivery of Product for up to thirty (30) days from the issue date of COC/COA. Catalytica shall select the carrier and arrange for shipment. Subject to any security interest reserved and granted pursuant to this Agreement, title and risk of loss and/or damage to the Product shall pass to ORPHAN upon delivery of the Product to the carrier at Catalytica’s Greenville, North Carolina plant.

5.5 Purchase Quantities. Each purchase order shall specify the quantity of units of Product being ordered. Quantities actually shipped pursuant to a given purchase order may vary from the quantities reflected in such purchase order by up to five percent (5%) and still be deemed to be in compliance with such purchase order; provided, however, ORPHAN shall only be invoiced and required to pay for the quantities of Product which Catalytica actually ships to ORPHAN.

5.6 Certifications. For each Production Batch of the Product manufactured for ORPHAN hereunder, Catalytica shall furnish the following to ORPHAN at the time of delivery. Originals are to be retained by Catalytica:

(a) representative samples of such batch for assay and other testing;

(b) batch records and quality assurance data for such batch; and

(c) a certificate of analysis that such batch conforms to the Specifications and a certificate of compliance which confirms that the Product was manufactured, tested, and delivered in full compliance with all applicable laws and regulations.

In addition, ORPHAN shall ensure that Lonza furnishes to Catalytica with each shipment of Active Ingredients hereunder a certificate of analysis for each Active Ingredient reflecting that each Active Ingredient meets the Specifications.

ARTICLE 6. ACTIVE INGREDIENTS

6.1 Active Ingredients Supply. On ORPHAN'S behalf, Catalytica shall submit purchase orders to Lonza for the Active Ingredients for the Product. ORPHAN shall be solely responsible for delivery of Active Ingredients to Catalytica and shall be solely responsible to Lonza for payment for the Active Ingredients delivered to Catalytica. Within thirty (30) days after submitting each purchase order for Product, ORPHAN shall ensure that Lonza provides to Catalytica sufficient quantities of Active Ingredients necessary for Catalytica to manufacture Product thereunder , as well as the certificates of analysis as set forth in Section 5.6 hereof. In the event ORPHAN is unable to provide such Active Ingredients within any such thirty (30) day period, the ninety (90) days' (105 days' if the Product is to be shipped, used or sold outside the United States) "lead time" period for the manufacture of Product under the affected purchase order shall be extended for a period of two (2) days for each day of delay in the supply of Active Ingredients by ORPHAN. Upon request by Catalytica, ORPHAN shall promptly send Catalytica all reference standards relating to the Active Ingredients developed by or for ORPHAN. ORPHAN shall ensure that all imported Active Ingredients or other materials supplied to Catalytica by or on behalf of ORPHAN comply with all applicable

laws and regulations relating to the import of such Active Ingredients and materials and receive all required governmental and regulatory approvals, including without limitation customs and FDA approvals.

6.2 Supply by Catalytica. At ORPHAN'S request and upon ninety (90) days prior written notice, Catalytica shall supply the Active Ingredients for the Product and in that event, notwithstanding Section 7.1 hereof, the Product Price will be increased to reflect Catalytica's Acquisition Costs of the Active Ingredients.

6.3 Manufacturing Loss. Catalytica shall use all reasonable care to prevent manufacturing waste of the Active Ingredients supplied by ORPHAN for the manufacture of the Product and shall be accountable to ORPHAN for Catalytica's use of such Active Ingredients. Accordingly, Catalytica shall grant credits or pay to ORPHAN its Acquisition Costs of Active Ingredients lost by Catalytica, due to Catalytica's negligence or willful misconduct, in excess of normal manufacturing loss. For purposes of this Agreement, the normal manufacturing loss for any given Production Batch shall be mutually established by Catalytica and ORPHAN following Catalytica's manufacture of twelve (12) Production Batches, not to exceed 5%. Catalytica shall dispose of manufacturing waste consistent with its handling of other waste and in compliance with DEA requirements

6.4 Title to Active Ingredients Supplied by ORPHAN. ORPHAN shall retain title to all Active Ingredients supplied to Catalytica.

ARTICLE 7 PRICES AND PAYMENTS

7.1 First Contract Year Manufacturing Price. After completion of the Services as identified in the Technical Services Agreement attached as Appendix A, Catalytica will notify ORPHAN of the Product Price that ORPHAN shall pay to Catalytica for any orders of the Product manufactured during the first Contract Year. Subject to Section 6.2 hereof, the Product Price for the first Contract Year shall be no higher than the Product Price estimate set forth in Appendix D for the volume range which is appropriate unless

assumptions listed in Appendix D are no longer valid. The Product Price for the first Contract Year will be lower than the maximum Product Price estimate contained in Appendix D to the extent that there are improvements in the Manufacturing Price thereof from the assumptions for Manufacturing Prices set forth in Appendix D.

7.2 Minimum Purchase Requirements. In the event ORPHAN does not meet the minimum purchase requirements set forth in Section 4.2 hereof with respect to any Contract Year, ORPHAN shall within thirty (30) days after the end of such Contract Year pay Catalytica the Product Price less any packaging material costs applicable at the end of such Contract Year for the quantity of Product not purchased that would satisfy the applicable minimum purchase requirement.

7.3 Annual Price Adjustment Notification. At least sixty (60) days prior to the end of the first Contract Year of this Agreement and each Contract Year thereafter, Catalytica shall notify ORPHAN of the Product Price for the next succeeding Contract Year provided, however, that the Product Price for each new Contract Year shall be equal to the then current price increased by a percentage amount equal to the percentage increase in the Producer Price Index for Finished Goods, Pharmaceutical Preparations, Ethical (Prescription), series code PCU-2834 #1, issued by the Bureau of Labor Statistics, U.S. Department of Labor, or comparable successor index, during the twelve (12) month period ending with the most recent month for which published monthly statistics are available as of the first day of such new price year ("PPI"). Increases in the Product Price pursuant to this Section 7.3 shall become effective as of the anniversary date of the Effective Date.

7.4 Specification Changes.

(a) Specification Changes. In the event that ORPHAN wishes to change the Specifications, or in the event that ORPHAN is required to change the Specifications pursuant to applicable law or regulation or in response to the order or request of a governmental authority or regulatory body, the following provisions will apply.

(1) ORPHAN shall promptly advise Catalytica in writing of any such change(s)

to the Specifications, and Catalytica shall promptly advise ORPHAN as to any scheduling and/or Product Price adjustments which may result from any such change(s), if any. The notification and approval procedure shall be in accordance with APPENDIX F, as well as any additional standard operating procedures (*i.e.*, change control procedures) agreed upon by ORPHAN and Catalytica in writing from time to time.

(2) Prior to implementation of such change(s) to the Specifications, ORPHAN and Catalytica shall negotiate in good faith in an attempt to reach agreement on (i) the new Product Price, if any, for any Drug Product and/or Finished Product provided hereunder by Catalytica which embodies such change(s) to the Specifications, giving due consideration to the effect of such change(s) on Catalytica's manufacturing costs for Drug Product and/or Finished Product and (ii) any other amendments to this Agreement which may be necessitated by such changes (*e.g.*, an adjustment to the lead time for Firm Orders). Implementation of such change(s) to the Specifications shall be as set forth in APPENDIX F.

(3) ORPHAN will reimburse Catalytica for the reasonable and necessary expenses incurred by Catalytica as a result of any such change(s) to the Specifications , including, but not limited to, reimbursing Catalytica for its validation and development costs and capital expenditure costs.

(4) If any such change(s) to the Specifications renders obsolete or unusable any materials or components for Drug Product or Finished Product, and to the extent such materials or components may not be returned to the appropriate vendor for a credit , ORPHAN shall purchase from Catalytica, at Catalytica's Acquisition Cost, that amount of inventory of materials or components, as the case may be, so rendered obsolete or unusable, not to exceed the amount of such materials or components which would have

been required for Catalytica to manufacture and supply the total quantity of Drug Product and/or Finished Product specified in Firm Orders currently pending and not yet filled hereunder.

7.5 Taxes. The Product Price does not include sales, use, consumption, or excise taxes of any taxing authority. The amount of such taxes, if any, will be added to the Product Price in effect at the time of shipment thereof and shall be reflected in the invoices submitted to ORPHAN by Catalytica pursuant to this Agreement. ORPHAN shall pay the amount of such taxes to Catalytica in accordance with the payment provisions of this Agreement.

7.6 Additional Payments. As additional consideration for Catalytica's performance of its obligations hereunder, ORPHAN shall pay Catalytica the amounts set forth below (with all payments being due within thirty (30) days of receipt of the relevant Catalytica invoice, unless otherwise provided below):

(a) ORPHAN shall pay Catalytica, at Catalytica's standard hourly rates, for regulatory consulting services performed in connection with this Agreement. These services are to be approved in advance by Orphan.

(b) ORPHAN shall reimburse Catalytica for all reasonable and necessary travel and lodging expenses incurred in the performance of this Agreement which have been requested or approved by ORPHAN.

7.7 Cost Reductions Through Process Improvements. To encourage active and open consideration of Manufacturing Price reductions, it is agreed that any cost reduction benefit will be shared based on Catalytica's and ORPHAN'S relative contributions to funding the cost reduction benefit. Proposals for improvements will be outlined in writing or communicated verbally and will detail how the improvement should be realized. This sharing of benefits will come into effect only after (i) full amortization of the capital investment (if any) made necessary to implement the cost improvement and (ii) full amortization of the associated development costs (including without limitation, laboratory and validation work, engineering costs, and any associated regulatory costs.)

7.8 Invoice Payment. Payment for the Product shall be due net thirty (30) days from the date of the invoice therefor, provided that no invoice shall be dated prior to the date of actual release of the Product reflected therein. All amounts not paid when due shall bear interest from the due date at the rate of one and one-half percent (11/2%) per month (or such other percentage, if lower, as shall not exceed the maximum rate permitted by law), and ORPHAN shall be responsible for reasonable attorneys' fees and expenses incurred by Catalytica in connection with the collection thereof.

ARTICLE 8 REPRESENTATIONS, WARRANTIES, INSPECTIONS, REGULATORY AND QUALITY

8.1 Representations and Warranties.

(a) ORPHAN represents and warrants to Catalytica that:

(i) the execution of this Agreement and the performance by ORPHAN of its obligations hereunder have been duly authorized by all necessary corporate action and are within the power and authority of ORPHAN;

(ii) the processes transferred to Catalytica by ORPHAN pursuant to the Services do not infringe any Third Party patents, copyrights, trademarks, trade secrets or other Third Party intellectual property rights;

(iii) at the time it releases or causes to be released the Active Ingredients to Catalytica for use in the manufacture of the Product, the Active Ingredients shall meet the specifications therefor and shall be suitable for use in the manufacture of the Product; and

(iv) that upon delivery to Catalytica, no Active Ingredients constituting or being part of any shipment or other delivery now or hereafter made to Catalytica will be adulterated or misbranded within the meaning of the FD&C Act or would be an article which may not be introduced into interstate commerce under the provisions of Section 404 or 505 of the FD&C Act.

(b) Catalytica represents and warrants to ORPHAN that:

(i) The execution of this Agreement and the performance by

Catalytica of its obligations hereunder have been duly authorized by all necessary corporate action and are within the power and authority of Catalytica;

(ii) To the best of its knowledge, Catalytica will not use in any capacity persons, or the services of persons that are debarred, are on the Debarment List, or that have been convicted of actions that could lead to debarment as described in Section 306(a) and (b) of the FD&C Act,; and

(iii) at the time of sale and shipment by Catalytica, each Production Batch will:

(A) have an expiration date equal to that approved by the FDA, via the initial NDA submission or via extended stability study data subsequently submitted;

(B) conform to the Specifications; and will have been stored in accordance with storage specifications;

(C) have been manufactured in compliance with all applicable laws and regulations, including, without limitation, current cGMP regulations;

(D) not be adulterated or misbranded by Catalytica within the meaning of the FD&C Act, as amended, or be an article which may not be introduced into interstate commerce under Sections 404 or 505 of such Act;

(E) be free from all material liens and encumbrances provided, however, **THE WARRANTIES SET FORTH HEREIN ARE EXPRESSLY IN LIEU OF AND EXCLUDE, AND CATALYTICA EXPRESSLY DISCLAIMS AND NEGATES, ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, ARISING BY OPERATION OF LAW OR OTHERWISE, INCLUDING IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NON-INFRINGEMENT OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS' and**

(F) be shipped in accordance with Orphan's reasonable instructions.

(c) Catalytica shall have no responsibility for, or liability with respect to, any Product that fails to comply with the warranties set forth in Section 8.1(b) hereof due in whole or in part to the failure of any Active Ingredient to comply with the warranties set forth in this Section 8.1.

8.2 Manufacturing Audits and Observation Rights.

(a) Annual MA. With respect to any Contract Year, ORPHAN shall have the right to conduct one (1) Manufacturing Audit (as defined below) according to the terms specified in Sections 8.2(b) and 8.2(c) hereof (such annual Manufacturing Audit to be hereinafter referred to as an "Annual MA").

(b) Event MA. In addition to the Annual MA referred to in Section 8.2(a) hereof, in the event that (i) Catalytica shall receive a "Warning Letter" from the FDA relating to the manufacture, packaging or labeling of the Product by Catalytica, (ii) ORPHAN has rejected a shipment of Product for a mutually agreed upon failure to meet Specifications or (iii) ORPHAN or Catalytica shall have received a series of complaints (i.e., 3 or more complaints on at least 2 Production Batches) from Third Parties within any Contract Year relating to the manufacturing process for the Product (individually or collectively, an "Event"), ORPHAN shall have the right to conduct an additional Manufacturing Audit or Audits according to the terms specified in Section 8.2(c) hereof (such Event Manufacturing Audit or Audits to be hereinafter referred to as an "Event MA"). It is understood and agreed, however, that with respect to any Contract Year, if ORPHAN has not yet conducted an Annual MA and ORPHAN elects to exercise its rights with respect to an Event MA, then in such case, such Event MA and Annual MA shall be conducted at the same time; provided, however, an Annual MA shall not be conducted within six (6) months of the immediately preceding Annual MA.

(c) Definition. For purposes of this Agreement, the term

"Manufacturing Audit" shall mean an audit by no more than two (2) employees and/or one (1) agent of ORPHAN of that portion of Catalytica's manufacturing facility where the Product is manufactured for purposes of reviewing Catalytica's procedures and processes used in manufacturing the Product. Any such employees and/or agent shall be accompanied by Catalytica personnel at all times, shall be qualified to conduct manufacturing audits, shall comply with Catalytica's rules and regulations relating to facility security, health and safety, and shall execute a written agreement to maintain in confidence all information obtained during the course of any such audit except for disclosure to ORPHAN. Each Manufacturing Audit shall be conducted during Catalytica's normal business hours and upon at least sixty (60) days' prior written notice to Catalytica in the case of an Annual MA, or upon at least ten (10) days' prior written notice to Catalytica in the case of an Event MA. The written notice shall identify any specific audit requests that ORPHAN intends to make of Catalytica and ORPHAN'S contact person with regard to the Manufacturing Audit. In no event shall a Manufacturing Audit exceed three (3) days in duration (ORPHAN will be billed at Catalytica's standard full time equivalent rates for any Manufacturing Audit that, with Catalytica's permission, exceeds three (3) days), and in all cases ORPHAN shall ensure that its employees or agents will conduct each Manufacturing Audit so as not to interfere with the normal and ordinary operation of Catalytica's manufacturing facility. All Manufacturing Audits shall be at ORPHAN'S sole expense.

(d) Observation Rights. In addition to the Annual MA and Event MA referred to in Sections 8.2(a) and (b) hereof, ORPHAN shall have the right to be present at and to observe up to two (2) production runs of the Product in any Contract Year. Such observations shall be conducted by no more than two (2) employees and/or one (1) agent of ORPHAN solely for purposes of observing Catalytica's manufacture of the Product. Any such employees and/or agent shall be accompanied by Catalytica personnel at all times, shall comply with Catalytica's rules and regulations relating to facility security, health and safety, and shall execute a written agreement to maintain in confidence all information obtained during the course of any such observation. Each observation shall be conducted during Catalytica's normal business hours and upon at least ten (10) days' prior written notice to Catalytica. In all cases ORPHAN shall ensure that its employees or agents will conduct each observation so as

not to interfere with the normal and ordinary operation of Catalytica's manufacturing facility. All observations shall be at ORPHAN'S sole expense. Upon ORPHAN'S request, Catalytica shall notify ORPHAN at least thirty (30) days in advance of any production run of the Product.

(e) Limitation. Except as set forth in this Section 8.2, neither ORPHAN nor its Affiliates, employees or agents shall have access to Catalytica's manufacturing facilities.

8.3 Regulatory correspondence and Inspections. Catalytica shall promptly inform ORPHAN of any regulatory correspondence or inspection with respect to Catalytica's manufacture of the Product as follows:

(a) Catalytica shall provide ORPHAN with copies of any correspondence and other documentation received or prepared by Catalytica in connection with the manufacture and testing of the Product in the Territory, including, but not limited to, copies of the proposed NDA (but only of those portions for which Catalytica is responsible) and of the potential DMF for the Product and of annual submissions to the FDA and other regulatory authorities in the Territory. Copies of all such correspondence or other documentation prepared by Catalytica shall be reviewed and approved by ORPHAN prior to its submission, such approval not to be unreasonably withheld.

(b) If Catalytica receives any regulatory correspondence or comments from any federal, state, or local regulatory agency related to its manufacture of the Product, or affecting the Product, requiring a response or action by Catalytica, including, without limitation, receipt of an FDA Form 483 (Inspectional Observations) or an FDA "Warning Letter", Catalytica shall immediately provide ORPHAN with a copy of each such regulatory correspondence or comment and a copy of Catalytica's proposed response thereto for ORPHAN'S review and approval (such approval not to be unreasonably withheld or delayed) prior to its submission if Catalytica's manufacture of additional products are not involved. In cases where Catalytica's manufacture of additional products are involved, a good faith effort will be made to reach joint approval within an appropriate timeframe.

(c) If Catalytica's manufacturing facility is inspected by representatives of any federal, state, or local regulatory agency in connection with Catalytica's manufacture of the Product, including, but not limited to, any pre-NDA approval inspection by the FDA, Catalytica shall notify ORPHAN within one (1) working day (by telephone and, if possible, by fax or letter) upon learning of such inspection, and shall supply ORPHAN with copies of any correspondence or portions of correspondence which relate to such regulatory inspection. ORPHAN may send representatives to Catalytica's manufacturing facility to observe any portion of such regulatory inspection relating to the Product.

8.4 Regulatory Support.

(a) Catalytica will provide ORPHAN with standard regulatory support as identified under the heading "Regulatory Support" in Appendix E attached hereto. In addition, Catalytica shall provided ORPHAN with regulatory consulting services as identified under the heading "Regulatory Consulting" in Appendix E attached hereto. Regulatory support services, as identified in Appendix E, shall be at no additional charge to ORPHAN; regulatory consulting services shall be billed at Catalytica's standard hourly rates and payable pursuant to Section 7.7 of this Agreement. Additional regulatory services and/or documentation may be provided by Catalytica, subject to agreement of the parties and subject to additional charges.

(b) Notwithstanding the above or anything in this Agreement or Appendix E to the contrary, ORPHAN is solely responsible for (i) its use of any documentation provided by Catalytica, including without limitation use in any regulatory submission to the FDA or any other regulatory agency inside or outside of the United States, (ii) document control and retention, (iii) determining the suitability of any documentation provided by Catalytica hereunder for use in any regulatory submission; and (iv) all regulatory submission, CMC and other regulatory strategies.

(c) Catalytica may, at its option, retain copies of any documentation provided to ORPHAN hereunder; provided, however, that Catalytica cannot and does not provide any assurances that Catalytica's records will match or otherwise correspond to any submission that ORPHAN may provide to the FDA or any other regulatory agency inside or outside the United States.

(d) ORPHAN shall provide Catalytica with all documents reasonably requested by Catalytica relating to the FDA's pre-approval inspection of Catalytica's manufacturing facility, including, but not limited to, development reports, CMC sections of ORPHAN'S NDA and stability data. In addition, ORPHAN shall provide to Catalytica at least thirty (30) days prior to filing with the FDA a copy of ORPHAN'S annual report (see 21 C.F.R. Section 314.81(b)(2)(iv)) with respect to the manufacture and control of the Product , and ORPHAN shall take into consideration any Catalytica comments to such annual report with respect to the Product. Notwithstanding the foregoing or anything in this Agreement to the contrary, ORPHAN shall be solely responsible for the CMC regulatory strategy.

8.5 Quality Agreement. Catalytica and ORPHAN will negotiate in good faith and use their best efforts to arrive at a mutually acceptable Quality Agreement, which shall be substantially in the form attached hereto as Exhibit F, to further detail the quality assurance obligations and responsibilities of the parties with respect to the Product. Notwithstanding anything to the contrary in this Agreement or in any other document or agreement, in the event of a conflict between this Agreement and the Quality Agreement, this Agreement shall govern and control.

ARTICLE 9 ACCEPTANCE, REJECTION, AND CLAIMS

9.1 Placed on Hold. In the event that a production batch is placed on hold, Catalytica will work to resolve the hold within thirty (30) days. If the hold can not be resolved within (30) days a replacement production batch will be produced , at Orphan's expense. A batch placed on hold will be handled as per sections 9.2 and 9.3 herein.

9.2 Acceptance and Rejection. Each shipment shall be deemed accepted by ORPHAN and considered to conform to the Specifications and the other warranties set forth in Section 8.1(b) which relate to quality unless ORPHAN gives Catalytica notice in writing that it does not consider a particular shipment to conform, together with supporting

documentation specifying the manner in which the Product fails to meet such warranties or the Specifications, within thirty (30) days of receipt of such shipment (or, in the case of nonconformity that could not be reasonably discovered by ORPHAN'S analysis within ten (10) days of such discovery). ORPHAN will analyze (or cause to be analyzed by its designated product manufacturer) each shipment of Product using the validated methods approved by the FDA for release of Product. Such testing will be done for acceptance or rejection of the lot. If ORPHAN gives Catalytica notice of rejection, Catalytica shall thereupon be given access to the shipment in question to conduct its own analysis thereof, and the parties will endeavor to agree amicably as to whether or not the shipment does conform to the Specifications and such other warranties and, if not, whether such non-compliance was due to any breach on the part of Catalytica.

In the event that the parties are unable to agree as to whether or not the shipment conforms with the Specifications or other warranties set forth in Section 8.1(b), the question will be submitted to an independent quality control laboratory which the parties shall mutually agree upon. Cost for the independent quality control laboratory shall be borne by the party whose results are shown by such laboratory to have been wrong. During the pendency of a dispute that requires settlement by an independent laboratory under this section, if requested to do so by ORPHAN, Catalytica will replace, at ORPHAN'S expense, the portion of such shipment under dispute until such dispute is resolved.

9.3 Rejected Shipments. If the nonconformity in a rejected shipment of the Product was due to any action or inaction of ORPHAN or the carrier subsequent to shipment (F.O.B. Catalytica's Greenville, North Carolina plant) of the Product by Catalytica or results from Active Ingredients supplied by ORPHAN, Catalytica shall have no liability for such rejected shipment. If the nonconformity in a properly rejected shipment of the Product was due to Catalytica's negligence or willful misconduct prior to shipment (F.O.B. Catalytica's Greenville, North Carolina plant), Catalytica at its cost and option shall either credit ORPHAN'S account for the full Manufacturing Price of such shipment or replace it with a conforming shipment within thirty (30) days of the Notification of rejection. Such credit or replacement will be ORPHAN'S sole remedy for such rejected Product provided Catalytica provides replacement or credit within thirty (30) days of Notification of rejection.

