JAZZ PHARMACEUTICALS INC
Form S-1
November 25, 2009
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As filed with the Securities and Exchange Commission on November 25, 2009

Registration No. 333 -

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-1

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

JAZZ PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**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)

Bruce C. Cozadd

Chief Executive Officer

3180 Porter Drive

Palo Alto, CA 94304

(650) 496-3777

(Name, address, including zip code, and telephone number, including area code, of agent for service)

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Approximate date of commencement of proposed sale to the public: From time to time after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box: þ

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer ¨	Accelerated filer ¨	Non-accelerated filer þ (Do not check if a smaller reporting company)	Smaller reporting company ¨

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be Registered(1)	Proposed Maximum Offering Price Per Unit(2)	Proposed Maximum Aggregate Offering Price(2)	Amount of Registration Fee
Common Stock, $0.0001 par value per share	5,142,064	$7.145	$36,740,047.28	$2,050.09

(1) Includes 220,000 shares of the registrant s common stock that may be issued upon the exercise of an outstanding warrant. Pursuant to Rule 416 under the Securities Act, the shares being registered hereunder include such indeterminate number of shares of common stock as may be issuable with respect to the shares being registered hereunder as a result of stock splits, stock dividends or similar transactions.

(2) Estimated solely for the purpose of calculating the amount of the registration fee pursuant to Rule 457 promulgated under the Securities Act. The offering price per share and the aggregate offering price are based upon the average of the high and low prices of the registrant s common stock as reported on The NASDAQ Global Market on November 23, 2009.

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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Subject to Completion, Dated November 24, 2009

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

PROSPECTUS

5,142,064 Shares

Common Stock

This prospectus relates to the disposition from time to time of up to 5,142,064 shares of our common stock that we may issue to the selling stockholder listed in the section beginning on page 44 of this prospectus. The shares of common stock offered under this prospectus by the selling stockholder are issuable to Kingsbridge Capital Limited, or Kingsbridge, pursuant to a common stock purchase agreement between Jazz Pharmaceuticals, Inc. and Kingsbridge, dated May 7, 2008, as amended, and a warrant we issued to Kingsbridge on that date. We are not selling any common stock under this prospectus and will not receive any of the proceeds from the sale of shares by the selling stockholder.

The selling stockholder, or its permitted transferees or other successors-in-interest, may offer the shares from time to time through public or private transactions at prevailing market prices, at prices related to prevailing market prices, or at privately negotiated prices. We provide more information about how the selling stockholder may sell its shares of common stock in the section entitled Plan of Distribution beginning on page 45 of this prospectus. We will not be paying any underwriting discounts or commissions in connection with any offering of common stock under this prospectus.

Our common stock is listed on The NASDAQ Global Market under the symbol JAZZ. On November 23, 2009, the last reported sale price of our common stock on The NASDAQ Global Market was $7.08.

Investing in our common stock involves a high degree of risk. You should review carefully the risks and uncertainties described under the heading Risk Factors beginning on page 6 of this prospectus, and under similar headings in any amendments or supplements to this prospectus.

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

The date of this prospectus is , 20 .

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ABOUT THIS PROSPECTUS

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

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

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

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PROSPECTUS SUMMARY

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

Jazz Pharmaceuticals, Inc.

Overview

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

Our marketed products and late-stage product candidate are:

Xyrem (sodium oxybate) oral solution. Xyrem is the only product approved by the U.S. Food and Drug Administration, or FDA, for the treatment of both excessive daytime sleepiness and cataplexy in patients with narcolepsy. Narcolepsy is a chronic neurologic disorder caused by the brain s inability to regulate sleep-wake cycles. We promote Xyrem in the U.S. for its FDA-approved indications to sleep specialists, neurologists, pulmonologists and psychiatrists through our specialty sales force. We have significantly increased U.S. sales of Xyrem since acquiring the rights to Xyrem in June 2005. We have licensed the rights to commercialize Xyrem in 54 countries outside of the U.S. to UCB Pharma Limited, or UCB, and in Canada to Valeant Canada Limited, or Valeant. UCB currently markets Xyrem in 14 countries.

Luvox CR (fluvoxamine maleate) Extended-Release Capsules. Once-Daily Luvox CR was approved by the FDA for the treatment of both obsessive compulsive disorder and social anxiety disorder on February 28, 2008. We began promoting Luvox CR through our specialty sales force in April 2008. Luvox CR is a once-daily extended-release formulation of fluvoxamine, a selective serotonin reuptake inhibitor, or SSRI. Luvox CR was developed by Solvay Pharmaceuticals, Inc., or Solvay, in collaboration with Elan Pharma International Limited, or Elan. We obtained the exclusive rights to market and distribute Luvox CR in the U.S. from Solvay in January 2007. Solvay retained the rights to market and distribute Luvox CR outside of the U.S.