9.4 Disposal; Return Material Authorization. If ORPHAN expects to make a claim against Catalytica with respect to a rejected shipment of the Product, ORPHAN shall not dispose or allow the disposal of such Product shipment without the express written authorization and instructions of Catalytica. ORPHAN shall not return any rejected shipment of the Product to Catalytica without a Return Material Authorization ("RMA") from Catalytica (Appendix C). Upon written request of ORPHAN, Catalytica shall promptly issue an RMA for any rejected shipment, provided, however, appropriate samples may be retained as evidence of the basis for such rejection. If the Product is returned to Catalytica, all risk of loss and/or damage to such Product shall remain with ORPHAN unless and until such Product is returned to such place as Catalytica designates in writing.

9.5 Product Recalls. Each party shall promptly notify the other party if any batch of the Product is alleged or proven to be the subject of a recall, market withdrawal or correction ordered by the FDA or any other regulatory authority in the Territory. The parties shall cooperate in good faith to handle and dispose of such recall, market withdrawal or correction; provided, however, that in the event of a disagreement as to any matters related to such recall, market withdrawal or correction, ORPHAN'S decision shall prevail. ORPHAN shall bear all the costs of any such recall, market withdrawal or correction unless such recall, market withdrawal or correction was solely the result of Catalytica's negligence or willful misconduct, or breach of Article 8.1(b), in which case Catalytica shall upon substantiation bear the direct cost of administering such recall, market withdrawal, or correction; provided, however, in no event shall Catalytica's aggregate liability with regard to any recall, market withdrawal or correction exceed the amount of consideration received by Catalytica from ORPHAN hereunder for the Product subject to such recall, market withdrawal or correction. Catalytica will not bear the cost for recalls made as a result of errors that could have been detected by ORPHAN through acceptance and rejection testing as outlined in this Article 9. ORPHAN shall in all events be responsible for conducting any recalls, market withdrawals or corrections with respect to the Product.

ARTICLE 10 INDEMNIFICATION

10.1 Catalytica's Indemnification of ORPHAN. Catalytica hereby indemnifies, defends, and holds ORPHAN, its Affiliates and their respective directors, officers, employees, agents; successors and assigns harmless from and against any and all damages, judgments, claims, suits, actions, liabilities, costs and expenses (including, but not limited to, reasonable attorneys' fees) resulting from any Third Party claims or suits arising solely out of (a) Catalytica's material breach of any of its warranties or representations hereunder or (b) Catalytica's negligent acts or omissions or willful misconduct in the manufacture or labeling of the Product; provided, however, Catalytica's collective, aggregate liability under this Section 10.1 shall not exceed seven and one-half (7.5) million dollars.

10.2 ORPHAN'S Indemnification of Catalytica. Except as otherwise provided in Section 10.1 above, ORPHAN hereby indemnifies, defends, and holds Catalytica, its Affiliates and their respective directors, officers, employees, agents, successors and assigns harmless from and against any and all claims, damages, judgments, suits, actions, liabilities, costs and expenses (including, but not limited to reasonable attorneys' fees) arising out of or connected with (a) the use, handling, distribution, marketing or sale of the Product (except to the extent caused solely by Catalytica's negligent acts or omissions or willful misconduct in the manufacture or labeling of the Product), (b) ORPHAN'S material breach of any of its warranties or representations hereunder, (c) ORPHAN'S negligent acts or omissions or willful misconduct or (d) any proceeding instituted by or on behalf of a Third Party based upon a claim that the manufacture, use or sale of the Product infringes a United States patent or any other proprietary rights.

10.3 Indemnification Procedures. A party (the "Indemnitee") which intends to claim indemnification under this Article 10 shall promptly notify the other party (the "Indemnitor") in writing of any action, claim or other matter in respect of which the Indemnitee or any of its Affiliates, or any of their respective directors, officers, employees, or agents intend to claim such indemnification; provided, however, the failure to provide

such notice within a reasonable period of time shall not relieve the Indemnitor of any of its obligations hereunder except to the extent the Indemnitor is prejudiced by such failure. The Indemnitor shall be in charge of and control of any such investigation, negotiation, compromise, settlement and defense and shall have the right to select counsel with respect thereto, provided that the Indemnitor shall promptly notify the Indemnitee of all developments in the matter. In no event shall the Indemnitor or Indemnitee compromise or settle any such matter without the prior written consent of the other party, which shall not be bound by any such compromise or settlement absent its prior consent, which shall not be unreasonably withheld or delayed. The Indemnitee, its Affiliates, and their respective directors, officers, employees, and agents shall cooperate fully with the Indemnitor and its legal representatives in the investigation, negotiation, compromise, settlement and defense of any action, claim or other matter covered by this indemnification. The Indemnitee shall have the right, but not the obligation, to be represented by counsel of its own selection and at its own expense.

10.4 Survival of Indemnification Obligations. The provisions of this Article 10 shall survive the expiration or termination of this Agreement.

10.5 Limitation of Liability and Claims. In no event shall either party be liable to the other party for incidental, special, consequential or punitive damages, including, but not limited to, any claim for damages based upon lost profits. No action, regardless of form, arising out of or in any way connected with this Agreement or Products or services furnished by Catalytica may be brought by ORPHAN more than one (1) year after the cause of action accrued.

10.6 Insurance. ORPHAN shall provide Catalytica, on request, documentation assuring Catalytica that ORPHAN maintains product liability and other insurance coverage in amounts reasonably satisfactory to Catalytica consistent with industry practices.

ARTICLE 11 INVENTIONS AND PATENTS

11.1 Inventions by Catalytica. Catalytica hereby assigns, releases, and transfers to ORPHAN its entire right, title and interest in and to any invention (whether patentable or not) conceived, reduced to practice or created by Catalytica and/or its agents during the performance of the Services and relating to the Product (collectively “Inventions”)

provided, however, ORPHAN hereby grants to Catalytica an unlimited, worldwide, perpetual, royalty-free license to use the Inventions. Catalytica shall promptly disclose to ORPHAN any and all Inventions and shall assign all its interests to ORPHAN or its designee in accordance with this Section. Catalytica shall execute at ORPHAN'S expense any assignments, applications or other instruments or documents reasonably requested by ORPHAN in accordance with this Article 11 and, at ORPHAN'S expense, give testimony which shall be deemed necessary to apply for and obtain Letters Patent of the United States or of any other country and otherwise to perfect ORPHAN'S interest therein. Catalytica's and ORPHAN'S obligations hereunder shall survive termination of this Agreement. All data obtained during the Services are the property of ORPHAN and cannot be used without its consent except for the performance by Catalytica of its obligations hereunder.

11.2 Inventions by ORPHAN. ORPHAN shall own all right, title and interest in and to any invention, discovery or improvement relating to the Product (whether patentable or not) made or conceived solely by ORPHAN employees or by anyone other than Catalytica, including, without limitation, any manufacturing or analytical process, or procedure or method or any source of synthesis given to Catalytica.

ARTICLE 12 CATALYTICA INTELLECTUAL PROPERTY

12.1 ORPHAN acknowledges that Catalytica possesses certain inventions, processes, know-how, trade secrets, improvements, other intellectual properties and other assets, including but not limited to procedures and techniques, computer technical expertise, software, and certain technical expertise and conceptual expertise in the area of drug processing and manufacturing, which have been independently developed by Catalytica or its Affiliates without the benefit of any information provided by ORPHAN (collectively "Catalytica Property"). ORPHAN and Catalytica agree that any Catalytica Property or improvements thereto which are used, improved, modified or developed by Catalytica under or during the term of this Agreement are the product of Catalytica's technical expertise possessed and developed by Catalytica or its Affiliates prior to or during the performance of this Agreement and are the sole and exclusive property of Catalytica or its Affiliates, as the case may be.

ARTICLE 13 TRADEMARKS

13.1 ORPHAN Trademarks. ORPHAN may originate, select and apply to register one or more trademarks ("ORPHAN Trademarks") under which the Product will be sold and distributed by ORPHAN or its Affiliates and distributors. ORPHAN shall own all right, title, and interest in the ORPHAN Trademarks, subject to the limited license granted to Catalytica in this Article 13. ORPHAN shall be solely responsible for all prosecution, defense, maintenance and costs relating to the ORPHAN Trademarks.

13.2 Limited Trademark License. ORPHAN hereby grants Catalytica an unlimited worldwide, perpetual, royalty-free license to the ORPHAN Trademarks solely for purposes of manufacturing and distributing the Product under this Agreement. In that regard, Catalytica shall be permitted to use ORPHAN'S Trademarks and name in connection with general advertising and promotional activities. Catalytica shall comply with ORPHAN'S reasonable policies and procedures for the use of the ORPHAN Trademarks and shall furnish ORPHAN with copies of any packaging, or other materials incorporating the ORPHAN Trademarks for ORPHAN'S review and approval prior to any use thereof. Catalytica shall make any changes or additions reasonably requested by ORPHAN to comply with ORPHAN'S standard policies and procedures for the use of the ORPHAN Trademarks. Upon termination of this Agreement, Catalytica shall promptly cease any use of the ORPHAN Trademarks.

13.3 Limitations. Catalytica shall not use, or assert any claims to, any of the ORPHAN Trademarks or any trademark confusingly similar to any ORPHAN Trademarks, provided that ORPHAN shall not choose a trademark which is the same as, or confusingly similar to, a trademark previously used by Catalytica.

13.4 Infringement. Catalytica shall promptly notify ORPHAN if Catalytica knows or reasonably suspects that a Third Party is infringing any ORPHAN Trademark. At ORPHAN'S expense, Catalytica shall reasonably cooperate in any investigation or other legal action with regard to such infringement.

ARTICLE 14 CONFIDENTIALITY

14.1 Proprietary Information. During the term hereof and for a period of five (5) years thereafter, any Proprietary Information disclosed by the Disclosing Party, directly or indirectly, to the Receiving Party under this Agreement shall be deemed confidential and trade secret information and shall not be disclosed by the Receiving Party to any Third Party or used by the Receiving Party, except as set forth below. Access to such Proprietary Information will be limited to employees, agents, or consultants of the Receiving Party who reasonably require such Proprietary Information for purposes of performing the Receiving Party's obligations hereunder and who are bound to the Receiving Party by similar obligations in respect of confidentiality and use. Such employees, agents, or consultants will be advised of the nature and existence of the undertakings in respect of such Proprietary Information pursuant to this Agreement and of the applicability of such undertakings to them. The Receiving Party will use such Proprietary Information only to carry out its obligations or to exercise its rights hereunder and will not use such Proprietary Information for its own benefit or for the benefit of others or in any way inconsistent with this Agreement.

14.2 Disclosure by the Receiving Party to a Third Party shall be made only to the extent necessary to enable the Receiving Party to comply with its contractual obligations to the Disclosing Party.

14.3 Each Third Party to which Proprietary Information is disclosed other than a governmental agency must agree in writing prior to such disclosure to keep the Proprietary Information in strict confidence and to comply with the terms of this Article 14.

14.4 Both parties agree to limit access of Proprietary Information to those of its officers, directors, or employees, or any Third Party who must have Proprietary Information to carry out or enforce the terms of any agreement made between the parties.

14.5 Neither party shall utilize the Proprietary Information disclosed to it by the Disclosing Party after the completion of the Agreement between the parties, either in its own development work or for commercial purposes, without advance written consent of the Disclosing Party.

14.6 No Right or License. The Receiving Party will obtain no right or license of any kind under any patent applications, patent or otherwise by reason of this Agreement and all Proprietary Information will remain the sole property of the Disclosing Party unless provided otherwise in this Agreement.

14.7 Prior Confidentiality Agreement. The Confidential Disclosure Agreement between the parties hereto dated December 1, 1997 and the Mutual Non-Disclosure Agreement between the parties hereto dated November 23, 1998 , as well as the confidentiality provisions of the Technical Services Agreement dated November 20, 1999, are hereby superseded and terminated. Any disclosure of Proprietary Information by either party pursuant to such Confidentiality Agreements shall be deemed to have been made hereunder and shall be subject to this Article 14.

14.8 Terms of Agreement; Press Releases. Except as otherwise required by law or the rules and regulations of any stock exchange on which a party's securities may be publicly traded or in disclosures made in confidence to a party's professional or financial advisors, applicable regulations or the terms of this Agreement or mutually agreed upon by the parties hereto, each party shall treat the terms, conditions and existence of this Agreement as Proprietary Information. The parties shall cooperate in good faith in the preparation of any press releases or other public disclosures of their business relationship, and neither party shall issue any such press release or other disclosure without the prior approval of the other party, which approval shall not be unreasonably held.

ARTICLE 15 TERM OF AGREEMENT

15.1 Unless sooner terminated pursuant to Article 16 below, the initial term of this Agreement shall commence on the Effective Date and end upon expiration of the seventh (7th) Contract Year. Unless otherwise terminated pursuant to Article 16 below,

this Agreement shall be automatically renewed for additional one (1) year terms after the end of the initial term, unless either party provides written notice to the other at least eighteen (18) months prior to the expiration of the initial or any extended term, as the case may be, that this Agreement shall expire at the end of the initial term or such renewal term, as the case may be. All references herein to “term of this Agreement” shall be deemed to include both the initial and any extended terms.

ARTICLE 16 TERMINATION

16.1 Termination by Either Party. In addition to any other legal or equitable remedies it may have, either party may terminate this Agreement prior to the expiration of the term of this Agreement upon written notice to the other party:

(a) If the other party breaches any material term or condition of this Agreement, including any term or condition in any appendix attached hereto, provided such other party has not cured such breach within ninety (90) days of written notice thereof (ten (10) days in the event of a payment breach by ORPHAN); provided, further, that if at the end of such ninety (90) day period the party in breach is making a good faith effort to cure, a reasonable time thereafter (not to exceed an additional sixty (60) days) shall be allowed for such cure.

(b) If the other party is declared bankrupt or insolvent, or makes an assignment for the benefit of its creditors, or if a receiver is appointed or any proceedings are commenced, voluntary or involuntary, by or against either party under any bankruptcy or similar law, and such status is not cured within thirty (30) days from its occurrence.

(c) If an event of force majeure continues for more than six (6) months, either party, at its option, may elect to treat such continued suspension of performance as a material breach and may terminate this Agreement.

16.2 Effects of Expiration or Termination. Upon expiration or termination of this Agreement for any reason:

(a) Catalytica shall manufacture and ship, and ORPHAN shall purchase,. Production Batches of the Product ordered by ORPHAN prior to the effective date of such expiration or termination.

(b) Other than termination by ORPHAN pursuant to Section 16.1(a) hereof, (i) at Catalytica's option, ORPHAN shall purchase from Catalytica at Catalytica's Acquisition Cost all materials acquired by Catalytica hereunder, (ii) at Catalytica's option, ORPHAN shall purchase from Catalytica all work-in progress for the Product at Catalytica's cost, (iii) at Catalytica's option, ORPHAN shall purchase all other finished Product then in Catalytica's possession, (iv) ORPHAN shall compensate Catalytica for all other uncancellable commitments made by Catalytica to satisfy the existing purchase orders, and (v) ORPHAN shall compensate Catalytica for any and all technology transfer and other capital costs that were incurred and not recovered by Catalytica.

(c) Catalytica shall take all steps reasonably requested by ORPHAN to confirm the assignment to ORPHAN all of Catalytica's right, title and interest in the Inventions, including, without limitation, to execute or cause its employees to execute such documents as may be reasonably requested by ORPHAN to vest all such right, title and interest in such Inventions in ORPHAN, provided ORPHAN shall pay all reasonable expenses, including any of time and travel of Catalytica's employees.

(d) Each party shall return to the other party any Proprietary Information of the other party except for one (1) archival copy as may be required for purposes of compliance with any FDA regulation or other applicable law or regulation in the Territory.

16.3 Survival. The provisions of Articles 7 (Prices and Payments), 8 (Representations, Warranties, Inspections, Regulatory and Quality), 9 (Acceptance, Rejection and Claims), 10 (Indemnification), 11 (Inventions and Patents), Article 12 (Catalytica Intellectual Property), 13 (Trademarks), 14 (Confidentiality), 15 (Term of Agreement), 16 (Termination), 17 (Force Majeure), 18 (Dispute Resolution) and 19 (Miscellaneous) shall survive the expiration or termination of this Agreement and shall remain in full force and effect in accordance with the terms thereof.

ARTICLE 17 FORCE MAJEURE

17.1 Events of Force Majeure. Either party shall be excused from the performance of its obligations (other than the payment of money, including without limitation payment for minimum purchase requirements) in the event such performance is prevented by a cause beyond the reasonable control of such party, including, without limitation, any act of God; regulation or law of any government or an agency thereof; war; insurrection or civil commotion; earthquake, tornado, fire, hurricane, flood or storm; epidemic; or failure of suppliers, public utilities or common carriers. Such excuse shall continue as long as the Force Majeure Event and consequences to supply continue, except that Customer will have the right to (i) terminate the Agreement without further obligation in the event that Catalytica is not able to supply Customer with Product for a continuous period of six (6) months and (ii) seek an alternate supplier of the Product during the continuation of, and only during the continuation of, such a Force Majeure Event unless Customer can only secure an alternate supplier for a time period in excess of the Force Majeure Event period, in which case Customer will resume its exclusive supply relationship with Catalytica at the end of such period and extend the term of this Agreement by a maximum of six (6) months. If no such termination by Customer occurs, upon cessation of such Force Majeure Event, the Parties shall promptly resume performance hereunder.

17.2 Notice. A party affected by an event of force majeure shall give the other party prompt written notice of the occurrence of any event of force majeure and the nature and duration thereof. An affected party shall use all reasonable efforts to resume performance as quickly as possible and to give the other party prompt written notice when it is again fully able to perform such obligations. If Catalytica is the affected party, such notice of resumption of performance shall state the quantities of Product manufactured but not shipped by Catalytica due to any event of force majeure and the expiration dates thereof.

17.3 Cover. During, and only during, any suspension of performance by Catalytica under Section 17.1 above, ORPHAN may, at its option, purchase elsewhere the quantities of the Product ORPHAN has ordered which Catalytica is unable to deliver.

ARTICLE 18 DISPUTE RESOLUTION

18.1 Negotiation. The parties intend that any dispute, controversy or claim arising out of or relating to this Agreement, or any breach thereof, shall be resolved under the procedures set forth in this Article 18. The parties recognize that a bona fide dispute as to certain matters may from time to time arise during the term of this Agreement which relates to either party's rights and/or obligations hereunder. In the event of the occurrence of such a dispute, either party may, by notice to the other party, have such dispute referred to their respective officers designated below, or their successors, for attempted resolution by good faith negotiations within thirty (30) days after such notice is received. Such designated officers are as follows:

For ORPHAN – John H. Bullion

For Catalytica – Michael Thomas

18.2 Mediation. If attempts to resolve the dispute pursuant to Section 18.1 are unsuccessful, mediation shall be conducted by a single mediator appointed by mutual agreement of the parties. The mediator shall not have the power to bind the parties to the resolution. The mediation session shall take place in Raleigh, North Carolina if ORPHAN requests mediation or in Minnetonka, Minnesota if Catalytica requests mediation, on two (2) consecutive business days and shall be attended by a representative of each party with full authority to settle the matter, along with any other representatives reasonably necessary to discuss and address the issues involved in the dispute. On the first day of mediation, each party shall be allotted a maximum of four (4) hours with other representatives necessary to discuss and address the issues involved in the dispute to state its views of the dispute to the mediator and to the other party. On the second day of mediation, the parties shall attempt to resolve the dispute with the aid of the mediator in a format agreed to by the parties or imposed by the mediator. If the parties cannot agree upon a mutually acceptable mediator within ten (10) days of the end of the 30-day negotiation period in Section 18.1 or if the dispute is not resolved by mediation within ten (10) days after completion of the mediation session, either party shall have the right to pursue any and all remedies available at law or in equity.

ARTICLE 19 MISCELLANEOUS

19.1 Choice of Law. This Agreement shall be governed by and interpreted in accordance with the laws of North Carolina, without regard to its conflict of laws provisions.

19.2 Notifications. Any and all notices provided for shall be sent to the respective parties at the following addresses by certified or registered mail or sent by a national courier service with proof of delivery, by personal delivery or by facsimile with an electronic and verbal confirmation of receipt:

If to Catalytica: Chief Executive Officer
Catalytica Pharmaceuticals, Inc.
Intersection US 13/NC11 and US 264
Greenville, North Carolina 27834
Fax (252) 707-2450

If to ORPHAN: Chief Executive Officer
Orphan Medical, Inc.
3911 Ridgedale Drive, Suite 250
Minnetonka, Minnesota 55305
Fax: (612)541-9209

with a copy to each Legal Council's office, or to such other addresses as may be subsequently furnished by one party to the other in writing. Any such notice shall be deemed effective three (3) days after mailing or upon receipt if sent by courier service, personal delivery or facsimile.

19.3 Severability. If any term or condition of this Agreement is found by a court of competent jurisdiction in a final unappealed or unappealable order to violate the provisions of any applicable statute, law or regulation, the remainder of this Agreement shall remain in full force and effect. The parties shall then negotiate in good faith to modify this Agreement, but only to the extent necessary to make the affected term or condition of this Agreement valid and enforceable, having full regard for applicable laws and the intent and purposes of the parties entering into this Agreement.

19.4 Integration; Amendment. This Agreement and all appendices hereto constitute the entire agreement between the parties relating to the subject matter of this Agreement and supersedes all prior agreements, representations, and understandings. This Agreement may not be amended, modified, or varied except in writing signed by a duly authorized representative of each party. In the event of a conflict between the terms of this Agreement, and any appendix hereto, the terms of this Agreement shall control.

19.5 Assignment. Neither party may assign or otherwise transfer this Agreement without the prior written consent of the other party except that either ORPHAN or Catalytica may assign, without such consent, this Agreement (a) to an Affiliate, (b) in connection with the sale or transfer of all or substantially all of the assets of such party or the line of business of which this Agreement forms a part, or (c) in the event of the merger or consolidation of a party hereto with another company, provided, however, any permitted assignee shall assume all obligations of its assignor under this Agreement. Any purported assignment in violation of the foregoing sentence shall be null and void. No assignment shall relieve either party of responsibility for the performance of any accrued obligation under this agreement. Subject to the foregoing, this Agreement shall be binding upon and inure to the benefit of the permitted successors or permitted assigns of Catalytica and ORPHAN respectively.

19.6 Waiver. No course of dealing between Catalytica and ORPHAN or delay or failure to exercise any rights hereunder shall operate as a waiver of such rights or preclude the exercise of any other rights hereunder.

19.7 Relationship. Each of the parties hereto is an independent contractor and nothing herein shall be deemed to constitute the relationship of partners, joint venturers, nor of principal and agent between the parties hereto.

19.8 Captions. The captions to the several Articles hereof are not a part of this Agreement, but are merely guides or labels to assist in locating and reading the several Articles hereof and shall not affect the meaning or interpretation hereof.

19.9 Counterparts. Two (2) or more counterparts of this Agreement may be signed by the parties, each of which shall be an original, but all of which together shall constitute the same instrument.

IN WITNESS WHEREOF, the parties have caused this Agreement to be entered into by their duly authorized representatives as of the Effective Date.

CATALYTICA PHARMACEUTICALS, INC.

By: /s/ Michael H. Thomas
Print: Michael H. Thomas
Its: CEO
Date: 7/17/00

ORPHAN MEDICAL

By: /s/ John Howell Bullion
Print: John Howell Bullion
Its: CEO
Date: 6/30/00

APPENDIX A

TECHNICAL SERVICES AGREEMENT

TECHNICAL SERVICES AGREEMENT

THIS AGREEMENT is made and entered into this __ day of November, 1999 by and between Catalytica Pharmaceuticals, Inc., a Delaware corporation, having an address at Intersection US 13/NC11 and US 264, Greenville, North Carolina 27834 ("Catalytica") and Orphan Medical, Inc., a Minnesota corporation, having an address at 13911 Ridgedale Drive, Suite 475, Minnetonka, Minnesota 55305 ("Orphan") (Catalytica and Orphan may be referred to collectively as the "Parties" or individually as a "Party").

W1TNESSETH:

WHEREAS, the Parties are in the process of negotiating and intend to enter into a definitive Supply Agreement (the "Supply Agreement") pursuant to which Catalytica would manufacture and supply Orphan's Xyrem™ Oral Solution (the "Product"); and

WHEREAS, in anticipation of the Supply Agreement and the services that Catalytica will perform thereunder, the Parties desire to enter into a binding agreement pursuant to which Catalytica would undertake certain technical services in order to prepare its facilities for performance of the Supply Agreement.

NOW THEREFORE, in consideration of the mutual covenants contained herein and other good and valuable consideration, the Parties hereby agree as follows:

1. Best Efforts. Catalytica and Orphan will negotiate in good faith and use their best efforts to arrive at a mutually acceptable Supply Agreement not later than March 31, 2000, with terms consistent with those set forth in Catalytica's proposal dated October 1, 1999 (a copy of which is attached hereto as Exhibit 1), which includes a commercial per unit cost of $.95 per bottle, (based on 300,000 bottle annual production). Packaging material costs have been estimated at $1.15 and includes the cap, bottle, label, insert, carton and shipper. Pricing is subject to confirmation upon completion of transfer activities.

2. Services.

(a) Description of Services. Catalytica shall perform the services listed in Exhibit 1 hereto, including any modifications and additions thereto agreed upon in writing by the Parties, to develop and confirm the manufacturing process for the Product (the "Services") (Catalytica's performance of the Service is based on the assumptions set forth in Exhibit 1). In that regard, Catalytica shall use reasonable efforts to complete the Services in a timely fashion in accordance with a schedule to be mutually agreed upon by the Parties,

(b) Cost and Payment. The cost of the Services shall be $92,500 (the "Cost"). Orphan shall make an fixed fee payment equal to one-half of the Cost ($46,250), upon execution of this Agreement, Orphan shall make two subsequent equal payments equal to the balance of the Cost ($46,250), or such higher amount agreed to by the Parties in the event Catalytica performs services in addition to those identified in Exhibit 1, on September 30 and December 31, 2000; provided, however, Catalytica shall not perform services hereunder in addition to those identified in Exhibit 1 which cost more than $1,000 without Orphan's prior written consent. In addition, Orphan shall make

an up-front payment of $22,500 for the estimated cost of specialized equipment required to manufacture the Products (the "Equipment"). If the actual cost paid by Catalytica (including tax, shipping, insurance, etc.) for the Equipment exceeds $22,500, Orphan shall promptly, upon receipt of Catalytica's invoice, reimburse Catalytica for any such excess; provided, however, Catalytica shall not pay more than $25,000 for the Equipment without Orphan's prior written consent. Catalytica shall own all of the Equipment.

(c) Orphan's Responsibilities. To assist Catalytica in its performance of the Services, Orphan shall provide Catalytica, in a timely fashion, all relevant material, information and data in its possession which Orphan, in its good faith opinion, believes is necessary for Catalytica to carry out and complete the Services.

(d) Reporting, Catalytica shall respond to Orphan's reasonable inquiries regarding the status of the Services on an ongoing basis, including if requested periodic meetings at Catalytica's facility to discuss the results and progress of the Services.

(e) Validation Batches. At Orphan's option and request, after execution of the Supply Agreement, Orphan may purchase validation batches of Product prepared in connection with the Services, pursuant to the terms and conditions of the Supply Agreement (including without limitation the terms and conditions governing price, payment, warranty, indemnification and limitation of liability). Catalytica shall retain representative samples from each batch of the Products for record keeping, testing and regulatory purposes.

(f) Ownership of Tangible Materials. Orphan shall retain ownership of all information, documents and materials which Orphan provides to Catalytica in connection with the performance of the Services hereunder. Further, Orphan shall have full ownership, possession of, and all rights to use, any reports, documents and other tangible materials which Catalytica provides to Orphan as part of the Services.

(g) Ownership of Inventions. All inventions, whether patentable or not, conceived, reduced to practice or created by Catalytica and/or its agents during the performance of the Services and relating to the Product shall be owned by Orphan; provided, however, Catalytica shall have, and Orphan hereby grants to Catalytica, an unlimited, worldwide, perpetual, royalty-free license to use such inventions. Orphan shall be responsible for the costs of filing, prosecution and maintenance for patents and patent applications with regard to inventions owned by Orphan pursuant to this paragraph.

3. Exclusive Dealing. In recognition of the substantial effort and expense to be incurred by Catalytica in undertaking a detailed analysis in anticipation of the Supply Agreement contemplated hereunder, neither Orphan nor any of its affiliates, shareholders, partners, directors, officers, employees or agents, shall discuss, negotiate, solicit, or in any manner encourage any transaction or proposal for a transaction involving the manufacture or supply of the Products, other than the transaction contemplated by this agreement, until March 31, 2000. Without limiting the foregoing, none of the foregoing shall directly or indirectly furnish to any third party any non-public information concerning the manufacture or supply of the Product, or otherwise engage in any act related to or likely to induce any actual or potential transaction inconsistent with this Agreement.

4. Confidentiality. Catalytica and Orphan, including all their respective

representatives, agents, accountants and counsel, shall treat confidentially all of the information received from one another in connection with this Agreement that is not publicly available and will not, without the prior consent of the other party, disclose any information to any third party except as required by law and will not use any such information for purposes other than in furtherance of this Agreement, Information shall be deemed "publicly available" if, other than as a result of a breach of the obligation of this Agreement, it is or becomes generally available to the public or is or becomes a matter of public knowledge or if it is or becomes available to a party on a non-confidential basis from a source, other than from the other party, that is not known to be bound by a confidentiality agreement or otherwise prohibited from transmitting such information. Except to the extent inconsistent herewith, all prior agreements (if any) between the parties regarding confidentiality shall remain in full force and effect. The confidentiality obligations set forth in this paragraph 4 shall survive the termination or expiration of this Agreement for a period of three (3) years.

5. Termination. Unless extended by mutual agreement of the Parties, this Agreement shall terminate on March 31, 2000, or earlier upon the mutual agreement of the Parties.

6. Force Majeure. No failure or omission by the Parties in the performance of any obligation of this Agreement (other than the payment of money) shall be deemed a breach of this Agreement nor shall it create any liability (other than as set forth herein), if the same shall arise from any cause or causes beyond the reasonable control of the affected Party (a "Force Majeure"), including, but not limited to, the following, which for purposes of this Agreement shall be regarded as beyond the control of the Party in question: acts of God; fire; storm; flood; earthquake; accident; war; rebellion; insurrection; riot; invasion; strikes; and lockouts or the like; provided that the Party so affected shall use its commercially reasonable best efforts to avoid or remove such causes of non-performance and shall continue performance hereunder with the utmost dispatch whenever such causes are removed.

7. Indemnification.

(a) Orphan shall indemnify, defend and hold Catalytica, its affiliates and their respective directors, officers, employees, agents, successors and assigns harmless from and against any damages, judgments, claims, suits, actions, liabilities, costs and expenses (including, but not limited to, reasonable attorneys' fees) arising out of or connected with (a) the Services and the use, handling, distribution, marketing or sale of the Product (except to the extent caused solely by Catalytica's negligent acts or omissions or willful misconduct), (b) Orphan's breach of any of its warranties or representations hereunder, (c) Orphan's negligent acts or omissions or willful misconduct or (d) any proceeding instituted by or on behalf of a third party based upon a claim that the Services or the manufacture, use or sale of the Product infringes a United States patent or any other proprietary rights.

(b) Except as otherwise provided in Section 7(a), Catalytica shall indemnify, defend and hold Orphan, its affiliates and their respective directors, officers, employees, agents, successors and assigns harmless from and against any damages, judgments, claims, suits, actions, liabilities, costs and expenses (including, but not limited to, reasonable attorneys' fees) resulting from any third party claims or suits arising solely out of (i) Catalytica's material breach of any of its warranties or representations hereunder or (b) Catalytica's negligent acts or omissions or willful misconduct in the performance of the Services or the manufacture of the Product;

provided, however, Catalytica's collective, aggregate liability under this Section 7(b) shall not exceed the amount of compensation actually received by Catalytica from Orphan pursuant to this Agreement.

(c) A party (the "Indemnitee") which intends to claim indemnification under this Section 7 shall promptly notify the other party (the "Indemnitor") in writing of any action, claim or other matter in respect of which the Indemnitee or any of its Affiliates, or any of their respective directors, officers, employees or agents intend to claim such indemnification; provided, however, the failure to provide such notice within a reasonable period of time shall not relieve the Indemnitor of any of its obligations hereunder except to the extent the Indemnitor is prejudiced by such failure. The Indemnitee, its affiliates, and their respective directors, officers, employees and agents shall cooperate fully with the Indemnitor and its legal representatives in the investigation, negotiation, compromise, settlement, and defense of any action, claim or other matter covered by this indemnification. The Indemnitor shall be in charge of and control of any such investigation, negotiation, compromise, settlement and defense and shall have the right to select counsel with respect thereto, provided that the Indemnitor shall promptly notify the Indemnitee of all developments in the matter. In no event shall the Indemnitor or Indemnitee compromise or settle any such matter without the prior written consent of the other party, which shall not be bound by any such compromise or settlement absent its prior consent, which shall not be unreasonably withheld or delayed. The Indemnitee shall have the right, but not the obligation, to be represented by counsel of its own selection and at its own expense.

(d) In no event shall either party be liable to the other for incidental, special, consequential or punitive damages, including, but not limited to, any claim for damages based upon lost profits, In addition, in no event shall the collective, aggregate liability of Catalytica and its affiliates and its and their respective directors, officers, employees and agents under this Agreement exceed the amount of compensation actually received by Catalytica from Orphan pursuant to this Agreement. No action, regardless of form, arising out of or in any way connected with this Agreement or Products or Services furnished by Catalytica may be brought by Orphan more than one (1) year after the cause of action accrued.

(e) The provisions of this Section 7 shall survive the expiration or termination of this Agreement.

8. Governing Law. This agreement shall be governed by and construed in accordance with the laws of the State of North Carolina without reference to principles of conflicts of laws.

9. Assignment. This Agreement may not be assigned or otherwise transferred by either party without the prior written consent of the other; provided, however, either party may, without such consent, assign this Agreement (a) in connection with the transfer or sale of all or substantially all of the assets of such party or the line of business of which this Agreement forms a part, (b) in the event of the merger or consolidation of a party hereto with another company, or (c) to any affiliate of the assigning Party. Any purported assignment in violation of the preceding sentence shall be void. Any permitted assignee shall assume all obligations of its assignor under this Agreement. No assignment shall relieve either party of responsibility for the performance of any obligation which accrued prior to the effective date of such assignment.

10. Survivability. The following paragraphs shall survive the termination or expiration of this Agreement: 2(f), 2(g), and 7.

IN WITNESS WHEREOF, this Agreement has been executed by the Parties hereto as of the day and year first written above.

ORPHAN MEDICAL, INC.	CATALYTICA PHARMACEUTICALS, INC.
By: /s/ Dayton Reardan	By: /s/ Gabriel Cipau
Title: Vice President	Title: President & CEO

EXHIBIT 1 PROPOSAL

(See attached)

October 1, 1999

Orphan Medical
13911 Ridgedale Drive
Suite 475
Minnetonka, Minnesota 55305

ATTN: Randy Tlachac

Dear Randy:

I am pleased to provide the attached proposal for the Xyrem™ Oral Solution. The proposal includes the commercial estimate, the associated transfer costs and the equipment requirements to produce your product at our Greenville facility.

Please note that Orphan would be responsible for the capital equipment costs estimated at $22,500. Also, the commercial prices would be subject to annual price increases based on the Producer Price Index.

Catalytica Pharmaceuticals, being the largest full-service pharmaceutical company in the world, provides a full spectrum of capabilities tailored to meet your needs. We are committed to delivering the finest products, services, and performance available to you including:

- full-service development, and manufacturing,
- access to the newest technology,
- assistance from professionals who are among the best in the business,
- unsurpassed regulatory expertise, and
- a workforce dedicated to continuous quality improvement and ongoing professional development.

Catalytica appreciates the opportunity to bid on this project and hope that arrangements can be made to expedite its transfer, If you have any questions or need further clarification, please don’t hesitate to call. I will try to contact you next week to discuss the proposal and the next steps.

Sincerely,

David Hamby

cc: Dr. Cipau
Tom Mulligan Bob
Peoples
File (2)

Proposal Summary for Xyrem Oral Solution

Commercial Estimate:

Product	Price/Unit
Xyrem Oral solution – 8oz	**$ .95**

Active and packaging materials are not included.
Subject to 3- year contract, minimum volumes and annual price increases.

Packaging material costs have been estimated at $1.15 and includes the cap, bottle, label, insert, carton and shipper

Transfer Estimate:

Xyrem Transfer Costs **(See activities attached)**	**$92,500**
Estimated Capital Requirements **See attached for details** **Customer to assume**	**$22,500**

Amy DelaCourt
Vice President, Pharmaceutical Marketing & Sales

Proposal valid for 60 days. A change in scope will necessitate a re-evaluation of resources.
CONFIDENTIAL

Packaging Assumptions

1. No change in standard Catalytica cleaning procedures will be required for cleaning equipment after running this product.
2. Lot number and expiration date coding will comply with current Catalytica methods, format and size.
3. Literature/insert size and shape will be compatible with Catalytica equipment and only one piece of literature will be required.
4. Cartons will be a standard reverse tuck.
5. Labels will be applied lo one side of bottle only and can be adhered by brushing down.
6. Test will be conducted if PET bottle is selected to insure labels will not wrinkle.
7. Cap design will be compatible with current tooling. If not additional capital will be required.
8. Product will be bundled X6 and packed in shippers X24.
9. Shippers will be sealed with tape, lot/exp. printed on one side of shipper.
10. Current Catalytica component verification systems can be used for component verification.
11. No cost involved for special handling or safety equipment in the packaging of this product.
12. No special handling or costs associated with disposal of product.
13. Shrink bands will not be required.

Equipment requirements (estimated);

Manufacturing	
Sanitary Housing	$ 1,500
Filters	$ 500
Packaging	
Bottle Unscrambler change-parts	$10,000
Feed screws	$ 8,000
Bundler change-parts	$ 2,500
Total cost	$22,500

Transfer Activities

CATEGORY	ACTIVITY
Predevelopment	Review product info. Establish scope Create 2 new raw material and 1 product item numbers, critical documents; SOPs, PWOs BOM, etc Pass raw materials
Process Development	Prepare/approve batch records Perform validation activities to include VPS, PQ-mfg, PQ-pkg, PQ-cleaning
Clinical Batch	Prepare Nonproduction formula Manufacture and package 1 x 100gallon batch. Activities include equipment set up, mfg, and cleaning. Perform in process testing Perform cleaning verification testing Transfer drug product analytical methods to AR&D Review final batch record and prepare report
Validation Batches	Prepare and approve Master Formula Monitor manufacturing and packaging of 3 validation batches Perform cleaning validation testing Transfer drug product analytical methods to QC Perform cleaning validation testing Prepare transfer report
Reports	Prepare “Data Only” documentation for CMC section.

Development Assumptions

ORPHAN MEDICAL - XYREM SOLUTION

1. One 25-gallon development batch will be manufactured to evaluate the processing parameters.
2. Orphan medical will provide suitable filter cartridges for processing.
3. All lab testing for the development and CTM batch will be performed by Orphan Medical.
4. Although the NDA has not been filed, this is considered a Tech Transfer that requires no formulation or analytical development activities.
5. Prior to the manufacture of the batches, AR&D will perform a collaborative type method transfer utilizing Orphan Medical's existing contract lab(s).
6. AR&D is responsible for the development of the method transfer protocol. Orphan Medical will review and approve the transfer protocol prior to implementation.
7. No stability testing is included in this estimate,
8. Regulatory documentation deliverables include:
    - Submission-ready packaging description
    - Categorical exclusion
    - Submission-ready certificates of analysis
    - C*P name/address/registration number
    - Certificate of GMP compliance
    - Debarment Certification
    - Batch Records
    - Analytical controls

(Additional Regulatory support will be billed at $175 per hour)

APPENDIX B

Specifications

Catalytica Document	Title
SPC-1152/TEST-1118	Bulk Drug Substance Specification, Sodium Oxybate
00100	Physical Examination
04001	Identification: HPLC
04003	Identification: IR
16001	Total Impurities
16003	Samma-Butyrolactone
16005	Specified A
16007	Unspecified
16009	Water Determination
16011	Residual Solvents
16015	Heavy Metals
26001	HPLC Assay
26003	Titration
SPC-95/TEST-95	Raw Material Specification, Purified Water USP
16000	Total Organic Carbon
16005	Nitrates
16008	Heavy Metals
16010	Conductivity: microSiemens per cm
16020	Conductivity: USP, EP
23061	Microbial Plate Count
SPC-174/TEST-173	Raw Material Specification, Sodium Hydroxide (NaOH), NF
01183	Physical Examination
04930	Identification, EP
04933	Identification, NF
16001	Insoluble Substances and Organic Matter, NF
18032	Heavy Metals, EP
18033	Potassium,NF
18034	Appearance: Clarity
18035	Appearance: Color
18036	Chlorides, EP
18038	Sulfates, EP
18039	Iron, EF

26591	Assay, Sodium Carbonate, EP
26592	Assay, Sodium Hydroxide, EP
SPC-1151/TEST-1117	Raw Material Specification, Malic Acid, USP/NF
00100	Appearance
04001	Identification: IR
05111	OVI: Benzene
05112	OVI: Chloroform
05113	OVI: 1,4 Dioxane
05114	OVI: Methylene Chloride
05115	OVI Trichloroethylene
16001	Assay, Malic Acid
16005	Heavy Metals
16010	Residue on Ignition
16020	Fumaric Acid
16025	Maleic Acid
16030	Water-insoluble Substances
SPC-1163/TEST-1133	Drug Product Specification, Xyrem
00100	Physical Examination
04001	Identification by HPLC
04003	Identification by IR
14001	pH
16001	HPLC Total Impurities
16003	HPLC Gamma Butyrolactone
16005	Specified A
16007	Unspecified
16009	Volume in Container
26001	HPLC Assay
SPC-1158/TEST1128	Component Specification, Filter Cartridge, Pall
00100	Appearance
Z157	Bill of Materials, Bottling, Xyrem - 100 gallon, Catalytica
595371	Component Specification, Xyrem, Label, bottle, front
595372	Component Specification, Xyrem, Label, bottle, back
542593	Component Specification, Xyrem, Insert
542594	Component Specification, Xyrem Carton
X1468	Component Specification, Xyrem, Shipper Label
14549	Component Specification, Xyrem, Carton Security, (Unprinted) Catalytica
014550	Tubing, PVC, Unprinted, 54 mm, Roll-Feed
690083	Component Specification, Xyrem, Shipper , Unprinted, General Use

012731F	Component Specification, Xyrem, Tape, Pressure Sensitive Case Sealing
003900B	Component Specification, Xyrem, Shipper Label, Unprinted, Thermal Transfer, Catalytica
302102	Component Specification, Bottle, Catalytica, Owens Brockway, Mold 10004, Amber Eastman 5214 PET, 8 ounce
013525	Component Specification, Catalytica, Closure, Owens Brockway, 24-400 Clic-Loc III
X1478	Component Specification, Press-In Bottle Adapter (PIBA), Baxa Corporation
X1479	Component Specification, Exacta-Med Dispenser, Baxa Corporation
NP-0046-00	tester Production Record: Xyrem (sodium oxybate) oral solution Catalytica 400 gallon
QC-493	HPLC assay for sodium oxybate in Xyrem (sodium oxybate) oral solution
QC-495	HPLC assay for gamma-butyrolactone and impurities in Xyrem (sodium oxybate) oral solution
SPC-1151	Raw Material Specification, Malic Acid Specification USP/NF, Catalytica
RS-400	Specification, Reference Standard, Sodium Oxybate
RS-450	Impurity Reference Standard, Gamma-Butyrolactone
003900B	Label, Unprinted, Thermal Transfer
595371	Label Copy Specification, Xyrem (sodium oxybate) oral solution, bottle, front, TxIND, Catalytica
595372	Label Copy Specification, Xyrem (sodium oxybate) oral solution, bottle, back, TxIND, Catalytica
542593	Label Copy Specification, Xyrem (sodium oxybate) oral solution, Patient Use Instructions, Catalytica
542594	Label Copy Specification, Xyrem (sodium oxybate) oral solution, unit carton, TxIND, Catalytica
X1468	Label Copy Specification, Xyrem, Shipper X1467, Catalytica
014549	Label Copy Specification Xyrem, Carton Security (Unprinted), Catalytica

APPENDIX C

Return Material Authorization (RMA)

For material return, Catalytica operates a paperless, computer-supported system. The following procedure will be followed:

1. ORPHAN can request return authorization by calling Catalytica at 252-707-2484 and requesting the “Customer Service Department”.
2. Catalytica will issue a material return authorization number generated by its quality performance database according to standard work practices in effect within Catalytica at that time.
3. Catalytica will organize transport of material through coordination with ORPHAN. The appropriate contact will be given by ORPHAN at the time of request for return of material.
4. Upon receipt of returned material, Catalytica will send a confirmation of this to the designated contact at ORPHAN.

APPENDIX D
PRODUCT PRICE ESTIMATES
according to Section 7.1

Tiered pricing for Xyrem 200ml

Volume Breaks Unit Price	Conversion	Materials	Total
< 300,000 units/year	.95	2.49	3.44
300,000 to 1,000,000 units/year	.87	2.29	3.16
> 1,000,000 units/year	.70	2.11	2.81

The following assumptions apply:

- Volume price breaks based on annual production
- 7 year Commercial Supply Agreement
- Subject to annual price increase specified in commercial supply agreement
- DEA Schedule CIII with ARCOS reporting
- Sodium Oxybate supplied by Orphan
- Orphan to supply C of C on Sodium Oxybate
- Manufactured four times per year or once per quarter (campaign)
- Minimum of three batches per campaign
- Each additional campaign will carry a setup charge of $ 15,500
- Manufacturing batch size of 1,000 gallon / ~15,360 200ml bottles
- To be ordered in full batch size quantities
- Batches shipped within 30 days of Catalytica issuing C of C/C of A
- Packaging components
    1. Bottle, plastic 8 oz
    2. Screwcap, 24mm/400 C/R
    3. Front bottle label, 16mm width x 70mm height
    4. Security label
    5. Carton, 76.2mm length x 57.15mm width x 158.75mm depth
    6. Insert, one page/single sided
    7. Tubing, PVC, printed, 54mm, R/F
    8. Press-In bottle adapter (PIBA)
    9. Exacta med dispenser
    10. Shipper, unprinted
    11. Pressure sensitive tape
    12. Bar code label
    13. Thermal label
    14. Shipper label

APPENDIX E

Regulatory Support

Attend all Catalytica project team meetings

Provide the following documents to ORPHAN'S regulatory affairs department to support submissions under the Agreement:

- Copies of applicable executed batch records
- Copies of blank master production batch records
- Database printout of analytical results for drug substance, inactive ingredients, and drug products
- Stability database printout of stability data and stability protocol
- Copies of Catalytica analytical standards (specifications and testing instructions) for drug substance, inactive ingredients and drug product
- Catalytica official name, address and establishment registration number
- Certificate of cGMP compliance
- Debarment certification
- Submission-ready packaging description
- Submission-ready environmental assessment categorical exclusion (when appropriate)

Perform regulatory review of the above-listed documents. Unless noted otherwise, such documents will not be suitable for submission to Regulatory Agencies.

Regulatory Consulting

Act as on-site coordinating resource to Catalytica scientists regarding CMC issues for the project

Act as point of contact between ORPHAN regulatory affairs department and Catalytica regarding issues that impact registration of CMC information

Keep ORPHAN regulatory affairs informed of all CMC regulatory issues regarding Catalytica's manufacture of the Product

Agree on final documentation deliverables to support regulatory submissions

Provide CMC regulatory advice regarding strategy/documentation to support regulatory submissions

APPENDIX F
Quality Agreement

INTERCOMPANY QUALITY AGREEMENT

ORPHAN MEDICAL, INC.
13911 Ridgedale Drive, Suite 475
Minnetonka, Minnesota 55305
(hereafter called "ORPHAN")

Approved by: /s/ Randall Tlachac Date: 6/12/00
Director, Quality Assurance, ORPHAN

AND

Catalytica Pharmaceuticals, Inc.
Greenville, North Carolina
(hereafter called "C*P")

Approved by: /s/ K.S. Manning Date: 14 June 2000
Vice President, Quality Operations, C*P

The Products and Drug Substance Listed in Appendix
(hereafter called "the PRODUCTS")
are subject to the following conditions:

Section	TABLE OF CONTENTS (Cont'd)	Page

1. QUALITY AGREEMENT

1.1 Purpose

1.1.1 This agreement defines the roles and responsibilities for Catalytica Pharmaceuticals (C*P) Quality Operations in providing services to ORPHAN.

1.1.2 This agreement also defines how C*P Quality Operations and ORPHAN Quality Department will interact with each other.

1.2 Relationship to Definitive Agreement

1.2.1 This agreement shall be incorporated within and constitute a part of the Definitive Agreement between the two companies.

1.2.2 In the event of a conflict between any of the provisions of the Quality Agreement and the Definitive Agreement, the provisions of the Definitive Agreement shall govern.

2. PRODUCTS

2.1 The PRODUCTS prepared for ORPHAN by C*P are described in Appendix I.

3. ADMINISTRATIVE INFORMATION

3.1 ORPHAN contact names: See Appendix II

3.2 C*P contact names: See Appendix II

3.3 Emergency contact names and numbers, during and outside working hours:

ORPHAN
Randall Tlachac

Director Quality
Assurance
Work: (612)513-6998
Home: (612) 557-0382

CATALYTICA

Ken Manning, Ph.D
Vice President, Quality
Operations Work: (252) 707-2104
Beeper: (252) 551-1262

4. DURATION OF AGREEMENT

The agreement will expire with termination of the Definitive Agreement. The agreement can be modified as needed with the written approval of both parties.

5. MANUFACTURING GMP COMPLIANCE

5.1 General

5.1.1 The manufacturing operations for the PRODUCTS to be performed by C*P are defined in the Definitive Agreement.

5.2 Premises

5.2.1 C*P will perform required operations for manufacturing activities at the Greenville site.

5.2.2 The premises and equipment used to manufacture the PRODUCTS will meet or exceed current regulatory requirements.

5.2.3 The production of the PRODUCTS will be conducted in a suitably controlled environment and such facilities will be regularly monitored for parameters critical to the process to demonstrate compliance with applicable GMP guidelines, and any disclosed conditions registered in the manufacturing authorization.

5.2.4 C*P will maintain controlled access to the premise.

5.3 GMP Guidelines

5.3.1 The principles detailed in the US Current Good Manufacturing Practices (21 CFR 200, 211, and 600) and the Rules Governing Medicinal Product in The European Community—Volume IV Good Manufacturing Practice for Medicinal Products Guidelines will cover the standards of manufacture of the PRODUCTS, as well as, the product specifications and any applicable product license or pharmacopoeia or formulatory requirements.

5.4 Materials

5.4.1 C*P will use only chemical materials, packaging, and labeling components approved by ORPHAN and tested in accordance with the documentation reviewed and approved by ORPHAN.

5.4.2 Materials procured by C*P

5.4.2.1C*P is responsible for ensuring that all DRUG SUBSTANCES, materials, and components procured by C*P for use in the PRODUCTS are in full compliance with the specifications listed in the documentation reviewed and approved by ORPHAN.

5.4.2.2 C*P is responsible for ensuring that all materials are stored properly, used correctly, appropriately tested upon receipt, and traceable to the relevant Certificate of Analysis for the materials.

5.4.2.3 C*P is responsible for auditing and qualifying vendors of drug substances used in PRODUCTS and will provide ORPHAN with a Certificate of Conformance statement for such vendors when requested.

5.4.3 Materials Provided by ORPHAN for C*P

5.4.3.1 ORPHAN is responsible for ensuring that all materials and components provided by ORPHAN for use in the PRODUCTS are in full compliance with the specifications registered. ORPHAN will provide C*P a Certificate of Conformance statement for the vendors that ORPHAN is responsible for qualifying.

5.5 Master Production Records

5.5.1 C*P may transcribe the manufacturing information (i.e., formulation, filing work order, packaging work order) into its own format and may obtain written approval from ORPHAN for each document version before manufacturing. However, agreed upon changes to documentation will be handled as outlined by Change Management (see section 10) of this agreement.

5.6 Standard Operating Procedures

5.6.1 C*P is responsible for maintaining any SOPs required to manufacture, test, and store the PRODUCTS at C*P in accordance with applicable GMP guidelines.

5.7 Batch Numbers

5.7.1 The convention for the C*P “Batch Identification Number” (BIN) is as follows:

- The first digit of the BIN is the last number of the year that the working formula was issued or the labwork was requested.
- The second digit of the BIN is the letter that corresponds to the month that the working formula was issued or the labwork was requested. The letter assignment is as listed for the following years:

From 1997 through 2006	
A = January	G = July
B = February	H = August
C = March	I = September
D = April	J = October
E = May	K = November
F = June	L= December

From 2007 through 2016	
M = January	T = July
N = February	U = August
O = March	W = September
P = April	X = October
R = May	Y= November
S = June	Z= December

- The third through the sixth digits are four sequential numbers that are assigned from the reserved number series (1200 to 2599) designated for routine pharmaceutical production.

5.8 Dates of Manufacture and Expiration

5.8.1 Date of Manufacture - C*P will allocate the Date of Manufacture based on the completion of compounding the PRODUCT.

5.8.2 Expiration Date - C*P will calculate the expiry date from the Date of Manufacture using the currently approved expiry period. The expiration date will be the last day of the month computed above.

5.9 Manufacturing and Equipment Data

5.9.1 C*P is responsible for keeping records of equipment usage (previous PRODUCT produced in non-dedicated equipment), cleaning, and any maintenance/calibration performed.

5.10 Storage and Shipment

5.10.1 Storage - C*P will store the PRODUCTS under conditions approved by ORPHAN as listed in the specifications. C*P will ensure that during storage before shipping of the PRODUCTS that appropriate controls are in place to ensure no interference, theft, product contamination, or admixture with any other materials. ORPHAN will provide details of any labeling requirements and container sealing and integrity.

5.10.2 Packaging and Labeling for Transit - The PRODUCTS will be labeled and packaged for transit as per ORPHAN.

5.10.3 Mixing of PRODUCTS - C*P will maintain proper segregation of the PRODUCTS according to systems reviewed and approved by ORPHAN.

5.10.4 Shipment of Product to ORPHAN - Only approved, finished (unless required by ORPHAN), labeled PRODUCTS will be shipped by C*P to ORPHAN. Any shipment of product from C*P which is Unapproved or under Quarantine requires prior written consent by the ORPHAN'S Quality Unit. This authorization will be on a lot by lot basis.

6. QUALITY CONTROL

6.1 General

6.1.1 The testing activities for the PRODUCTS are to be performed by C*P as defined in the Definitive Agreement. In general, C*P is responsible for final product assays and product release.

6.2 Materials supplied by C*P

6.2.1 Quality control of materials supplied by C*P will be undertaken by C*P.

6.3 In-Process and Finish Product Testing

6.3.1 C*P will perform all in-process and finished product testing using approved specifications and methods of analysis listed in the Definitive Agreement.

6.3.2 A C*P Qualified Person/QA Representative will sign a Certificate of Conformity confirming that the product has been manufactured, packaged, tested, and meets the requirements of the Master Batch Record and Drug Product Specification. The current release documentation information can be found in Appendix III.

6.3.3 ORPHAN may perform testing to confirm the C*P data. ORPHAN may perform confirmatory testing during the initial term of the agreement to validate the C*P data. Periodically thereafter, ORPHAN may test material to confirm the C*P data. Dispute resolutions in conflicting test data will be handled per Section 9.

6.3.4 ORPHAN may perform release testing at a contract laboratory. Copies of all related documentation will be provided to C*P upon request to support final release.

6.4 Retained Samples

6.4.1 Active Ingredients - C*P will retain samples of the active ingredients as agreed between C*P and ORPHAN. The amount of sample retained will be twice the quantity required to carry out all of the tests required to determine if the material meets its specifications.

6.4.2 Products - C*P will retain samples of the PRODUCTS for at least one year beyond the expiry period. The amount of sample retained will be twice the quantity required to carry out all of the tests required to determine if the material meets its specifications.

6.5 Routine Stability Program

6.5.1 ORPHAN is responsible for maintaining a Stability Program and will request samples from Drug Product lots to be placed on stability.

6.6 Out-of-Specification (OOS) Investigations

6.6.1 C*P is responsible for investigating any testing performed by C*P that fails to meet specifications. Each investigation will be reviewed by C*P’s designated Quality person per internal SOPs, and will comply with Section 7.1 (Deviations and Investigations) of this agreement. C*P will inform Orphan of all Phase I OOS

results and any subsequent retest results. C*P will inform ORPHAN of all confirmed OOS (Phase II) Investigations prior to their resolution and final determination.

6.7 Contract QC Laboratories

6.7.1 ORPHAN is responsible for ensuring the compliance of any QC lab contracted to perform testing of the PRODUCTS used in the manufacture of the PRODUCTS.

7. QUALITY ASSURANCE

7.1 Deviations and Investigations

7.1.1 Deviations - Any deviation from the process during manufacture must be carefully explained and documented in the batch records, justified, and approved by C*P Quality Assurance and Production Management and included in the document package. ORPHAN will be informed at the time of all PFERs and reserves the right to participate in the investigation. Deviations will be processed per C*P SOP “Pharmaceutical Process/Formulation Exception Report (PFER)”.

7.1.2 C*P will notify ORPHAN of any batch of PRODUCTS rejected by C*P.

7.1.3 C*P will notify ORPHAN immediately, in writing, if any problems are discovered that may impact PRODUCTS batch(es) previously shipped to ORPHAN.

7.1.4 Some deviations/failures may require additional testing to be performed as agreed by both parties.

7.2 Batch Disposition

7.2.1 For each batch, C*P will provide the documentation required in Appendix III.

7.2.2 Certificate of Compliance/Analysis

7.2.2.1 C*P is responsible for ensuring and certifying that the PRODUCTS have been manufactured according to the specifications/procedures documented in the Master Production Records.

7.2.2.2 C*P Qualified Person/QA Representative will sign a Certificate of Compliance confirming that the PRODUCTS have been manufactured, packaged, tested and stored according to the requirements of the Master Production Record and the Drug Product Specification.

7.2.2.3 C*P will provide a Certificate of Analysis indicating the test result from each test performed.

7.3 Product Release

7.3.1 Release of the PRODUCTS is the absolute responsibility of ORPHAN Quality and will be undertaken by ORPHAN based on ORPHAN'S internal procedures, the full document package provided by C*P, and completion of any release testing required by ORPHAN Quality Control.

7.3.2 Any problem discovered by ORPHAN likely to cause rejection of the PRODUCTS will be communicated to C*P within 30 days from receipt of the full release documentation package (see Appendix III).

7.4 Product Complaints and Recalls

7.4.1 Product Complaints - ORPHAN is responsible for receiving and initially investigating any PRODUCTS complaints. ORPHAN will notify C*P of any problems thought to be due to manufacture, which are found during the distribution of the PRODUCTS. When requested by ORPHAN, C*P will promptly perform investigations for these problems. Investigation reports will be forwarded to ORPHAN within 30 days.

7.4.2 Product Recall - ORPHAN is responsible for instituting a PRODUCTS recall due to any defect considered sufficiently serious. ORPHAN will notify C*P of any recall which may be due to the manufacturing of PRODUCTS. C*P will provide a rapid initial response, perform investigations and provide a full report within ten working days.

7.5 Records Retention

7.5.1 C*P will retain, at a minimum, batch production records for the PRODUCTS and materials for seven years.

7.6 QA Presence in the Manufacturing Facility

7.6.1 C*P will maintain adequate QA presence and permit ORPHAN'S presence in the manufacturing facility during the manufacture of the PRODUCTS to ensure compliance with applicable GMPs.

8. REGULATORY ;

8.1 Regulatory Inspections

8.1.1 C*P will immediately inform ORPHAN of any regulatory inspections that may involve the PRODUCTS and permit a representative of ORPHAN Quality to be present at such inspections, if required by ORPHAN.

8.1.2 C*P will secure ORPHAN'S approval prior to making any commitment to a regulatory agency regarding ORPHAN'S PRODUCTS.

8.1.3 Additionally, C*P will immediately forward any regulatory correspondence on the PRODUCTS to ORPHAN.

8.1.4 ORPHAN will inform C*P in writing of any regulatory issue that impacts C*P's ability to manufacture the PRODUCTS.

8.2 Regulatory Actions

8.2.1 ORPHAN will notify C*P of any regulatory actions on the PRODUCTS that may impact C*P.

8.2.2 C*P is responsible for supporting all batch record investigations associated with regulatory actions.

8.2.3 C*P agrees to supply ORPHAN with any manufacturing, testing, or storage data within 48 hours, if requested, as the result of a regulatory inspection, or a potential regulatory exposure such as a recall or significant product complaint.

8.3 Regulatory Affairs

8.3.1 ORPHAN is responsible for ensuring all appropriate regulatory filings and export documentation are filed with Regulatory Agencies prior to shipment/human administration.

8.3.2 ORPHAN will be responsible for making final decisions regarding CMC regulatory strategy.

8.3.3 ORPHAN will provide a copy of final Regulatory Submissions to C*P Regulatory Affairs for reference during inspections.

8.4 Right to Audit

8.4.1 C*P will allow representatives of ORPHAN Quality to have access to relevant manufacturing, warehousing, laboratory premises, and records for audit purposes listed below in 8.4.2 through 8.4.4. ORPHAN representatives will be escorted at all times by C*P personnel.

8.4.2 ORPHAN will give C*P a 30 day notification for all planned audits.

8.4.3 C*P will permit representatives of ORPHAN Quality to conduct preparatory audits either for initiation of GMP manufacture of the PRODUCTS or for preapproval inspections (PAI).

8.4.4 C*P will permit representatives of ORPHAN Quality to conduct audits to address significant product quality problems.

8.4.5 C*P will permit representatives of ORPHAN Quality to perform one standard GMP compliance audit per year not to exceed three working days and two groups of two auditors each. This includes audits required by ORPHAN'S commercial partners.

8.5 Audit Closeout

8.5.1 An exit meeting will be held with representatives of C*P and ORPHAN to discuss significant audit observations.

8.5.2 ORPHAN will provide a written report of all observations within 30 days to C*P. Within 30 days of the audit report receipt, C*P will provide a written response to all findings that details corrective action to be implemented. C*P will follow up to ensure that all corrective actions are implemented.

9 DISPUTE RESOLUTION

9.1 Non-Conformity Dispute

9.1.1 In the event that a dispute arises between C*P and ORPHAN in the nonconformity of a batch of the PRODUCTS, the heads of Quality from both companies shall in good faith promptly attempt to reach an agreement. Whatever the outcome, ORPHAN Quality retains the absolute right to determine product release status. Financial liability is determined in the Definitive Agreement.

9.2 Test Result Dispute

9.2.1 In the event that a dispute arises between C*P and ORPHAN in the testing performed by C*P for the PRODUCTS, the resolution will proceed in stages. The first stage requires direct communication between analysts from both parties to determine that the methods of analysis are the same and are being executed in the same manner at both sites. Second, carefully controlled and split samples should be sent from one site to another in an attempt to reach agreement. Should there be a failure to achieve resolution, analysts from both parties will be required to meet to work through the analysis of a mutually agreeable sample. If these actions fail to achieve resolution, and only after these avenues have been exhausted, a qualified referee laboratory will be used to achieve resolution. This laboratory must be agreeable to both parties prior to use. The results from this referee laboratory will be used as final authority to determine responsibilities, but whatever the outcome, ORPHAN retains the right to determine product release status. Financial liability is determined in the Definitive Agreement.

10. CHANGE MANAGEMENT

10.1 Controlled Documentation

10.1.1 All manufacturing, testing, and storage operations performed by C*P for the PRODUCTS will have ORPHAN Quality review and written approval within five business days of notification. ORPHAN'S Quality review and approval signifies the conformance of C*P documents to ORPHAN'S CMC regulatory submissions.

10.1.2 Any significant changes will be mutually agreed upon in writing prior to implementation. All required regulatory approvals will be obtained prior to implementation.

10.1.3 ORPHAN shall provide to C*P a list of all documents referenced in the CMC submissions which are subject to Change Control. These documents will be required to be approved by both ORPHAN and C*P, and both parties agree to subject these documents for approval per Change Control. ORPHAN shall be responsible for meeting regulatory submission requirements based on the status of these documents.

10.2 Change Control

10.2.1 Changes to the controlled documents or to validated equipment and systems specific to the PRODUCTS must have ORPHAN Quality written approval, prior to implementation.

10.2.2 Administration changes to the controlled documents (e.g., typo corrections, formatting) do not require ORPHAN Quality written approval prior to implementation, but these changes must be submitted to ORPHAN Quality in a timely manner for review and approval.

11. PRODUCT AND PROCESS VALIDATION

11.1 Process - C*P is responsible for ensuring that the manufacturing process is validated. The validation should ensure that the process is capable of consistently achieving the PRODUCTS acceptance specification.

11.2 Cleaning Validation - C*P is responsible for ensuring that adequate cleaning is carried out between batches of different products to prevent contamination. ORPHAN will provide information (i.e. LD50, toxicity, solubility, batch size, fill volume, product min dose/70Kg patient) to establish cleaning limits. The cleaning procedure and analytical methodology will be reviewed before the first product batches are made.

11.3 Equipment, Computer, Facility, and Utilities Qualification — C*P is responsible for all equipment, computer, facility, and utility qualification activities associated with the PRODUCTS.

11.4 Laboratory Qualification - C*P is responsible for ensuring that all laboratories are in compliance with applicable GMP guidelines. If analytical work is performed at C*P, then ORPHAN will also provide any existing analytical documentation to assist in methods transfer or methods validation. In addition, if analytical work is not performed at the Greenville site, C*P may elect to perform an audit on vendors to be used for analytical testing appropriate to manufacture of the PRODUCTS.

12. ANNUAL PRODUCT REVIEW, ANNUAL REPORT AND DRUG LISTING

12.1 Annual Product Review

12.1.1 C*P will perform an Annual Product Review for the PRODUCTS and will issue a report to ORPHAN. This report will cover all manufacturing, testing, and storage activities performed by C*P. It will be a review of any changes at C*P in the manufacturing, testing, storage or validation of the PRODUCTS in the previous calendar year and a summary of lots made, released, and rejected. Also, control charting or trend analysis of key product parameters will be performed. Any abnormalities will be explained in the annual review.

12.1.2 ORPHAN is responsible for preparing any Annual Report as required by applicable regulations, including 21 CFR314.7(g)(3), 314.81(b)(2), and/or 601.12(d), (f)(3). At least 90 calendar days before the Annual Report due date, ORPHAN shall request in writing from C*P the chemistry, manufacturing, and controls data required for submission of the Annual Report. C*P will provide the requested information to ORPHAN within 30 days.

12.2 Drug Listing

12.2.1 C*P is responsible for drug listing as the manufacturer of the PRODUCTS, while ORPHAN is responsible for drug listing as the distributor of the PRODUCTS. ORPHAN will provide C*P with all required information needed by them for their listing. ORPHAN will notify C*P of the scheduled PRODUCTS launch date.

APPENDIX I

The PRODUCTS

XYREM ORAL SOLUTION

APPENDIX II

List of Quality Contacts
(name, phone, fax, e-mail)

ISSUE	ORPHAN	C*P
Product Release	Brian Miller, Ph.D Ph: (612) 513-6978 Fax:(612)541-9209 bmiller@orphan.com	Jason Williams Ph: (252) 707-2182 Fax: (252) 707-7306 jwilliams@catalytica-pharm.com
QC Testing	Brian Miller, Ph.D Ph: (612) 513-6978 Fax:(612)541-9209 bmiller@orphan.com	Kirit Amin Ph: (252) 707-2372 Fax: (252) 707-7027 kamin@catalytica-pharm.com
Investigations	Brian Miller, Ph.D Ph: (612) 513-6978 Fax:(612)541-9209 bmiller@orphan.com	Madhukar Mehta Ph: (252) 707-2004 Fax: (252) 707-2134 mmehta@catalytica-pharm.com
Regulatory Affairs	Nancy Teasdale Ph: (612) 513-6975 Fax:(612)541-9209 nteasdale@orphan.com	Beverly Lewis Ph: (252) 707-7913 Fax: (252) 2326 blewis@ catalytica-pharm.com
Validation	Brian Miller, Ph.D Ph: (612) 513-6978 Fax: (612) 541-9209 bmiller@orphan.com	Frank Anasti Ph: (252) 707-2651 Fax: (252) 707-7678 fanasti@catalytica-pharm.com
Compliance Audits	Randall Tlachac Ph: (612) 513-6998 Fax: (612) 541-9209 rtlachac@orphan.com	Madhukar Mehta Ph: (252) 707-2004 Fax:(252)707-2134 mmehta@catalytica-pharm.com
Product Complaints	Brian Miller, Ph.D Ph: (612) 513-6978 Fax:(612)541-9209 bmiller@orphan.com	Madhukar Mehta Ph: (252) 707-2004 Fax:(252)707-2134 mmehta@catalytica-pharm.com
Change Management	Brian Miller, Ph.D Ph: (612) 513-6978 Fax:(612)541-9209 bmiller@orphan.com	Madhukar Mehta Ph: (252) 707-2004 Fax:(252)707-2134 mmehta@catalytica-pharm.com

APPENDIX III Release

Documentation

The Batch/Lot Release Document Package will include a Certificate of Analysis and Certificate of Compliance.

Certificate of Analysis (COA)

This document will include the name of the PRODUCT, the batch number and the date of manufacture. The COA will list the In-Process QC tests performed by C*P and actual test results. The COA will also list the product release QC tests performed by C*P and actual test results.

Certificate of Compliance (COC)

This document will attest to the fact that the batch of PRODUCTS was made in accordance with all applicable regulations, product licenses, and company policies. This document will include the batch quantity approved, the batch yield, and the expiration date. It will also include a listing of all manufacturing variances and/or incidents for the batch.

Catalytica

Pharmaceuticals

November 9, 2000

Mr. Randall J. Tlachac
Orphan Medical
13911 Ridgedale Drive
Suite 475
Minnetonka, MN, 55305

Dear Randy,

I am pleased to provide this revised commercial pricing for Xyrem Oral Solution. The new pricing includes the requested component/packaging changes. I have also attached an amended "APPENDIX D" which includes the pricing, packaging details and related assumptions. All raw materials and packaging components are included, except the sodium oxybate bulk active.

Commercial Pricing

Volume Breaks	Conversion	Materials	Total Unit Price
< 300,000 units/year	1.07	3.43	4.50
300,000—1,000,000 units/year	.98	3.19	4.17
> 1,000,000 units/year	.80	3.02	3.82

- Volume price breaks based on annual production
- Pricing is based on the assumptions listed on page 2 of this letter
- Any change in the assumptions listed on page 2 of this letter will require that pricing be re-evaluated

Please indicate Orphan's approval/acceptance of the above commercial pricing by having the appropriate individual sign and date in the space provided below.

If you have any questions or need further clarification, please do not hesitate to call.

Sincerely,

/s/ David Smithwick
David Smithwick, Contract Manager

/s/ Randall Tlachac — 12/5/00
Orphan Representative — Date

Director, Quality Assurance
Title

cc: Marie Mayo Lori Thigpen File (2)

Proposal Valid for 60 days
Confidential

ASSUMPTIONS

- Volume price breaks based on annual production
- 7 year Commercial Supply Agreement
- Subject to annual price increase specified in commercial supply agreement
- DEA Schedule CIII with ARCOS reporting
- Sodium Oxybate supplied by Orphan
- Orphan to supply C of C on Sodium Oxybate
- Manufactured four times per year or once per quarter (campaign)
- Minimum of three batches per campaign
- Each additional campaign will carry a setup charge of $15,500
- Manufacturing batch size of 1,000 gallon /~15,360 200ml bottles
- To be ordered in full batch size quantities
- Batches shipped within 30 days of Catalytica issuing CofC/CofA
- Packaging components
    1. Bottle, plastic 8 oz
    2. Screwcap, 24mm/400 C/R
    3. Front bottle label, 60mm width x 70mm height
    4. Security label—(2) top and bottom of carton
    5. Carton, 98.42mm length x 93.66mm width x 156.37mm depth
    6. Insert, one page/single sided
    7. Tubing, PVC, unprinted, 54mm, R/F
    8. Press-In bottle adapter (PIBA)
    9. Exacta med dispenser
    10. Shipper, Preprinted
    11. Pressure sensitive tape
    12. Bar code label
    13. Vial (2)
    14. Screwcap (for Vial) (2)

Proposal Valid for 60 days
Confidential

AMENDMENT NO. 2
TO
XYREM SUPPLY AGREEMENT

THIS AMENDMENT NO. 2 dated this 19th day of **August 2002** (this "Amendment") to Xyrem Supply Agreement is made and entered into as of the 19th day of August, 2002, by and between **Orphan Medical, Inc.,** a Delaware corporation ("Orphan"), and **DSM Pharmaceuticals, Inc**. (formerly, Catalytica Pharmaceuticals, Inc.), a Delaware corporation ("DSM"):

W I T N E S S:

WHEREAS, Orphan and Catalytica Pharmaceuticals, Inc. have previously executed a Xyrem Supply Agreement, dated June 30, 2000, and amended by Amendment No. 1 dated November 9, 2000 (collectively, the "Agreement"); and

WHEREAS, Catalytica's interest in, and obligations under, the Agreement have been acquired and assumed by DSM; and

WHEREAS, DSM and Orphan desire to amend the Agreement as set forth in this Amendment;

NOW, THEREFORE, for and in consideration of the premises, the respective commitments and undertakings of Orphan and DSM set forth in this Amendment, and other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, Orphan and DSM hereby agree as follows:

1. Unless otherwise defined in this Amendment, capitalized terms used in this Amendment shall have the meanings ascribed to them in the Agreement.

2. Effective as of the date of this Amendment, the Product Price shall be as set forth on Appendix D to this Amendment, which Appendix D shall supersede Appendix D to the Agreement in all respects.

3. Section 7.3 of the Agreement shall be amended in its entirety and shall hereafter read as follows:

"7.3 Product Price Adjustments. The Product Price, as specified on Appendix D, shall be subject to adjustment from time to time as follows:

(a) The conversion component of the Product Price, as set forth on Appendix D, shall be adjusted for each Contract Year, commencing with the Contract Year beginning in 2003, and shall be equal to the conversion component

of the Product Price for the prior Contract Year increased by a percentage amount equal to the percentage increase in the Producer Price Index for Finished Goods, Pharmaceutical Preparations, Ethical (Prescription), series code PCU-2834 #1, issued by the Bureau of Labor Statistics, U.S. Department of Labor, or comparable successor index, during the twelve (12) month period ending with the most recent month for which published monthly statistics are available as of the first day of such new price year ("PPI"). Increases in the conversion component Product Price pursuant to this Section 7.3(a) shall become effective as of the start of the appropriate Contract Year.

(b) The materials component of the Product Price shall also be subject to adjustment from time to time as follows:

(i) Effective as of the start of each Contract Year, commencing with the Contract Year beginning in 2003, the materials component may be increased by DSM by the amount of (A) the increase in costs incurred by DSM to third party suppliers for materials incorporated into the Product over the cost of such materials to DSM in the prior Contract Year, plus (B) a margin/overhead factor equal to twenty-five percent (25%) of such cost increase. DSM shall provide Orphan with written notification of any increase in the materials component of the Product Price at least sixty (60) days prior to the start of the Contract Year to which such increase applies. Orphan shall have the option, upon reasonable notice to DSM, to appoint an independent financial auditor to verify the price increase; and DSM shall make available to the auditor appropriate documentation substantiating DSM's cost increase. The auditor shall be subject to the confidentiality requirements of Article 14 and shall only disclose to Orphan the auditor's opinion as to whether or not the price increase is consistent with the documentation of increased material costs. If there is any disagreement with respect to any price increase, the dispute shall be resolved in accordance with Article 18.

ii. Notwithstanding the provisions of subpart (i), if, during any Contract Year, DSM experiences an increase in the aggregate cost of the Materials incorporated into the Product of more than ten percent (10%) from the start of such Contract Year, then DSM shall be entitled to increase the Materials component of the Purchase Price during such Contract Year upon sixty (60) days prior written notification by utilizing the protocol set forth in subpart (i)."

4. Section 15.1 of the Agreement shall be amended in its entirety and shall hereafter read as follows:

"15.1 Unless sooner terminated pursuant to Article 16 below, the initial term of this Agreement shall commence on the Effective Date and end upon the

expiration of the third (3rd) Contract Year. Unless otherwise terminated pursuant to Article 16 below, this Agreement shall be automatically renewed for additional one (1) year terms after the end of the initial term, unless either party provides written notice to the other at least twelve (12) months prior to the expiration of the initial or any extended term, as the case may be, that this Agreement shall expire at the end of the initial term or such renewal term, as the case may be. All references herein to "term of this Agreement" shall be deemed to include both the initial and any extended terms."

5. Article 16 of the Agreement is amended by relabeling current Sections 16.2 and 16.3 as Sections 16.3 and 16.4, respectively, and by adding a new subsection 16.2, which shall read as follows:

"16.2 Termination by Orphan. In addition to any other legal or equitable remedies that it may have, Orphan may terminate this Agreement prior to the expiration of the term of this agreement upon written notice to DSM in the event that (a) DSM is cited for, or receives any warnings about, any material compliance deficiencies by the FDA that could adversely affect the manufacturing or sales of the Product, and the deficiencies noted in such FDA citation or warning are not cured by DSM to Orphan's reasonable satisfaction within 180 days after receipt by DSM of such warning or citation; or (b) the FDA initiates any compliance action against DSM that directly affects the manufacturing or testing of Product by DSM under the Agreement." During this period DSM agrees to manufacture product and fill all Purchase Orders submitted as requested by ORPHAN.

6. Section 16.3(b) of the Agreement (formerly Section 16.2(b)) shall be amended by restating the lead-in clause of section 16.3(b) to read as follows:

"Other than termination by ORPHAN pursuant to Section 16.1(a) or Section 16.2 hereof . . ."

7. As amended pursuant to this Amendment, the Agreement is hereby ratified and confirmed in all respects by each of DSM and Orphan as a legally enforceable agreement between them.

{Signatures on following page}

IN WITNESS WHEREOF, each of DSM and Orphan has caused this Amendment No. 2 to be executed by a fully authorized corporate officer as of the date first set forth above.

ORPHAN MEDICAL, INC.

By: /s/ John H. Bullion
Name/Title:

DSM PHARMACEUTICALS, INC.

By: /s/ Terence S. Novack
Terence S. Novack
Sr. Vice President of Commercial Operations

Appendix D

Product Commercial Pricing

Product Price is based on component costs represented in Letter dated March 11, 2002, attached.

Tiered pricing for Xyrem® Oral Solution 200ml

Volume Breaks Five (5) Batches per Run	Conversion	Materials	Total Unit Price
<300,000 units/year	$1.70	$4.77	$6.47
300,000 to 1,000,000 units/year	$1.46	$4.56	$6.02
>1,000,000 units/year	$1.29	$4.37	$5.66

Volume Breaks Three (3) Batches per Run	Conversion	Materials	Total Unit Price
<300,000 units/year	$1.75	$4.77	$6.52
300,000 to 1,000,000 units/year	$1.51	$4.56	$6.07
>1,000,000 units/year	$1.34	$4.37	$5.71

March 11, 2002

Mr. Randy Tlachac
Orphan Medical
13911 Ridgedale Drive, Suite 250
Minnetonka, Minnesota 55305

Dear Mr. Tlachac:

The purchasing department at DSM is working together with our vendors to obtain the best purchase price for components. The purchase price of the components for Xyrem® is in most cases higher than the pricing estimated by Orphan. We have listed below the actual purchase costs for the Xyrem® components paid (or to be paid) by DSM for component purchases to date as requested in your e-mail note dated 03/04/02.

Component Description	Purchase Costs Unit of Measure = each	Extended Purchase Costs
Bottle Plastic 8 oz.	$ 0.2400	$ 0.2400
Screwcap 24mm/400 CR	$ 0.0530	$ 0.0530
Tubing PVC (measured in meters)	$ 0.2610	$ 0.2610
Label Bottle	$ 0.0320	$ 0.0320
Carton plus gluing Medguide	$ 0.2631	$ 0.2631
Insert Prefold	TBD	$ 0.0607*
Medication Guide	$ 0.1331	$ 0.1331
PIBA	$ 1.4300	$ 1.4300
Exacta-Med Dispenser	$ 0.2100	$ 0.2100
Vial 20 Dram (**Requires 2 Vials**)	$ 0.2390	0.4780
Cap 20 Dram (**Requires 2 Caps**)	$ 0.0873	0.1746
Label Carton Security (**Requires 2 Labels**)	$ 0.1240	0.2480
Shipper x 15 Xyrem	$ 0.9480	$ 0.9480
Tape Press Sensitive Case Seal ($22.4000 per full roll)	$ 0.0020	$ 0.0020
Label Bar Code	$ 0.0370	$ 0.0370
TOTAL		**$ 4.5705**

* estimate

In the event that Orphan Medical elects to have DSM purchase from other vendors, not yet DSM qualified, Orphan Medical would accept all associated costs of changes that would be required to transition from the established vendors to new vendors for the Xyrem© components, including qualification audits, establishing new specifications and item numbers, all costs associated with machinability and line testing, and any other changes that would be required. If Orphan Medical negotiates lower prices, DSM will take every effort to negotiate these same prices with DSM suppliers.

As noted in previous correspondence, any last minute changes to components may impact the timeline for the commercial introduction of Xyrem® after FDA approval (anticipated April 9, 2002). The commercial pricing updates are due to Orphan Medical requirements as mandated by the FDA that a Medguide be included on the inside of the commercial carton and that the Medguide be referenced on the outside of the carton.

Call me if you have any questions (252-707-7322).

Sincerely,

/s/ Trudy Briley

Trudy Briley
Account Manager
Pharmaceutical Sales & Marketing

cc: Michel Deinum (DSM)
Terry Novak (DSM)
Lori Thigpen (DSM)
Bill Conway (DSM)
Collins Hines (DSM)
File (2)

AMENDMENT NO. 3
TO
XYREM SUPPLY AGREEMENT

THIS AMENDMENT NO. 3 dated this **21st** day of **March, 2005** (this "Amendment") to Xyrem Supply Agreement dated June 30, 2000 by and between **Orphan Medical, Inc**., a Delaware corporation ("ORPHAN"), and **DSM Pharmaceuticals, Inc.** (formerly, Catalytica Pharmaceuticals, Inc.), a Delaware corporation ("DSM"):

W I T N E S S:

WHEREAS, ORPHAN and DSM have previously executed the Xyrem Supply Agreement, dated June 30, 2000, as amended by Amendment No. 1 dated November 9, 2000, and Amendment No. 2 dated August 19, 2002 (collectively, the "Agreement"); and

WHEREAS, DSM and ORPHAN desire to amend the Agreement as set forth in this Amendment;

NOW, THEREFORE, for and in consideration of the premises, the respective commitments and undertakings of ORPHAN and DSM set forth in this Amendment, and other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, ORPHAN and DSM hereby agree as follows:

1. Unless otherwise defined in this Amendment, capitalized terms used in this Amendment shall have the meanings ascribed to them in the Agreement.
2. Effective as of the date of this Amendment, the Product Price and package configurations shall be as set forth in **Appendix D** to this Amendment, which Appendix D shall supersede Appendix D to the Agreement, and Appendix D to Amendment No. 2 to the Agreement, in all respects.
3. Section 4.2 of the Agreement shall be amended to read, in its entirety, as follows:

4.2 Manufacture and Supply

During each Contract Year of this Agreement, and subject to the provisions of Section 7.2 hereof as well as other provisions herein, ORPHAN agrees to purchase all of its requirements for the Product in the Territory from DSM, but no less than the minimum quantities of Product indicated below:

Year	ORPHAN's Minimum Purchase Quantity
2006	120,000 bottles
2007	120,000 bottles
2008	80,000 bottles

DSM shall manufacture the Product in accordance with the Specifications and applicable cGMP requirements, and shall package, label, and/or otherwise prepare the Product for bulk delivery to an ORPHAN-designated distribution site.

4. Section 5.1, "Forecasts", of the Agreement shall be amended in its entirety and shall hereafter read as follows:

5.1 Forecasts.

5.1.1 Long Term Forecast. Within thirty (30) days after the Effective Date, of this Amendment, ORPHAN shall deliver to DSM a non-binding three (3) year forecast of Orphan's quantity requirements for each Commercial Product and for each Contract Year during the Term (the "Long Term Forecast"). The Long Term Forecast shall thereafter be updated every six (6) months (as of June 1 and December 1) during the Term of this Agreement. If DSM is unable to accommodate any portion of the Long Term Forecast, it shall notify ORPHAN and the Parties shall agree on any revisions to the forecast.

5.1.2 Monthly Forecast. ORPHAN shall submit to DSM a written non-binding estimate of its monthly requirements for each Product for each of the next succeeding eighteen (18) months (the "Monthly Forecast"). The Monthly Forecast shall be updated monthly on the third (3rd) business day of the month, on an eighteen (18) month rolling basis. If DSM is unable to accept (i) quantities stated for any new month in the Monthly Forecast, or (ii) quantities in excess of previously forecasted quantities (collectively, the quantities in (i) and (ii) referred to as "Additional Quantities"), then DSM shall notify ORPHAN in writing within five (5) calendar days after receipt of the Monthly Forecast; otherwise such Additional Quantities shall

be deemed to have been approved and accepted by DSM. The Parties shall negotiate in good faith to resolve any issues in respect of the Additional Quantities, which DSM is unable to accept for any month(s) stated in the Monthly forecast, according to DSM's available capacity.

5.1.3 Firm Purchase Commitment. The forecast of the most current six (6) month period from the monthly Forecast required under section 5.1.2 shall always constitute a binding firm purchase commitment (the "Firm Purchase Commitment") which shall state in detail the quantities of Products ordered and the required delivery dates, and shall be binding on the Parties regarding Products to be purchased. The forecast for the remaining twelve (12) month period of the Monthly Forecast is for planning purposes only and shall not constitute a commitment to purchase or supply Product. In the event that ORPHAN does not ultimately purchase the forecast quantities for the Firm Purchase Commitment period, it shall be obligated to pay to DSM for any deficient quantities on the basis of the Product Price, less cost of materials which were, otherwise not utilized by DSM for production of Product as the result of Orphan's failure to purchase the required quantities. However, if DSM is unable for any reason other than, the failure of Orphan's designated vendors to provide API and/or Excipients, to supply the Firm Purchase Commitment to ORPHAN, ORPHAN shall not be obligated to pay for that portion of the Firm Purchase Commitment which DSM could not deliver. As of the end of each calendar year hereunder, if ORPHAN has failed to purchase the minimum annual quantity as set forth in Section 4.2, it shall likewise pay DSM for any deficient quantities on the basis set forth above in this Section 5.1.3.

5. Section 5.5 of the Agreement, Purchase Quantities, shall be amended to read, in its entirety, as follows:

5.5 Purchase Quantities. Each purchase order shall specify the quantity of units of Product being ordered. Quantities actually shipped pursuant to a given purchase order may vary from the quantities reflected in such purchase order by up to ten percent (10%) and still be deemed to be in compliance with such purchase order, *provided however*, that ORPHAN shall only be invoiced and required to pay for the quantities of Product which DSM actually ships to ORPHAN.

6. Section 6.2, Supply By DSM: This section is deleted in its entirety.

7. Section 6.3, "Manufacturing Loss": Financial liability related to API loss shall no longer be governed by Section 6.3. Financial liability shall be governed by section 10.5, as amended by this Amendment.

8. Section 7.3, "Annual Price Adjustment Notification", as referenced in Amendment 2 and the Agreement, shall be amended and hereafter read as follows

7.3 Product Price Adjustments. The Product Price, as specified on **Appendix D**, shall be subject to adjustment from time to time as follows:

(a) The conversion component of the Product Price, as set forth on Appendix D, shall be adjusted as of January 1 of each calendar year beginning January 1, 2006, and shall be equal to the conversion component of the Product Price for the prior calendar year, increased by a percentage amount equal to the percentage increase in the Producer Price Index for Finished Goods, Pharmaceutical Preparations, Ethical (Prescription), series code PCU-2834 #1, issued by the Bureau of Labor Statistics, U.S. Department of Labor, or comparable successor index, during the twelve (12) month period ending with the most recent month for which published monthly statistics are available as of the first day of such new price year ("PPI"). Increases in the conversion component Product Price pursuant to this Section 7.3(a) shall become effective as of January 1 of each calendar year for all shipment of Product during each such year.

(b) The materials component of the Product Price shall also be subject to adjustment from time to time as follows:

(i) Effective as of January 1, 2006 and each calendar year thereafter, the materials component may be increased by DSM by the amount of (A) the increase in costs incurred by DSM to third party suppliers for materials incorporated into the Product over the cost of such materials to DSM in the prior Contract Year, plus (B) a margin/overhead factor equal to twenty-five percent (25%) of such cost increase. DSM shall provide ORPHAN with written notification of any increase in the materials component of the Product Price at least sixty (60) days prior to the start of the calendar year to which such increase applies. ORPHAN shall have the option, upon reasonable notice to DSM, to appoint an independent financial auditor to verify the price increase; and DSM shall make available to the auditor appropriate documentation substantiating DSM's cost increase. The auditor shall be subject to the confidentiality requirements of Article 14 and shall only disclose to ORPHAN the auditor's opinion as to whether or not the price increase is consistent with the documentation of increased material costs. If there is any disagreement with respect to any price increase, the dispute shall be resolved in accordance with Article 18.

(ii) Notwithstanding the provisions of subpart (i), if, during any calendar year, DSM experiences an increase in the aggregate cost of the Materials incorporated into the Product of more than ten percent (10%) from the start of such calendar year, then DSM shall be entitled to increase the Materials component of the Purchase Price during such calendar year upon sixty (60) days prior written notification by utilizing the protocol set forth in subpart (i)."

9. Section 10.5, "Limitation of Liability and Claims, is deleted in its entirety and hereafter shall read as follow:

10.5 Limitation of Liability. Notwithstanding the foregoing warranties and representations and the further obligations of the Parties hereunder, in no event shall either Party be liable to the other Party for incidental, indirect, special, consequential or punitive damages, including without limitation any claim for damages based upon lost profits or lost business opportunity. Except for the obligations of indemnity as set forth in this Article 10 with respect to (i) claims for personal injury, illness or death resulting from use of or exposure to a Product supplied hereunder, and (ii) claims of patent infringement, which are not subject to the following limitation, aggregate damages for which either Party shall be liable to the other hereunder, including without limitation costs of API yield loss and/or rejected lots, shall not exceed, with respect to Product purchased and delivered during any Contract Year hereunder, (x) fifty percent (50%) of the aggregate revenues received from ORPHAN hereunder during such Contract Year or (y) two million dollars ($2,000,000), whichever is less. The foregoing limitations shall not apply if the damages otherwise subject to limitation result from gross negligence or willful misconduct.

10. Section 15.1 of the Agreement shall be amended in its entirety and shall hereafter read as follows:

15.1 Unless sooner terminated pursuant to Article 16 below, the initial term of this Agreement shall commence on the Effective Date and end on July 31, 2005. Thereafter, this Agreement shall continue in force and effect for an additional three (3) year term, ending on July 31, 2008 unless terminated earlier pursuant to Article 16 below.

11. Section 16.1 of the Agreement shall be amended by adding the following as a new Subsection (d):

(d) If either party, for any reason, elects to terminate this Agreement, in which case such party shall provide written notice thereof no less than twelve (12) months prior to the effective date of such termination.

12. Section 16.3(b) of the Agreement (formerly Section 16.2(b)) shall be amended by restating the lead-in clause of section 16.3(b) to read as follows:

"Other than termination by ORPHAN pursuant to Section 16.1(a) or Section 16.2 hereof, or termination by DSM pursuant to Section 16.1(d). . ."

13. The Agreement shall otherwise continue in force and effect according to its terms as herein amended; and the Agreement is hereby ratified and confirmed in all respects by each of DSM and ORPHAN as a legally enforceable agreement between them.

{Signatures on following page}

IN WITNESS WHEREOF, each of DSM and ORPHAN has caused this Amendment No. 3 to be executed by a fully authorized corporate officer as of the date first set forth above.

ORPHAN MEDICAL, INC.

By: /s/ Dayton T. Reardan
Dayton T. Reardan, Ph.D., RAC
Vice President of Regulatory Affairs

DSM PHARMACEUTICALS, INC.

By: /s/ Terence S. Novack
Terence S. Novack
Chief Marketing Officer

APPENDIX D

Product Commercial Pricing

Batch Price: Domestic Bulk Packaging

Description	Price
<300,000 units per year	$3.99

Batch Price: Export Bulk Packaging

Description	Price
<300,000 units per year	$3.96

Assumptions for Bulk Packaging (Domestic and Export):

1. Commercial price includes manufacturing, filling, and release requirements. The price includes bottle, cap, label, shipper and shipper label only
2. Assumes quarterly campaigns.
3. Assumes a three batch campaign minimum. Each additional campaign of 1 or more batches will carry a $15,500 set up charge.
4. Price does not include API. API to be supplied by ORPHAN Medical.

Batch Price: Domestic Current Package Configuration

Description – DSM Item #611	Price
Commercial Xyrem, < 300,000 per year	$6.60

Assumptions:

1. Currently approved package and product specifications.
2. Assumes quarterly campaigns.
3. Assumes a three-batch campaign minimum. Each additional campaign of one or more batches will carry a $15,500 set up charge.
4. DSM will not package this package configuration after July 31, 2005.
5. The terms and conditions of this Amendment and the Agreement do not apply to any request (Purchase Order and/or Forecast) for this product configuration received by DSM after May 1, 2005.
6. This price expires July 31, 2005.

Batch Price: Domestic New Terms

Description	Price
120,000 units	$8.10

Assumptions:

1. Commercial price includes manufacturing, filling, and release requirements. The price includes all primary and secondary components except for vial 20 dram and cap 20 dram.
2. Assumes quarterly campaigns.
3. Assumes a three-batch campaign minimum. Each additional campaign of 1 or more batches will carry a $15,500 set up charge.
4. Increased cost of combined carton and inserts, not included. Pricing will be amended when carton cost is available.
5. Assumes 3-year contract, beginning August 2005

EXHIBIT 10.43

Confidential: Execution Copy

SUPPLY AGREEMENT

Between
Jazz Pharmaceuticals, Inc.
and
Solvay Pharmaceuticals, Inc.
for
Fluvoxamine Maleate

SUPPLY AGREEMENT

This Supply Agreement (the "Agreement") is entered into as of the 31st day of January, 2007 (the "Effective Date"), by and between Jazz Pharmaceuticals, Inc., a Delaware corporation (together with its subsidiaries, "Jazz Pharmaceuticals"), and Solvay Pharmaceuticals, Inc., a Georgia corporation ("Solvay").

RECITALS

WHEREAS, Solvay is engaged in the manufacture of the active pharmaceutical ingredient fluvoxamine maleate;

WHEREAS, Jazz Pharmaceuticals and Solvay have entered into a License Agreement (the "License Agreement"), dated as of January 31, 2007, whereby Solvay transferred, assigned and licensed to Jazz Pharmaceuticals certain rights and interests in the pharmaceutical products referred to as LUVOX®-IR and LUVOX®-ER, as more fully described in the Assignment and License Agreement;

WHEREAS, in connection with the License Agreement, Jazz Pharmaceuticals wishes to have Solvay manufacture and supply API (as defined below) for use in the manufacture of LUVOX-IR and LUVOX-ER during the Term of this Agreement; and

WHEREAS, Solvay wishes to manufacture and supply Jazz Pharmaceuticals with the API on the terms and conditions set forth in this Agreement.

NOW, THEREFORE, in consideration of the mutual covenants and agreements set forth in this Agreement, and for other good and valuable consideration, the receipt of which is hereby acknowledged, the parties hereto agree as follows:

ARTICLE 1

DEFINITIONS

Capitalized terms used in this Agreement shall have the meanings ascribed to them in this Article 1 or as otherwise set forth herein. Unless the context indicates otherwise, the singular shall include the plural and the plural shall include the singular.

1.1 "Act" means the United States Food, Drug and Cosmetic Act, as amended from time to time, and the regulations promulgated thereunder.

1.2 "Affiliates" means a corporation or any other entity that directly, or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with, the designated party, but only for so long as the relationship exists. "Control" shall mean ownership of shares of stock having at least 50% of the voting power entitled to vote for the election of directors in the case of a corporation. Notwithstanding the foregoing, the owners of preferred stock (or common stock issued upon conversion thereof) of Jazz Pharmaceuticals such as financial institutions, venture capital funds and private equity investors shall not be its "Affiliates" for purposes of this Agreement.

1.3 “API” means fluvoxamine maleate conforming to cGMP, all applicable Laws and the API Specifications, as they may be updated from time to time in accordance with this Agreement or as required by applicable Regulatory Approvals.

1.4 “API Specifications” means the written specifications for the API as set forth in NDA# 21-519 and NDA# 22-033 as well as the corresponding Regulatory Approvals in the Territory.

1.5 “Batch” means a specific quantity of API that is intended to have uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture.

1.6 “Bulk API” means the API packaged in drums for delivery to a common carrier.

1.7 “Certificate of Analysis” means a certificate issued by the manufacturer of a lot or batch of a drug, which certificate contains such information as provided in the Quality Agreement (as defined below).

1.8 “cGMP” means current good manufacturing practices, as applicable, as described in:

(i) Parts 210 and 211 of Title 21 of the United States’ Code of Federal Regulations;

(ii) Division 2 of Part C of the Food and Drug Regulations (Canada);

(iii) EC Directive 91/356/EEC; and

(iv) the latest Health Canada, FDA and EMEA guidance documents pertaining to manufacturing and quality control practice, as updated, amended and revised from time to time and as applicable under the particular circumstances.

1.9 “EMEA” means the European Medicine Evaluation Agency or any successor European governmental agency performing similar functions with respect to pharmaceutical products.

1.10 “FDA” means the United States Food and Drug Administration or any successor United States governmental agency performing similar functions with respect to pharmaceutical products.

1.11 “Health Canada” means a section of the Canadian Government known as Health Canada and includes, among other departments, the Therapeutic Products Directorate and Health Products and Food Branch Inspectorate, or any successor Canadian governmental agency performing similar functions with respect to pharmaceutical products.

1.12 “Laws” means all laws, statutes, rules, regulations, ordinances and other pronouncements having the effect of law of the United States, Canada and the European Union or any domestic or other state, province, county, city or other political subdivision or any regulatory authority.

1.13 “NDA” means a New Drug Application pursuant to Section 505 of the Act (21 U.S.C. Section 355) submitted to the FDA or any successor application or procedure or any foreign counterpart of a United States New Drug Application for approval to market, including where applicable, applications for pricing and reimbursement approval.

1.14 “Quality Agreement” means the agreement to be entered into by the parties hereto, promptly after the date hereof, setting out the quality assurance standards to be applicable to the manufacturing services provided by Solvay.

1.15 “Regulatory Approval” means any and all approvals (including supplements, amendments, label expansions, pre- and post-approvals, pricing and reimbursement approvals), licenses, registrations or authorizations of any national, regional, state, provincial or local regulatory agency, department, bureau, commission, council or other governmental entity, that are necessary for the manufacture, distribution, use or sale of a product in a regulatory jurisdiction.

1.16 “Territory” means the entire world.

1.17 “United States” means the United States of America and its states, territories, possessions and protectorates thereof, the District of Columbia and the Commonwealth of Puerto Rico.

ARTICLE 2

MANUFACTURE, PURCHASE AND SUPPLY OF API

2.1 Supply. Pursuant to the terms and conditions of this Agreement, during the Term, Solvay agrees to supply or have supplied Jazz Pharmaceuticals’ requirements of API (including any API to be used for manufacturing clinical trial supplies). Subject to the provisions of Section 2.7, Jazz Pharmaceuticals agrees to purchase from Solvay, or its permitted designee, during the Term, certain quantities of API ordered pursuant to this Agreement. API supplied hereunder shall be supplied as Bulk API and shall meet the API Specifications. Each shipment shall be accompanied by a Certificate of Analysis in English. API shall be manufactured in accordance with cGMP and all other applicable Laws and any procedures set forth in the API Specifications, and such additional procedures as may be agreed upon by the parties. Notwithstanding the requirements for the purchase and delivery of API set forth in this Article 2, Solvay agrees to sell, and Jazz Pharmaceuticals agrees to purchase, up to 4,000 kilograms of API for $453 per kilogram and on the payment terms set forth in Section 3.3 of this Agreement.

2.2 Firm Orders.

(a) From time to time and subject to the other provisions of this Agreement, Jazz Pharmaceuticals shall place its firm orders for API, specifying requested delivery dates. The delivery dates specified in any such orders shall not be less than ninety (90) days from the date of such orders.

(b) To the extent that firm orders requested for shipment in any quarter exceed the most recent Jazz Pharmaceuticals forecast for such quarter provided under Section 2.4 by more than twenty-five percent (25%) (any excess of twenty-five percent (25%) or less shall, for this purpose, be deemed not to exceed forecast), Solvay shall use its commercially reasonable efforts to accommodate any such excess contained in Jazz Pharmaceuticals’ firm orders, but Solvay shall not be liable to Jazz Pharmaceuticals for any inability, despite its reasonable efforts, to fill orders in excess of such forecast.

(c) Solvay shall use commercially reasonable efforts to accommodate any Jazz Pharmaceuticals' request for the API in excess of the quantities described in any previously-submitted purchase order, or for delivery of the API sooner than as otherwise provided in such purchase order. Should Jazz Pharmaceuticals business conditions necessitate reduction or delay in purchase order requirements, then Solvay shall use commercially reasonable efforts to implement such requested changes; provided that Jazz Pharmaceuticals shall bear any and all additional costs or expenses related to the manufacturing of the API as a result of Solvay's compliance with such request. Notwithstanding the foregoing, Solvay shall not take any action in response to any such requests which would result in charges to Jazz Pharmaceuticals in addition to those set forth in the respective purchase order without Jazz Pharmaceuticals' prior written consent.

2.3 Acceptance. Orders placed with Solvay by Jazz Pharmaceuticals pursuant to the provisions of Section 2.2 shall be acknowledged by Solvay in writing. Solvay shall use commercially reasonable efforts to ensure that the API ordered by Jazz Pharmaceuticals in accordance with this Agreement is shipped in accordance with the delivery dates specified in Jazz Pharmaceuticals' purchase order accepted by Solvay, and Solvay shall notify Jazz Pharmaceuticals promptly of any significant anticipated delay.

2.4 Forecasts and Production Planning.

(a) On or before the fifth (5^{th}) working day of each month, Jazz Pharmaceuticals shall provide Solvay with an eighteen (18) month rolling forecast of the quantity of API required by Jazz Pharmaceuticals, by month, for the following eighteen (18) months (each, a "Forecast"). It is understood that such Forecasts, after the third (3^{rd}) month, are intended to be good faith estimates only, and shall not be binding upon Jazz Pharmaceuticals. Solvay's inability to supply amounts in excess of the foregoing amounts shall not constitute a breach of this Agreement by Solvay.

(b) Solvay shall base its production planning on the forecasts provided to Solvay by Jazz Pharmaceuticals pursuant to Section 2.4(a). Solvay shall have the right, at any time, to order materials and supplies to manufacture one hundred percent (100%) of those amounts of API ordered by Jazz Pharmaceuticals under Section 2.2 and forecast by Jazz Pharmaceuticals under Section 2.4(a) for the then current and next two calendar quarters. In addition, to the extent any materials necessary to the manufacture of the API require a longer lead time, Solvay shall be entitled to order such materials as it deems appropriate to fulfill its obligations hereunder and consistent with normal production practices in the pharmaceutical industry, and considering the term of this Agreement. If any such materials or any work in process become unusable due to a change in the API Specifications or orders lower than forecasts, Solvay shall have the right to invoice Jazz Pharmaceuticals for the full cost of unusable materials or work in process and Jazz Pharmaceuticals shall promptly pay such invoice. Jazz Pharmaceuticals shall have full rights and title to such obsolete materials (and work in process). At Jazz Pharmaceuticals' election, such materials (and work in process) shall be (i) destroyed by Solvay or (ii) transferred by Solvay to Jazz Pharmaceuticals.

(c) Notwithstanding the foregoing, Solvay agrees to use its commercially reasonable efforts to cooperate with Jazz Pharmaceuticals in connection with Jazz Pharmaceuticals' commercial launch of any pharmaceutical product containing the API. Such cooperation shall include, but not be limited to, joint review and revision of forecasts and firm orders during the period prior to FDA approval and during the twelve (12) months immediately following the commercial launch of such pharmaceutical product in the United States (and covering similar periods for other applicable countries). Solvay shall use its commercially reasonable best efforts to accommodate any changes requested by Jazz Pharmaceuticals during such period, but Solvay shall not be liable to Jazz Pharmaceuticals for any inability to accommodate such changes provided it has used its commercially reasonable efforts to respond to such changes.

2.5 Delivery. Shipments of API shall be made ex-works ("EXW") (as such term is defined in INCOTERMS 2000) Solvay's manufacturing facility unless otherwise mutually agreed to in writing by the parties. Risk of loss or of damage to the API shall remain with Solvay until such API is loaded onto the carrier's vehicle by Solvay for shipment at the shipping point at which time risk of loss or damage shall transfer to Jazz Pharmaceuticals. Solvay shall, in accordance with Jazz Pharmaceuticals' instructions and as agent for Jazz Pharmaceuticals, (i) arrange for shipping to be paid by Jazz Pharmaceuticals and (ii) at the Jazz Pharmaceuticals' risk and expense, obtain any export licence or other official documentation necessary to export the API from the United States. Jazz Pharmaceuticals shall arrange for insurance and shall select the freight carrier used by Solvay to ship the API and may monitor Solvay's shipping and freight practices as they pertain to this Agreement. API shall be transported in accordance with the API Specifications and other applicable Laws.

2.6 Manufacturing Changes.

(a) For changes to the API Specifications or manufacturing processes that are required by applicable Laws (collectively "Required Manufacturing Changes"), Solvay and Jazz Pharmaceuticals shall cooperate in making such changes and use commercially reasonable efforts to implement such changes promptly in a manner that minimizes any effect on the supply hereunder to Jazz Pharmaceuticals of API meeting the API Specifications.

(b) For changes to the API Specifications or manufacturing process that are not Required Manufacturing Changes (collectively "Discretionary Manufacturing Changes"), Solvay and Jazz Pharmaceuticals must each have agreed to any Discretionary Manufacturing Changes for them to be made and once agreed, each party shall, to the extent commercially reasonable under the circumstances, cooperate in making such changes, and each agrees that it shall not unreasonably withhold its consent to such Discretionary Manufacturing Changes.

(c) Notwithstanding the foregoing, all external costs, including, without limitation, obsolete raw materials, regulatory filings, work-in-process, equipment and API (i) associated with Required Manufacturing Changes that are caused by, or result from, the acts or omissions of a single party shall be borne by such party, (ii) associated with all Required Manufacturing Changes for use of the API in the United States shall be borne by Jazz Pharmaceuticals, (iii) associated with all Required Manufacturing Changes for use of the API in any country other than the United States shall be borne by Solvay and (iv) all costs associated with Discretionary Manufacturing Changes shall be borne by the party requesting such changes.

2.7 Shortages.

(a) During the Term of this Agreement, if Solvay is not able to meet firm orders submitted by Jazz Pharmaceuticals pursuant to Section 2.2 due to a shortage of API, Solvay shall promptly notify Jazz Pharmaceuticals of such shortage of such API, and, if possible, the date such shortage of API is expected to end. In such event, Solvay shall allocate its available supply of such API to Jazz Pharmaceuticals in such proportion as the quantity of such API supplied to Jazz Pharmaceuticals over the immediately preceding twelve (12)-month period bears to the total quantity of API supplied by Solvay to all parties over the preceding twelve (12)-month period. In addition, if Solvay is not able to supply any API, at such point in time when Solvay resumes supply of the API, Jazz Pharmaceuticals shall receive the first Batch of API available for commercial supply.

(b) In the event an interruption described in Section 2.7(a) continues for more than one hundred eighty (180) days, then upon Jazz Pharmaceuticals' written request, Solvay will provide all necessary information, licenses and technical assistance required to reasonably assist Jazz Pharmaceuticals in (i) the qualification of an alternate API manufacturer and (ii) obtaining all authorizations of the appropriate authorities for the approval of the alternate manufacturer of API for the Territory. Notwithstanding the foregoing, Solvay shall not incur any out of pocket costs as a result of providing this assistance, and Solvay shall only be responsible for assuming its own internal expenses incurred as a result of providing this assistance.

ARTICLE 3

PRICING AND PAYMENT

3.1 Price. Subject to the remainder of this Article 3, the price to be paid by Jazz Pharmaceuticals for API shipped in any calendar year shall be as set forth on Exhibit A.

3.2 Price Adjustment. The price for API under Section 3.1 may be increased or decreased by Solvay under this Section 3.2, by written notice to Jazz Pharmaceuticals, no more than once in any calendar year beginning January 1, 2008. Any such increase shall not exceed the increase in the United States Producers' Price Index, Pharmaceuticals Preparations, NAICS 325412 during the period since the last increase (and for the first increase, since January 1, 2007) under this Section 3.2 (the "Index Increase"). In addition to the Index Increase permitted in the previous sentence, Solvay will also be entitled to an additional price increase for API under this Section 3.2 if the aggregate cost to Solvay of the materials used in the manufacture of API increases by more than ten percent (10%) over Solvay's average aggregate cost for such materials during the previous calendar year, such additional price increase to be no greater than the difference between the increase in the aggregate cost for such materials and the Index Increase for such materials. Solvay shall submit evidence of material cost increases to Jazz Pharmaceuticals or a mutually agreed Third Party auditor for increase verification. Solvay must provide written notice prior to execution of any price adjustment made pursuant to this Section 3.2 and such price increase shall be effective as to any new orders placed thereafter.

3.3 Payment. Payment by Jazz Pharmaceuticals for API supplied by Solvay hereunder meeting API Specifications shall be in United States dollars and made within thirty (30) days after the date of Solvay's invoice by check or wire transfer to such bank as Solvay may

designate in writing, and shall be made without set-off and free and clear of, and without any deduction or withholding for or on account of any taxes, duties, levies, fees or charges. API shall be invoiced no sooner than the date of shipment by Solvay. Notwithstanding the foregoing, Jazz Pharmaceuticals may withhold any amounts invoiced by Solvay that it disputes. If Jazz Pharmaceuticals disputes any invoice, Jazz Pharmaceuticals, within thirty (30) days after such invoice is furnished to it, notify Solvay that it disputes the accuracy or appropriateness of such invoice and specify the particular respects in which such invoice is inaccurate or inappropriate. Jazz Pharmaceuticals and Solvay shall make good faith efforts to resolve any disputes within thirty (30) days thereafter. Any amounts that are disputed by Jazz Pharmaceuticals shall not be due until ten (10) days following the resolution of such dispute.

3.4 Foreign Exchange. Conversion to U.S. dollars of any amounts recorded in local currencies shall be made using the spot foreign exchange rate, noon buying rated certified by the Federal Reserve Bank of New York for customs purposes in New York City for cable transfers payable in foreign currencies on the date of the calculation.

3.5 Late Payments. All payments not made when due hereunder shall bear interest at an annual rate equal to the prime interest rate as published by the Wall Street Journal on the date the payment became due.

ARTICLE 4

QUALITY AND REGULATORY MATTERS

4.1 Quality Control. Solvay shall produce API in accordance with the API Specifications, cGMP, the Laws and any procedures agreed upon by the parties in writing, and shall permit quality assurance representatives of Jazz Pharmaceuticals or its designee to audit and inspect Solvay's manufacturing facilities and testing procedures for API and the related batch records, upon thirty (30) days written notice, twice in each calendar year (and additional times, if deficiencies are noted, to monitor correction thereof), during normal business hours and on a confidential basis. If deficiencies are found during any audits or inspections, the parties shall meet promptly to discuss and resolve them, and Jazz Pharmaceuticals or its designee shall be entitled to make reasonable follow-up inspections to monitor the correction of the deficiencies. Solvay shall use commercially reasonable efforts to obtain the right for Jazz Pharmaceuticals or its designee to have similar inspection, audit and follow-up rights with respect to all third-party suppliers used by Solvay to provide key materials for API. Solvay agrees to allow the FDA or any other applicable regulatory authority to inspect its facilities and all records required under cGMP and all other applicable regulations in connection with such production. Solvay shall furnish to Jazz Pharmaceuticals all material information supplied to, or supplied by, such regulatory authority or third party supplier to the extent that such report relates to API, or the ability of Solvay to supply such API, within five (5) business days of their receipt of such information or delivery of such information, as the case may be.

4.2 Testing.

(a) Solvay agrees to permit Jazz Pharmaceuticals or its designee to review Solvay's standard operating procedures for the manufacture of the API. Solvay shall test or cause to be tested each Batch of API to be supplied pursuant to this Agreement, in accordance

with the approved testing methods, before delivery of such API to Jazz Pharmaceuticals or its designee. Each time Solvay ships API to Jazz Pharmaceuticals or its designee, it shall provide Jazz Pharmaceuticals or its designee with the Certificate of Analysis that sets out the test results for each Batch of API and that certifies that such Batch of the API complies with the API Specifications and was manufactured in accordance with cGMP. Solvay shall retain a sample of each Batch of API shipped for at least the shelf life of such Batch plus one (1) year, or such longer period as may be required by cGMP. Nothing contained herein, however, shall be deemed or construed to require Solvay to turn over the DMF relative to the API.

(b) Solvay shall conduct stability testing on the API in accordance with the Quality Agreement and API Specifications. Solvay shall not make any changes to the API Specifications or testing protocols without prior written approval from Jazz Pharmaceuticals. Solvay shall promptly provide any and all data and results relating to the stability testing of the API upon request by Jazz Pharmaceuticals. In the event that any Batch of the API fails, or is suspected to fail, stability testing, Solvay shall notify Jazz Pharmaceuticals within two (2) business days and Solvay and Jazz Pharmaceuticals shall jointly determine the proceedings and methods to be undertaken to investigate the causes of such failure.

4.3 Notice of Failure to Meet API Specifications. Upon Solvay's discovery that any Batch of API fails to conform to the API Specifications, Solvay shall notify Jazz Pharmaceuticals within two (2) business days of discovery of such failure to meet the API Specifications and of the nature thereof. Solvay shall investigate all such failures and promptly and cooperate with Jazz Pharmaceuticals in determining the cause for the failure and a corrective action to prevent future failures.

4.4 Records. Solvay shall keep records of the manufacture, testing and shipping of the API, and retain samples of such API as are necessary to comply with the API Specifications and all manufacturing regulatory requirements and Laws applicable to Solvay, as well as to assist with resolving API complaints and other similar investigations. Copies of such records and samples shall be retained for a period of one (1) year following the date of API expiry or longer if required by Law, after which Solvay may destroy such records or samples; provided, however, Solvay shall notify Jazz Pharmaceuticals in writing at least thirty (30) days prior to such destruction and shall retain or deliver such records or samples to Jazz Pharmaceuticals, at Jazz Pharmaceuticals' option and expense, if Jazz Pharmaceuticals so requests.

4.5 Notice; Replacement. Jazz Pharmaceuticals or its designee shall notify Solvay in writing of (i) any claim relating to any API that fails to meet the API Specifications or (ii) any shortage in quantity of any shipment of API as soon as reasonably practical, but not later than forty-five (45) days of receipt of such API except where such failure to meet the API Specifications could not be reasonably known at such time, in which case such forty-five (45) day period commences when Jazz Pharmaceuticals could reasonably have known of such failure. Jazz Pharmaceuticals or its designee shall be deemed to have accepted the API if it does not provide Solvay written notice of such shortfall or failure to meet specification within such forty-five (45) day period. If the parties agree that such API is defective or that there is a shortage, Solvay shall replace the defective API or use its commercially reasonable best efforts to make up the shortage at the next practical delivery date, at no additional cost to Jazz Pharmaceuticals. Jazz Pharmaceuticals shall make arrangements with Solvay for the return or disposal of any rejected API; the costs of such return or disposal shall be paid by Solvay. In the event that only a limited supply of API is available to replace or supply such rejection or shortage, then Solvay

shall ship to Jazz Pharmaceuticals such amount of API as is available and Jazz Pharmaceuticals shall be promptly reimbursed or credited against future orders, at Solvay's option, for amounts paid for the remaining quantity of rejected API.

4.6 Disputes. If, for any reason (i) Jazz Pharmaceuticals disagrees with Solvay's certification that any API meets the API Specifications or that any API was manufactured in accordance with cGMP or both, or (ii) Jazz Pharmaceuticals rejects any shipment in accordance with Section 4.5 and Solvay disagrees, the relevant party shall assert any such disagreement or rejection in writing, setting forth the specifics of its disagreement or rejection within forty-five (45) days after Solvay's certification with respect to the API in question. The parties shall attempt in good faith, within the forty-five (45) day period following the other party's receipt of such written notice, to resolve the dispute. If the parties fail to agree during such time period, they shall retest jointly, in a laboratory agreed upon by the parties, in each case using the test methodology set forth in the API Specifications. If the joint tests substantiate Jazz Pharmaceuticals' disagreement or rejection, the API in question shall, at Solvay's election and cost, be destroyed or be returned to Solvay. Jazz Pharmaceuticals shall not be obligated to pay for justifiably rejected API and Solvay or Jazz Pharmaceuticals shall notify, if required by Law, the relevant government agencies regarding any affected API. If the joint test does not substantiate Jazz Pharmaceuticals' claim, Jazz Pharmaceuticals shall accept the API in question and pay the purchase price with respect to such API. The results of the joint testing shall be binding on the parties, and the costs of the joint testing shall be borne by the party whose results were not substantiated by the joint testing.

4.7 Recalls. In the event (i) the FDA or any other regulatory authority issues a request, directive or order that a product containing the API manufactured by Solvay pursuant to this Agreement be recalled, (ii) a court of competent jurisdiction orders such a recall, or (iii) Jazz Pharmaceuticals shall reasonably determine that the a product containing the API manufactured by Solvay pursuant to this Agreement should be recalled, all costs of such API recall shall be borne by Jazz Pharmaceuticals, except to the extent that any recall results from the breach by Solvay of its warranties under Article 5, which costs shall be governed by the provisions of Section 6.1.

4.8 Technical Complaints. Jazz Pharmaceuticals shall promptly submit to Solvay all API quality or manufacturing inquiries and technical API quality complaints, together with all available evidence and other information relating thereto, in accordance with procedures to be agreed upon by the parties. Except as otherwise required by Law, Solvay shall be responsible for investigating all such technical inquiries and complaints regarding the API and the outcome of such investigation shall be promptly reported by Solvay to Jazz Pharmaceuticals in writing. Where complaints or matters result from acts or omissions of Solvay, investigation and correction shall be at Solvay's expense; otherwise investigation and correction shall be at Jazz Pharmaceuticals' expense.

4.9 Response to Complaints and/or Adverse Drug Events. In the event of a reported complaint and/or adverse drug event, if the nature of the reported complaint and/or adverse drug event requires testing, Solvay shall, at Jazz Pharmaceuticals' reasonable request and expense (unless the event was the result of Solvay's failure to manufacture API in accordance with the terms hereof, in which case the reasonable costs of such testing shall be borne by Solvay), investigate and perform all requested testing including without limitation, analytical testing of corresponding retention samples, and provide the results thereto to Jazz Pharmaceuticals as soon as reasonably practicable. Such testing shall be performed using the approved testing procedures as set forth in the API Specifications.

4.10 Reports. For so long as Solvay is manufacturing and/or supplying API pursuant to this Agreement, Solvay shall furnish to Jazz Pharmaceuticals manufacturing reports reasonably requested by Jazz Pharmaceuticals, but in no event more than quarterly, including such information that is agreed upon by the parties.

4.11 Quality Agreement. Within three (3) months following the execution of this Agreement, the parties shall execute a Quality Agreement.

ARTICLE 5

WARRANTIES

5.1 Compliance with cGMP. Solvay warrants that any API supplied by it hereunder shall be manufactured in accordance with cGMP.

5.2 Conformity with Specifications. Solvay warrants that, at the time of shipment and for its shelf life, any API supplied by it hereunder shall meet the API Specifications except for any failure to meet API Specifications arising due to the handling, packaging or other act or omission of Jazz Pharmaceuticals.

5.3 Compliance with Laws. Solvay warrants that, during the two (2) year period prior to the Effective Date, Solvay has materially complied with all Laws applicable to the manufacture of the API. During the term of this Agreement, Solvay shall comply with all Laws applicable to the conduct of its business in the performance of this Agreement.

5.4 Exclusion of Other Warranties. EXCEPT WHERE OTHERWISE SET FORTH IN THIS AGREEMENT, SOLVAY'S WARRANTIES SET FORTH IN SECTIONS 5.1, 5.2 AND 5.3 ARE ITS EXCLUSIVE WARRANTIES TO JAZZ PHARMACEUTICALS WITH RESPECT TO THE API, AND ARE GIVEN AND ACCEPTED IN LIEU OF ANY AND ALL OTHER WARRANTIES, GUARANTEES, CONDITIONS AND REPRESENTATIONS, EXPRESS OR IMPLIED, CONCERNING THE PRODUCT, AND INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

ARTICLE 6

INDEMNIFICATION AND INSURANCE

6.1 Solvay Indemnity. Subject to Sections 6.2 and 6.4, Solvay shall indemnify and hold harmless Jazz Pharmaceuticals and its Affiliates against all third party claims, actions, costs, expenses, including court costs and legal fees or other third party liabilities ("Third Party Liabilities") whatsoever in respect of:

(a) Solvay's and/or its Affiliates', subcontractors' or suppliers' failure to comply with the API Specifications, cGMP or applicable Laws;

(b) any breach of a representation or warranty made by Solvay in Article 5;

(c) the use, marketing, storage, distribution, handling or sale of the API prior to the Effective Date by Solvay or any third party; and

(d) any negligence, omission or willful misconduct by Solvay and/or its Affiliates, subcontractors and suppliers in the manufacture, testing and handling of the API.

6.2 Jazz Pharmaceuticals Indemnity. Subject to Sections 6.1 and 6.4, Jazz Pharmaceuticals shall indemnify and hold harmless Solvay and its Affiliates against all Third Party Liabilities whatsoever in respect of (i) the use, marketing, storage, distribution, handling or sale of the API after the Effective Date by Jazz Pharmaceuticals or any third party, other than a third party acting on behalf of Solvay or its Affiliates and/or (ii) any breach by Jazz Pharmaceuticals hereunder.

6.3 Procedures for Indemnification. In the event that a party (the "Indemnified Party") is seeking indemnification under Sections 6.1 or 6.2, the Indemnified Party shall inform the other party (the "Indemnifying Party") of a claim as soon as reasonably practicable after the Indemnified Party receives notice of the claim, shall permit the Indemnifying Party to assume direction and control of the defense of the claim (including the right to settle the claim solely for monetary consideration), and shall cooperate as requested by the Indemnifying Party (at the expense of the Indemnifying Party) in the defense of the claim.

6.4 Mitigation. In the event of any occurrence which may result in either party becoming liable under Section 6.1 or Section 6.2, each party shall use its best efforts to take such actions as may be reasonably necessary to mitigate the damages payable by the other party under Section 6.1 or Section 6.2, as the case may be.

6.5 Limitation of Liability. EXCEPT AS SPECIFICALLY PROVIDED IN SECTIONS 6.1 AND 6.2, IN NO EVENT SHALL ANY PARTY, ITS DIRECTORS, OFFICERS, EMPLOYEES, AGENTS OR AFFILIATES BE LIABLE TO THE OTHER PARTIES FOR ANY INDIRECT, INCIDENTAL, SPECIAL, EXEMPLARY OR CONSEQUENTIAL DAMAGES, WHETHER BASED UPON A CLAIM OR ACTION OF CONTRACT, WARRANTY, NEGLIGENCE, STRICT LIABILITY OR OTHER TORT, OR OTHERWISE, ARISING OUT OF THIS AGREEMENT.

6.6 Insurance. Each party shall maintain commercial general liability insurance, through the term of this Agreement, which insurance shall afford limits of not less than $5,000,000 for each occurrence for personal injury or property damage liability. Furthermore, each party shall maintain products liability insurance, through the term of this Agreement and for a period of three (3) years thereafter, which insurance shall afford limits of not less than $5,000,000 in the aggregate per annum with respect to product and completed operations liability. This insurance shall be written to cover claims incurred, discovered, manifested, or made during or after the expiration of this Agreement. If requested, each party shall provide the other with a certificate of insurance evidencing the above and showing the name of the issuing company, the policy number, the effective date, the expiration date and the limits of liability. The insurance certificate shall further provide for a minimum of thirty (30) days' written notice to the insured of a cancellation of, or material change in, the insurance. If a party is unable to maintain the insurance policies required under this Agreement through no fault on the part of such party, then such party shall forthwith notify the other party in writing and the parties shall in good faith negotiate appropriate amendments to the insurance provision of this Agreement in order to provide adequate assurances.

ARTICLE 7

TERM AND TERMINATION

7.1 Term. This Agreement shall remain in effect until the termination of the Assignment and License Agreement pursuant to Article 11 thereof (the "Term") or until this Agreement is terminated earlier in accordance with Sections 7.2, 7.3 or 7.4 hereof.

7.2 Termination by Jazz Pharmaceuticals. Jazz Pharmaceuticals may terminate this Agreement at any time upon one hundred eighty (180) days' written notice to Solvay.

7.3 Termination for Breach. If either Jazz Pharmaceuticals or Solvay breaches or defaults in the performance or observance of any material provisions of this Agreement and such breach or default is not cured within thirty (30) days after written notice by the other party specifying such breach or default (or if such breach or default is not of a type which can reasonably be cured in thirty (30) days, then such longer period as is reasonable), such party shall have the right to terminate this Agreement upon a further thirty (30) days' written notice.

7.4 Termination for Insolvency. This Agreement may be terminated upon thirty (30) days' advance written notice by either party at any time during the Term upon the declaration by a court of competent jurisdiction that the other party is bankrupt and, pursuant to the U.S. Bankruptcy Code such other party's assets are to be liquidated; upon the filing or institution of bankruptcy, liquidation or receivership proceedings (other than reorganization proceedings under Chapter 11 of the U.S. Bankruptcy Code); or upon an assignment of a substantial portion of the assets for the benefit of creditors by the other party; or in the event a receiver or custodian is appointed for such party's business; provided, however, that in the case of any involuntary proceeding, such right to terminate shall only become effective if the proceeding is not dismissed within sixty (60) days after the filing thereof.

7.5 Rights on Termination. Termination of this Agreement for any reason shall not affect the accrued rights and obligations of either Jazz Pharmaceuticals or Solvay arising under or out of this Agreement. Upon early termination of this Agreement by Jazz Pharmaceuticals pursuant to Sections 7.3 or 7.4 above, Solvay shall transfer to Jazz Pharmaceuticals all regulatory information and other information and materials reasonably necessary for Jazz Pharmaceuticals to assume responsibility for performance of the manufacturing activities undertaken by Solvay under this Agreement, and the parties shall establish such operational procedures as are reasonably necessary for Jazz Pharmaceuticals to assume such responsibility as quickly as possible.

7.6 No Liability. Neither party shall incur any liability to the other by reason of the expiration or termination of this Agreement as provided herein for loss of goodwill, anticipated profits or otherwise, and the parties shall accept all rights granted and all obligations assumed hereunder, including those in connection with such expiration or termination, in full satisfaction of any claims resulting from such expiration or termination.

ARTICLE 8

CONFIDENTIALITY

8.1 Nondisclosure. During the Term of this Agreement and for a period of ten (10) years after expiration or termination of this Agreement, the parties, their Affiliates and their respective employees, directors, officers, consultants and contractors shall keep and maintain as confidential any Confidential Information (as defined below) supplied by the other party during the Term of this Agreement. For purposes of this Agreement, "Confidential Information" means all information disclosed by a party in connection with this Agreement other than: (i) information that at the time of disclosure by one party to the other is in the public domain or otherwise publicly known; (ii) information which after disclosure by one party to the other becomes part of the public domain, other than by breach of this Agreement by the receiving party; (iii) information which the receiving party can establish by documentary evidence was already in its possession without restriction at the time of receipt; or (iv) information received from a third party without restriction who was lawfully entitled to disclose such information without restriction.

8.2 Permitted Disclosure. Notwithstanding Section 8.1, the party receiving Confidential Information may disclose such Confidential Information to the extent such disclosure is reasonably necessary in the following instances: (i) to governmental or other regulatory agencies in order to file patent applications or prosecute such applications to grant or to gain approval to conduct clinical trials in relation to the API, provided that the disclosure is limited to the extent reasonably necessary to obtain such patents or authorizations and the disclosing party is notified of the proposed disclosure of its Confidential Information and consents to such disclosure, with such consent not to be unreasonably withheld; (ii) as required by this Agreement; (iii) to Affiliates, employees, consultants, vendors or agents who need to know and agree to be bound by similar terms of confidentiality and non-use at least equivalent in scope to those set forth in this Article 8; or (iv) to the extent that such disclosure has been ordered by a court of law or directed by a governmental authority, provided that, the disclosing party shall give the party that owns the Confidential Information prompt written notice, in advance, to enable it to seek protection or confidential treatment of such Confidential Information.

8.3 Injunctive Relief. The parties hereto understand and agree that remedies at law may be inadequate to protect against any breach of any of the provisions of this Article 8 by either party or their employees, agents, officers or directors or any other person acting in concert with it or on its behalf. Accordingly, each party may be entitled to seek injunctive relief from a court of competent jurisdiction against any action that constitutes any such breach of this Article 8.

ARTICLE 9

MISCELLANEOUS

9.1 Force Majeure. If any party is prevented from complying, either totally or in part, with any of the terms or provisions of this Agreement, by reason of force majeure, including, but not limited to fire, flood, earthquake, explosion, storm, strike, lockout or other labor trouble, riot, war, rebellion, accidents, acts of God and/or any other cause or externally induced casualty beyond its reasonable control, whether similar to the foregoing matters or not, then, upon written notice by the party liable to perform to the other party, the requirements of this Agreement or

such of its provisions as may be affected, and to the extent so affected, shall be suspended during the period of such disability; provided that the party asserting force majeure shall bear the burden of establishing the existence of such force majeure by clear and convincing evidence; and provided further, that the party prevented from complying shall use its best efforts to remove such disability within thirty (30) days, and shall continue performance with the utmost dispatch whenever such causes are removed, and shall notify the other party of the force majeure event not more than five (5) working days from the time of the event. When such circumstances arise, the parties shall discuss what, if any, modification of the terms of this Agreement may be required in order to arrive at an equitable solution.

9.2 Trademarks. Each party agrees and acknowledges that it shall not acquire by virtue of this Agreement any interest in or to any trademarks or trade names of the other party; provided, however, that Jazz Pharmaceuticals shall have the right to identify Solvay as the manufacturer of the API.

9.3 Notices. Except as otherwise specifically provided, any notice or other documents to be given under this Agreement shall be in writing and shall be deemed to have been duly given if sent by registered mail, nationally recognized overnight delivery service or facsimile transmission to a party or delivered in person to a party at the address or facsimile number set out below for such party or such other address as the party may from time to time designate by written notice to the other:

If to Solvay:

Solvay Pharmaceuticals, Inc.
901 Sawyer Road
Marietta, Georgia 30062
Attention: Senior Vice President, Law, Government and Public Affairs
Facsimile: (770) 578-5749

If to Jazz Pharmaceuticals:

Jazz Pharmaceuticals, Inc.
3180 Porter Drive
Palo Alto, CA 94304
Attention: General Counsel
Facsimile: (650) 496-3781

Any such notice provided pursuant to this Section 9.3 shall be deemed to have been received by the addressee five business days following the date of dispatch of the notice or other document by mail or, where the notice or other document is sent by overnight delivery service, by hand or is given by facsimile, simultaneously with the transmission or delivery. To prove the giving of a notice or other document it shall be sufficient to show that it was dispatched. Either party may change its address at which notice is to be received by written notice provided pursuant to this Section 9.3.

9.4 Waiver and Amendment. A waiver by either party of any term or condition of this Agreement in any one instance shall not be deemed or construed to be a waiver of such term or condition for any other time. All rights, remedies, undertakings, obligations and agreements contained in this Agreement shall be cumulative and none of them shall be a limitation of any other remedy, right, undertaking, obligation or agreement of either party. This Agreement may not be amended or modified, except in a writing signed by an officer of each party hereto.

9.5 Severability. If any one or more of the provisions of this Agreement shall be held to be invalid, illegal or unenforceable in any respect, the validity, legality or enforceability of the remaining provisions hereof shall not in any way be affected or impaired thereby. In the event any provisions shall be held invalid, illegal or unenforceable, the parties shall use their best efforts to substitute a valid, legal and enforceable provision which, insofar as practical, implements the purposes hereof.

9.6 Headings. The headings contained in this Agreement are included herein for reference and convenience and shall not affect the meaning of the provisions of this Agreement.

9.7 Assignment and Successors. This Agreement may not be assigned by either party to any third party without the prior written consent of the other party; except that either party may assign this Agreement, without the prior written consent of the other party, to any of its Affiliates, to any purchaser of all or substantially all of its assets or to any successor corporation resulting from any merger or consolidation with or into such corporation. In the event of any such assignment, the assignee shall expressly assume in writing the performance of all the terms and conditions of this Agreement and all of the obligations to be performed by the assignor. Any assignment not in accordance with this Agreement shall be void.

9.8 Governing Law. This Agreement shall be construed, and the rights of the parties determined, in accordance with the laws of the State of New York, excluding any choice of law rules which may direct the application of the laws of another jurisdiction.

9.9 Independent Parties. This Agreement shall not be deemed to create any partnership, joint venture, amalgamation or agency relationship between the parties. Each party shall act hereunder as an independent contractor. Neither party shall at any time enter into, incur, or hold itself out to third parties as having authority to enter into or incur, on behalf of the other party, any commitment, expense, or liability whatsoever.

9.10 Survival of Provisions. The provisions of Articles, 1, 5, 6 and 8 and Sections 3.3, 3.4, 3.5, 4.2(a), 4.3, 4.4, 4.6, 4.7, 4.8, 4.9, 7.5, 7.6, 9.3, 9.5, 9.8, 9.10, 9.12 and 9.14 shall survive the termination for any reason of this Agreement.

9.11 Publicity. Neither party shall make any public announcement concerning, or otherwise publicly disclose, any information with respect to the transactions contemplated by this Agreement or any of the terms and conditions hereof without the prior written consent of the other party hereto. Notwithstanding the foregoing, either party may make any public disclosure concerning the transactions contemplated hereby that in the opinion of such party's counsel may be required by law or the rules of any stock exchange on which such party's or its Affiliates' securities trade; provided, however, the party making such disclosure shall provide the non-disclosing party with a copy of the intended disclosure reasonably, and to the extent practicable, prior to public dissemination, and the parties hereto shall coordinate with one another regarding the timing, form and content of such disclosure.

9.12 Entire Agreement. This Agreement, together with the Quality Agreement and the License Agreement, constitutes the full, complete, final and integrated agreement between the parties hereto relating to the subject matter hereof and supersedes all previous written or oral negotiations, commitments, agreements, transactions or understandings with respect to the

subject matter hereof. Any modification, amendment or supplement to this Agreement must be in writing and signed by authorized representatives of both parties. In case of a conflict between the agreements, the License Agreement shall prevail.

9.13 No Third Party Beneficiaries. No person or entity not a party to this Agreement, including any employee of any party to this Agreement, shall have or acquire any rights by reason of this Agreement, nor shall either party have any obligations or liabilities to such other person or entity by reason of this Agreement.

9.14 Remedies Cumulative. Except as otherwise provided herein, any and all remedies herein expressly conferred upon a party shall be deemed cumulative with and not exclusive of any other remedy conferred hereby, or by law or equity upon such party, and the exercise by a party of any one remedy shall not preclude the exercise of any other remedy. If any action at law or in equity is necessary to enforce or interpret the terms of this Agreement, the prevailing party shall be entitled to reasonable attorney's fees, costs and necessary disbursements in addition to any other relief to which such party may be entitled.

9.15 Further Assurances. Each party shall execute and deliver such additional instruments and other documents and use commercially reasonable efforts to take or cause to be taken, all actions and to do, or cause to be done, all things necessary under applicable law to consummate the transactions contemplated hereby.

9.16 Counterparts; Facsimile Signatures. This Agreement may be executed in counterparts, each of which shall be deemed an original, and all of which together shall constitute a single agreement. This Agreement may be executed by facsimile signatures, which signatures shall have the same force and effect as original signatures.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed, as of the date first above written, by their duly authorized representatives.

Solvay Pharmaceuticals, Inc.	Jazz Pharmaceuticals, Inc.
By: /s/ Laurence J. Downey, M.D.	By: /s/ Samuel R. Saks, M.D.
Title: President and CEO	Title: Chief Executive Officer

Exhibit A

API Price

€223.10 per kilogram of API.

TRADEMARK LICENSE AGREEMENT

THIS TRADEMARK LICENSE AGREEMENT (the "Trademark License Agreement") is entered into as of the 31st day of January, 2007, by and between Solvay Pharmaceuticals, Inc. ("Licensor") and Jazz Pharmaceuticals, Inc. ("Licensee").

WHEREAS, Licensor and Licensee are parties to a License Agreement dated as of January 31, 2007 ("License Agreement");

WHEREAS, Licensor or its affiliates is the owner of the trademark Luvox ® for use with pharmaceutical products, (hereinafter referred to as the "Licensed Mark");

WHEREAS, Licensee desires to utilize the Licensed Mark in connection with the Products (as defined in the License Agreement); and

WHEREAS, Licensor is willing to grant to Licensee the right to use the Licensed Mark on the Products and has the ability to do so, on the terms and conditions hereinafter set forth.

NOW, THEREFORE, in consideration of the mutual promises and undertakings herein contained, and for other good and valuable consideration, the parties agree as follows:

I
GRANT OF LICENSE

Licensor hereby grants to Licensee, and Licensee hereby accepts, an exclusive license to use the Licensed Mark in the Territory (as defined below) in connection with the Products (including the right to sublicense), including but not limited to making, offering, advertising, marketing, providing, selling, and distributing the Products, subject to the terms and conditions set forth herein. Licensor, at its own cost, shall be responsible for maintaining and renewing trademark registrations for the Licensed Mark, subject to Section IX(c) below.

II
TERRITORY AND TERM

The Territory shall be as defined in the License Agreement. The term of this Trademark License Agreement shall be the same as the term set forth in Article 11 of the License Agreement unless terminated earlier pursuant to Section VI(a) below.

III
OWNERSHIP AND USE OF THE TRADEMARK

Licensee acknowledges that Licensor, or its affiliate, is the exclusive owner of all right title and interest in the Licensed Mark and any registration thereof in the Territory, and that all use of the Licensed Mark by Licensee inures to the benefit of Licensor. Licensee further acknowledges that the Licensed Mark embodies substantial goodwill and enjoys favorable public recognition, and that Licensor's rights therein constitute valuable assets of Licensor. Licensee will use all reasonable efforts to assist Licensor to protect and enforce the Licensed Mark, and Licensee agrees that it will not at any time knowingly do, or cause to be done, anything that would, to Licensor's knowledge, be detrimental to, injure or impair the Licensed Mark or their registration or goodwill, or any of Licensor's common law or other rights in the Licensed Mark, or the validity of or Licensor's exclusive ownership of all right, title and interest in and to the Licensed Mark.

IV
REPRESENTATIONS AND WARRANTIES OF LICENSOR

Licensor represents and warrants that (i) Licensor or its affiliates are the sole owners of the Licensed Mark in the Territory and the Licensor possesses sufficient powers and rights to grant the rights and license granted to the Licensee herein; (ii) to the best of Licensor's knowledge, there are not any adverse or concurrent rights of any third party with respect to the use of the Licensed Mark in the Territory; (iii) to the best of Licensor's knowledge, Licensee may use the Licensed Mark in accordance with this Trademark License Agreement and the License Agreement in the Territory, without breaching any rights of any third party; (iv) Licensee may advertise the Licensed Mark on the Products in the Territory without thereby infringing any rights of any third party; (v) Licensor is duly authorized to execute and deliver this Trademark License Agreement and to perform its obligations hereunder, and the person or persons executing this Trademark License Agreement on its behalf has been duly authorized to do so by all requisite corporate action; (vi) Licensor is aware of no action, suit or inquiry or investigation instituted by

or before any court or governmental agency which questions or threatens the validity of this Trademark License Agreement or the Licensed Mark; and (vii) Licensor shall not take (or cause any other person to take) any action which will conflict with, contravene or otherwise limit or restrict the rights of the Licensee hereunder or the right of the Licensee to enjoy the benefits of this Trademark License Agreement (other than as expressly provided herein).

V
QUALITY CONTROL

In order to protect the goodwill and reputation associated with the Licensed Mark, Licensee covenants and agrees that:

(a) Quality of Product:

(i) Licensee shall provide Licensor with representative specimens of the packaging, labeling, advertising, and promotional material showing Licensee's use of the Licensed Mark.

(ii) the Products shall be manufactured, sold and distributed in compliance with GMPs and with all applicable Federal, state and local laws and regulations in the Territory, including but not limited to, the laws and regulations of the Food and Drug Administration.

(iii) Within thirty (30) days from receipt of a written request by Licensor, Licensee will supply Licensor with representative samples of the Products bearing the Licensed Mark.

(b) Requirements of Trademark Use: In all publicly disseminated packaging, labeling, advertising, and promotional material referencing the Licensed Mark, Licensee shall use the Licensed Mark in the manner set forth in the Requirements of Trademark Use set forth as Exhibit A hereto. Any deviation from the Requirements of Trademark Use must be approved in writing by Licensor, such approval not to be unreasonably withheld.

VI
TERMINATION AND RENEWAL

(a) Licensor may terminate this Trademark License Agreement if Licensee has breached a material obligation under this Trademark License Agreement and has not cured the breach within sixty (60) days after notice by Licensor of such breach or, if such breach is not amenable to cure within such sixty (60) day period, Licensee has not commenced a cure within such period.

(b) Upon proper termination of this Trademark License Agreement by either party, or at the expiration of the term under Article II hereof, Licensee shall discontinue using the Licensed

Mark. Licensee may, continue to use any signs, advertising and marketing materials, purchase orders, and the like that bear the Licensed Mark and sell any Product bearing the Licensed Mark in its inventory as of the date of termination until the supplies have been exhausted. Thereafter, Licensee may not use the Licensed Mark.

VII
THIRD PARTY INFRINGEMENTS

If either party learns of any use by any person of any product or material bearing any name, mark, or designation that infringes or is likely to infringe the Licensed Mark in the Territory, it shall promptly notify the other party. Whether to take action shall be in Licensee's sole, reasonable discretion, subject to the remainder of this Article VII. If requested by Licensee, Licensor shall join with Licensee at Licensee's expense in such action as Licensee in its reasonable discretion may deem advisable for the protection of its rights, all at Licensee's expense. In connection therewith, Licensor shall cooperate to the extent reasonably required by Licensee to stop such infringement or act, and, if so requested by Licensee, shall join with Licensor as a party to any action brought by Licensee for such purpose. Licensee shall have full control over any action taken, including, without limitation, the right to select counsel, to settle on any terms it deems advisable in its discretion, to appeal any adverse decision rendered in any court, to discontinue any action taken by it, and otherwise to make any decision in respect thereto as it in its discretion deems advisable; provided, however, that any settlement of such action that would (i) include any admission of liability on the part of the Licensor or (ii) not include an unconditional release of the Licensor from all liability for claims that are the subject matter of such action, will require Licensor's prior written consent. Licensee shall bear all expenses connected with the foregoing. Any recovery as a result of such action shall belong solely to Licensee. In addition, if either party receives any written notice or claim that the use by Licensee of the Licensed Mark infringes the intellectual property rights of a third party, then such party will promptly so notify the other party in writing, and in such event: (i) if Licensee's use of the Licensed Mark was and/or is in accordance with the express terms and/or conditions of use provided for herein, Licensor will agree in writing, within ten days after Licensee's notice, to indemnify Licensee against all costs, losses and expenses resulting from the third party's claim, or, in the alternative, Licensee will have the right to immediately stop using the Licensed Mark as otherwise required pursuant to the License Agreement; or (ii) if Licensee's use of the Licensed Mark was and/or is contrary to the express terms and/or conditions of use provided for herein, Licensee will indemnify Licensor against all costs, losses and expenses resulting from the third party's claim.

VIII
TRADEMARK REGISTRATIONS

(a) If registration of Licensee as a registered user of the Licensed Mark is required, Licensee shall bear all expenses, including government fees and reasonable trademark agents' fees, relating to such registration.

(b) Licensor shall notify Licensee of any decision not to maintain any trademark registration for the Licensed Mark in the Territory at least 30 days prior to abandonment thereof, in which event Licensee shall have the right, but not the obligation, to continue to maintain the registration of such licensed mark at its own expense.

IX
MISCELLANEOUS PROVISIONS

(a) No Joint Venture: Nothing herein contained shall be construed to constitute the parties joint venturers, nor shall any similar relationship be deemed to exist between them.

(b) Waiver; Modification: No waiver or modification of any of the terms of this Trademark License Agreement shall be valid unless in writing and signed by both parties. No waiver by either party of a breach hereof or a default hereunder shall be deemed a waiver by such party of a subsequent breach or default of like or similar nature.

(c) Assignment and Transfer: Either party may assign or transfer this Trademark License Agreement pursuant to Section 13.8 of the License Agreement.

(d) Notices: Any communication to be given hereunder by either party to the other party shall be in writing and delivered by messenger, sent by air mail (postage prepaid), or transmitted by facsimile, to the address or designation of such party set forth below or as changed by such party by notice given hereunder. A communication transmitted by facsimile shall be deemed effective when received; a communication sent by mail shall be deemed effective ten days after posting; and a communication delivered by messenger shall be deemed effective when delivered.

Licensor: Solvay Pharmaceuticals, Inc.
901 Sawyer Road
Marietta, Georgia 30062
Facsimile: 770-578-5749
Attention: Senior Vice President, Law, Government and Public Affairs

Licensee: Jazz Pharmaceuticals, Inc.
3180 Porter Drive
Palo Alto, CA 94304
Facsimile: 650-496-3781
Attention: General Counsel

The foregoing is not intended to be exclusive; any written communication actually received shall be effective when received.

(e) Captions: The section captions used in this Trademark License Agreement are for reference and cross-reference purposes only and shall not otherwise affect the meaning or interpretation of this Trademark License Agreement.

(f) Counterparts and Attachments: This Trademark License Agreement may be executed in two or more counterparts, each of which shall be deemed to be an original and all of which shall be deemed to constitute the same Trademark License Agreement.

(g) Entire Agreement: This Trademark License Agreement, together with the License Agreement, expresses the entire understanding of the parties hereto with respect to the Licensed Mark. Neither this Trademark License Agreement nor any provision hereof may be changed, waived, discharged, or terminated orally, but only by an agreement in writing signed by the party against whom or which the enforcement of such change, waiver, discharge, or termination is sought.

(h) Conflict with License Agreement: If any provision of this Trademark License Agreement is deemed to conflict with or contradict the terms of the License Agreement, the terms of the License Agreement shall govern and be controlling.

(i) Injunctive Relief: It is further understood and agreed that money damages would not be a sufficient remedy for any breach of this Trademark License Agreement by either party. In the event of any breach or threatened breach of this Trademark License Agreement, the non-breaching party, in addition to any other remedies it may have at law or in equity, shall be entitled to equitable relief, including injunctive relief and specific performance, without proof of actual damages. Further, the breaching party shall reimburse the non-breaching party for all costs and expenses (including attorney fees) the non-breaching party may incur in connection with the enforcement of this Trademark License Agreement.

IN WITNESS WHEREOF, Licensor and Licensee have each caused this Trademark License Agreement to be duly executed in its corporate name by a duly authorized representative as of the date first above written.

LICENSEE:
Jazz Pharmaceuticals, Inc.

By: /s/ Samuel R. Saks, M.D.
Name: Samuel R. Saks, M.D.
Title: Chief Executive Officer

LICENSOR:
Solvay Pharmaceuticals, Inc.

By: /s/ Laurence J. Downey, M.D.
Name: Laurence J. Downey, M.D.
Title: President and CEO

EXHIBIT A

REQUIREMENTS OF TRADEMARK USE

1. The first or most prominent reference to the Licensed Mark shall be marked with a ®" symbol.
2. The Licensed Mark shall be followed by the appropriate generic term at least once in each package or promotional piece.
3. The Licensed Mark shall not be used in possessive form.
4. The Licensed Mark shall not be used in the plural form.

Exhibit 10.54

Amendment No.2
to
Sodium Gamma Hydroxybutyrate
Development and Supply Agreement

This Amendment No.2 (the "Amendment") to the Sodium Gamma Hydroxybutyrate Development and Supply Agreement dated November 6, 1996, as amended, is entered into as of March 30, 2007 (the "Execution Date") between Jazz Pharmaceuticals, Inc., a Delaware corporation ("Jazz Pharmaceuticals") and Lonza, Inc., a New York corporation ("Supplier").

RECITALS

WHEREAS, Supplier and Orphan Medical, Inc., a Delaware corporation ("Orphan Medical"), have previously executed the Sodium Gamma Hydroxybutyrate Development and Supply Agreement dated as of November 6, 1996, as amended by Amendment No. 1 dated February 7, 2005 (collectively, the "Agreement"). Capitalized terms not otherwise defined herein shall have the meaning set forth in the Agreement;

WHEREAS, pursuant to Section 18.5 of the Agreement, Orphan Medical assigned its rights and obligations under the Agreement to Jazz Pharmaceuticals and all references to "Orphan Medical" in the Agreement therefore have been replaced by "Jazz Pharmaceuticals"; and

WHEREAS, in accordance with Section 18.4 of the Agreement, the parties wish to amend the Agreement as set forth in this Amendment.

NOW THEREFORE, in consideration of the mutual agreements and covenants set forth hereinafter and in the Agreement and other good and valuable consideration, receipt of which is hereby acknowledged, Jazz Pharmaceuticals and Supplier hereby agree as follows:

1. Amendment of the Definitions. Jazz Pharmaceuticals and Supplier hereby amend Article 1 of the Agreement as follows:

   1.1 The definition of "Contract Year" set forth in Section 1.3 is amended and restated in its entirety to read as follows:

   "1.3 "Contract Year" means each twelve (12) month period during the term of this Agreement starting on January 1st and ending on December 31st."

   1.2 A new definition of "Quota" is hereby added to Article 1 as follows:

   "1.25 "Quota" means the manufacturing quota quantity of the Drug allotted by the DEA to Supplier in a Contract Year in order for Supplier to perform the services hereunder."

2. Section 5.5 and 5.6 remain as stated in the Sodium Gamma Hydroxybutyrate Development and Supply Agreement dated as of November 6, 1996

3. Amendment of Forecasts, Orders and Deliveries. Jazz Pharmaceuticals and Supplier hereby amend and restate Section 6.1 of the Agreement in its entirety as follows:

"6.1 No later than the tenth (10^{th}) calendar day of each calendar month during the term of the Agreement, Jazz Pharmaceuticals shall furnish to Supplier a written rolling twelve (12) month forecast of Jazz Pharmaceuticals' anticipated purchases, including shipment dates, of the Drug (the "Forecast"). The first three (3) months covered in each twelve (12) month Forecast provided shall constitute a firm order (each, a "Firm Order"); the remaining nine (9) months covered by each Forecast shall be a non-binding estimate only. Each Forecast shall cover a twelve (12)-month forecast period starting the first (1st) day of the calendar month that is three (3) months after the month in which Jazz Pharmaceuticals provided such Forecast to Supplier. By way of example, the Forecast which Jazz Pharmaceuticals provides by April 10, 2007 shall cover the period from July 1, 2007 until October 30, 2008. For amounts of the Drug set forth in the Forecast, Jazz Pharmaceuticals and Supplier realize that the Quota may restrict manufacturing and hence delivery of shipments throughout the calendar year for which such Quota applies. If the Quota restricts, and is anticipated to restrict, Supplier's ability to meet the manufacturing requirements set forth in the Forecast, Supplier will promptly notify Jazz Pharmaceuticals and the parties will meet and agree on a plan to resolve the anticipated shortfall in requested Drug within 30 days.

(a) To ensure an uninterrupted supply of the Drug and to mitigate manufacturing delays caused by the Quota, Supplier agrees to use its commercially reasonable efforts to manufacture and maintain a reserve of Drug (the "Target Reserve") for purchase by Jazz Pharmaceuticals based upon the Quota in such calendar year. The Target Reserve for any calendar year shall be calculated as follows:

Quota	Target Reserve
Less than 15 mT	2 mT
15 to 30 mT	4 mT
Greater than 30 mT	6 mT

The inventory must be moved every calendar year, if at any time, the manufacture date of the stock in inventory is greater than one (1) calendar year from the date is was released; which could equate to a portion of the inventory, Jazz Pharmaceuticals agrees to compensate Supplier for the inventory on stock if otherwise not consumed.

Notwithstanding the above, the parties acknowledge that the DEA has ultimate control of the amount of the Drug that can be produced each calendar year.

(b) Supplier agrees to use its commercially reasonable efforts to obtain from the DEA the manufacturing quota of the Drug requested by Jazz Pharmaceuticals in a Contract Year including, but not limited to, any additional manufacturing quota amounts of the Drug that Jazz Pharmaceuticals may request Supplier to obtain during the Contract Year.

(c) Supplier acknowledges that in connection with seeking additional manufacturing quota of the Drug from the DEA pursuant to Section 6.1(b) above, Jazz Pharmaceuticals may wish to reserve capacity in addition to the capacity required to manufacture the Forecast. Accordingly, Jazz Pharmaceuticals will notify Supplier at least ninety (90) days in advance if it wishes to reserve additional capacity to manufacture additional Drug that is subject to the approval of the DEA of additional manufacturing quota of the Drug. If the reserve capacity is not needed because of quota restrictions or other, Jazz Pharmaceuticals will pay Supplier the equipment changeover fee of $150,000 and fixed costs ($19/kg). If the reserve capacity is needed in a quota restricted situation, but the expected campaign is smaller than indicated, Jazz Pharmaceuticals will pay the price/gram indicative of the actual campaign. In either case, Supplier may accept other opportunities to use its production capacity; however, the fees could be waived or, if paid, then Jazz Pharmaceuticals will be credited against future Firm Orders if Supplier can fill the equipment with other projects.

(d) Supplier shall provide or purchase all materials and supplies necessary to manufacture the Drug. Supplier shall

manufacture the Drug in accordance with the Specifications, the Validation Protocol and applicable cGMPs and shall package, label and/or otherwise prepare the Drug for bulk delivery to a Jazz Pharmaceuticals designated drug product manufacturer. Supplier further agrees that the Drug shall meet FDA, European, and Canadian standards and specifications. The International Conference on Harmonization (ICH) guidelines will be followed for development and manufacturing decisions."

4. Amendment to Choice of Law. Jazz Pharmaceuticals and Supplier hereby amend and restate Section 18.1 of the Agreement in its entirety as follows:

"18.1 Choice of Law. This Agreement shall be governed by and interpreted in accordance with the laws of New York, without regard to its conflict of laws provisions."

5. Amendment to Notices. Jazz Pharmaceuticals and Supplier hereby amend Section 18.2 of the Agreement to replace the address set forth for Jazz Pharmaceuticals set forth in Section 18.2 with the following addresses:

"If to Jazz Pharmaceuticals:	Jazz Pharmaceuticals, Inc. 3180 Porter Drive Palo Alto, California 94304 Attn: Director of Manufacturing Fax: (650) 496-2641
with a copy to:	Jazz Pharmaceuticals, Inc. 3180 Porter Drive Palo Alto, California 94304 Attn: General Counsel Fax: (650) 496-3781"

Amendment of Appendix H. Appendix H of the Agreement is hereby deleted in its entirety and hereby replaced with the following, which is attached hereto as **Exhibit A**. Pricing is for 2007. However, Supplier will use its commercially reasonable efforts to make improvements to the manufacturing process which would result in reduced costs and thus reduced pricing to Jazz Pharmaceuticals.

6. Acknowledgement of Contract Year. Jazz Pharmaceuticals and Supplier acknowledge and agree that the Contract Year that commenced on August 1, 2006 under the Agreement shall continue until December 31, 2007 and thereafter each Contract Year shall commence on January 1st and end on December 31st.

7. No Other Changes. Except as provided in this Amendment, the Agreement remains in full force and effect as originally executed.

8. Headings. Headings in this Amendment are for convenience of reference only and shall not be considered in construing this Amendment.

9. Severability. If any provision of this Amendment is held unenforceable by a court or tribunal of competent jurisdiction because it is invalid or conflicts with any law of any relevant jurisdiction, the validity of the remaining provisions shall not be affected. In such event, the parties shall negotiate a substitute provision that, to the extent possible, accomplishes the original business purpose.

10. Counterparts. This Agreement may be executed in two counterparts, each of which shall be deemed an original, but both of which together shall constitute one and the same instrument. Signatures provided by facsimile transmission shall be deemed to be original signatures.

IN WITNESS WHEREOF, the parties have executed this Amendment No.2 as of the Execution Date.

Jazz Pharmaceuticals, Inc.	Lonza, Inc.
By: /s/ Carol A. Gamble	By: /s/ Vincent DiVito
Its: Senior V.P. & General Counsel	Its: VP and Chief Financial Officer

Exhibit A

Appendix H

Revised Drug Price

2007 Price: Below is the annual price or campaign price. The DEA quota granted at the end of each calendar year will define the annual price for the following year in the below table. If Jazz Pharmaceuticals and Lonza have quota restrictions and all orders can not be met then subsequent pricing will be dictated by campaign size below agreed to in writing by Jazz Pharmaceuticals and Lonza.

Campaign Size or Annual Price (MT) SXB Salt	**Price (USD)** *per/campaign*
2	$ 130
3	$ 120
4	$ 105
5	$ 95
6	$ 92
7	$ 90
8	$ 85
9	$ 83
10	$ 82.5
11	$ 81
12 to 20	$ 78
20+	$ 72

Assumptions:

- The lower number is the minimum manufactured in a single campaign for each price section
- Vessel size 750 gallon
- Cycle time 46-73 hours or less (including drying)
- Material purchased within 30 days of release
- Yield >/= 472.9 kg SXB/batch

This price includes:

- All raw materials, processing, depreciation, overheads, profit, packaging.
- Scale up from intermediate size reactors to 1500 gallon or larger vessels (if needed).
- DMF (or equivalent) modifications required
- Reasonable regulatory support to Jazz
- Ongoing process improvement efforts with benefit sharing with Jazz

Note:

- Lonza and Jazz agree that any campaign that would come UNDER 8 metric tons will trigger a discussion on how to plan the most beneficial campaign program. The second pricing schedule (shown below) will be used when improvements are made to the process.

Example of Price Targets based on improvements that need to be discussed with Jazz:

Annual or Campaign Size (MT)	Pricing ($USD)
2 to 5	$ 110
5 to 8	$ 85
8 to 12	$ 75
12 to 20	$ 65
20+	$ 60

Cooley
GODWARD KRONISH LLP

Chadwick L. Mills
(650) 843-5654
cmills@cooley.com

May 24, 2007

Via EDGAR and Courier

U.S. Securities and Exchange Commission
Division of Corporation Finance
100 F Street NE
Washington, DC 20549
Attn: Mary K. Fraser
Jeffrey P. Riedler

RE: Jazz Pharmaceuticals, Inc.
Amendment No. 4 to the Registration Statement on Form S-1
Registration No. 333-141164

Ladies and Gentlemen:

On behalf of Jazz Pharmaceuticals, Inc. (the "***Registrant***"), we are transmitting for filing Amendment No. 4 (the "***Amendment***") to the Registration Statement on Form S-1, File No. 333-141164 (the "***Registration Statement***"). We are also sending copies of this letter and the Amendment (including one set of Exhibits), as well as copies that are marked to show changes to Amendment No. 3 to the Registration Statement filed with the U.S. Securities and Exchange Commission (the "***Commission***") on May 17, 2007, to the staff of the Commission (the "***Staff***") in care of Ms. Fraser.

As we indicated in our correspondence dated May 16, 2007 to the Staff in connection with the filing of Amendment No. 3 to the Registration Statement (the "***Prior Amendment***" and together with the Amendment, the "***Amendments***") and in response to comments received from the Staff by letter dated May 15, 2007, the Registrant has commenced marketing of its initial public offering and intends to request that the Registration Statement be declared effective as of May 31, 2007. To date, we have not received comments from the Staff concerning the Registrant's confidential treatment request dated March 27, 2007 with respect to Exhibits 10.30-10.44 and 10.46-10.51 to the Registration Statement, and the confidential treatment request dated April 20, 2007 with respect to Exhibit 10.54 to the Registration Statement (together, the "***Confidential Treatment Requests***"). Pursuant to our telephone conversations with Ms. Fraser and Mr. Riedler, we understand that this is largely due to the high volume of filings and other matters requiring the Staff's attention. As a result, and as discussed with Mr. Riedler on May 23, 2007, in order to assist the Staff in expediting its review of the Confidential Treatment Requests and after taking into consideration the Registrant's intent to request that the Registration Statement be declared effective as of May 31, 2007, the Registrant hereby respectfully withdraws its Confidential Treatment Requests with respect to Exhibits 10.31-10.32, 10.37-10.40, 10.43-10.44 and 10.54, and has re-filed such Exhibits in unredacted form with the Amendment. We respectfully advise the Staff that, notwithstanding the potential competitive harm to the Registrant by filing the aforementioned Exhibits in unredacted form, the Registrant is willing to withdraw such Confidential Treatment Requests with respect to such Exhibits due to the potential greater harm to the Registrant in delaying the effectiveness of the Registration Statement and the associated pricing of the Registrant's initial public offering.

As mentioned above, the Registrant currently intends to request that the Registration Statement be declared effective as of May 31, 2007 and in connection therewith, intends to file its request for acceleration of effectiveness on Tuesday, May 29, 2007. Accordingly, we respectfully request any

comments regarding the Amendments and/or the Confidential Treatment Requests with respect to the remaining Exhibits for which the Registrant is requesting confidential treatment of as soon as possible. For your convenience, attached hereto is a list of the remaining Exhibits for which the Registrant is requesting confidential treatment of. In connection with its request for acceleration of effectiveness, which the Registrant expects to submit on May 29, 2007, the Registrant will furnish the acknowledgement letter requested from the Staff by letter dated April 13, 2007.

Please direct any questions or comments regarding this filing to me at (650) 843-5654, Suzanne Sawochka Hooper at (650) 843-5180 or John M. Geschke at (650) 843-5757 if the Staff requires any additional information prior to acceleration of effectiveness of if there is anything that we or the Registrant can do to further facilitate your review.

Sincerely,

/s/ Chadwick L. Mills

Chadwick L. Mills

cc: Matthew K. Fust, Jazz Pharmaceuticals, Inc.
Carol A. Gamble, Esq., Jazz Pharmaceuticals, Inc.
P.J. Honerkamp, Esq., Jazz Pharmaceuticals, Inc.
Bruce Dallas, Esq., Davis Polk & Wardwell
John M. Geschke, Esq., Cooley Godward Kronish LLP

Chadwick L. Mills
(650) 843-5654
cmills@cooley.com

List of remaining Exhibits for which the Registrant is requesting confidential treatment of:

Exhibit Number	Description of Document
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.
10.33	Amended and Restated Services Agreement, dated as of May 31, 2005, by and between Orphan Medical, Inc. and Express Scripts Specialty Distribution Services, Inc.
10.34	Consent and Addendum to Amended and Restated Master Services Agreement, dated as of June 1, 2006, by and between the Registrant and Express Scripts Specialty Distribution Services, Inc.
10.35	Addendum No. 2 to Amended and Restated Master Services Agreement, dated as of June 22, 2006, by and between the Registrant and Express Scripts Specialty Distribution Services, Inc.
10.36	Addendum No. 3 to Amended and Restated Master Services Agreement, dated as of August 17, 2006, by and between the Registrant and Express Scripts Specialty Distribution Services, Inc.
10.41	Amended and Restated Xyrem License and Distribution Agreement, dated as of June 30, 2006, by and between the Registrant and UCB Pharma Limited.
10.42	License Agreement, dated as of January 31, 2007, by and between the Registrant and Solvay Pharmaceuticals, Inc.
10.46	License Agreement, dated as of December 22, 1997, by and between Solvay Pharmaceuticals, Inc and Elan Corporation plc.
10.47	Amendment to License Agreement, dated as of March 1, 1999, by and between Solvay Pharmaceuticals, Inc and Elan Corporation plc.
10.48	Letter Amendment No. 2 to License Agreement, dated April 13, 2000, by and between Solvay Pharmaceuticals, Inc and Elan Pharmaceutical Technologies.
10.49	Amendment Agreement No. 3 to License Agreement, dated as of November 7, 2006, by and between Solvay Pharmaceuticals, Inc. and Elan Corporation, plc.
10.50	Xyrem Manufacturing Services and Supply Agreement, dated as of March 13, 2007, by and between the Registrant and Patheon Pharmaceuticals, Inc.
10.51	Quality Agreement, dated as of March 13, 2007, by and between the Registrant and Patheon Pharmaceuticals, Inc.

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