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

Our other product candidates in clinical development are JZP-8 (intranasal clonazepam), being developed for the treatment of recurrent acute repetitive seizures in epilepsy patients who continue to have seizures while on stable anti-epileptic regimens, JZP-4 (elpetrigine), being developed for the treatment of epilepsy and bipolar disorder, and

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

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

Corporate Information

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

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

Committed Equity Financing Facility With Kingsbridge

On May 7, 2008, we entered into a committed equity financing facility, or CEFF, with Kingsbridge Capital Limited, or Kingsbridge, pursuant to which Kingsbridge committed to purchase, subject to certain conditions, up to $75.0 million of our common stock. In connection with the CEFF, we entered into a common stock purchase agreement and registration rights agreement with Kingsbridge, both dated May 7, 2008, and on that date we also issued a warrant to Kingsbridge to purchase up to 220,000 shares of our common stock originally having an exercise price of $11.20 per share. This warrant is exercisable at any time in whole or in part until November 7, 2013. On November 20, 2009, we entered into an amendment agreement pursuant to which we and Kingsbridge amended certain of the terms of the CEFF and reduced the exercise price of the warrant from $11.20 to $9.20 per share. The following is a summary of the CEFF and the warrant we issued to Kingsbridge, in each case as amended by the November 2009 amendment agreement.

The common stock purchase agreement entitles us to sell and obligates Kingsbridge to purchase, from time to time over a period of three years, shares of our common stock for cash consideration up to an aggregate of $75.0 million, subject to certain conditions and restrictions. The shares of common stock that may be issued to Kingsbridge under the common stock purchase agreement and the warrant will be issued pursuant to an exemption from registration under the Securities Act of 1933, as amended, or the Securities Act. Pursuant to the registration rights agreement, as amended, we have filed a registration statement, of which this prospectus is a part, covering the possible resale by Kingsbridge of any shares that we may issue to Kingsbridge under the common stock purchase agreement or upon exercise of the warrant. Through this prospectus, the selling stockholder may offer to the public for resale shares of our common stock that we may issue to Kingsbridge pursuant to the common stock purchase agreement, or that Kingsbridge may acquire upon exercise of the warrant.

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For a period of 36 months from the first trading day following the effectiveness of the registration statement of which this prospectus is a part, we may, from time to time, at our sole discretion, and subject to certain conditions that we must satisfy, draw down funds under the CEFF by selling shares of our common stock to Kingsbridge. The purchase price of these shares will be at a discount of up to 9.5% percent from the volume weighted average price of our common stock for each of the eight trading days following our election to sell shares, or draw down under the CEFF. The discount on each of these eight trading days will be determined as follows:

VWAP*	PERCENT OF VWAP	(APPLICABLE DISCOUNT)
Equal to or greater than $2.50 but less than $6.75	90.5%	(9.5)%
Equal to or greater than $6.75 but less than $8.00	91.0%	(9.0)%
Equal to or greater than $8.00 but less than $12.00	92.0%	(8.0)%
Equal to or greater than $12.00 but less than $15.00	93.0%	(7.0)%
Equal to or greater than $15.00 but less than $17.50	94.0%	(6.0)%
Equal to or greater than $17.50	95.0%	(5.0)%

* As set forth in the common stock purchase agreement, VWAP means the volume weighted average price (the aggregate sales price of all trades of our common stock during each trading day divided by the total number of shares of common stock traded during that trading day) of our common stock during any trading day as reported by Bloomberg L.P. using the AQR function. The VWAP and corresponding discount will be determined for each of the eight trading days during a draw down pricing period.

During the eight trading day pricing period for a draw down, if the VWAP for any one trading day is less than the greater of (i) $2.50 or (ii) 90% of the closing price of our common stock on the trading day immediately preceding the beginning of the draw down pricing period, the VWAP for that trading day will not be used in calculating the number of shares to be issued in connection with that draw down, and the draw down amount for that pricing period will be reduced by one-eighth of the draw down amount initially specified. In addition, if trading in our common stock is suspended for any reason for more than three consecutive or non-consecutive hours during any trading day during a draw down pricing period, that trading day will not be used in calculating the number of shares to be issued in connection with that draw down, and the draw down amount for that pricing period will be reduced by one-eighth of the draw down amount initially specified.

The maximum number of shares of common stock that we can issue pursuant to the CEFF is 4,922,064 shares. An additional 220,000 shares of common stock are issuable if Kingsbridge exercises the warrant that we issued to it in connection with Kingsbridge s entry into the CEFF. We intend to exercise our right to draw down amounts under the CEFF, if and to the extent available, at such times as we have a need for additional capital and when we believe that sales of stock under the CEFF provide an appropriate means of raising capital.

Our ability to require Kingsbridge to purchase our common stock is subject to various limitations. We can make draw downs to a maximum of, at our option, the greater of (i) 2.0% of our market capitalization at the time of the commencement of the draw down pricing period or (ii) the lesser of (A) 3.75% of our market capitalization at the time of the commencement of the draw down pricing period or (B) a number of shares determined by a formula based in part on the average trading volume and trading price of our common stock prior to the date of the draw down notice issued by us with respect to that pricing period; provided, however, that in no event can we require Kingsbridge to purchase shares in any draw down pricing period having an aggregate purchase price in excess of $25.0 million. Unless we and Kingsbridge agree otherwise, a minimum of three trading days must elapse between the expiration of any draw down pricing period and the beginning of the next succeeding draw down pricing period.

During the term of the CEFF, without the prior written consent of Kingsbridge, we may not issue securities that are, or may become, convertible or exchangeable into shares of common stock where the purchase, conversion or exchange price for that common stock is determined using any floating discount or other post-issuance adjustable discount to the market price of the common stock, including pursuant to an equity line or other financing that is substantially similar to the arrangement provided for in the CEFF.

The issuance of our common stock under the CEFF or upon exercise of the Kingsbridge warrant will have no effect on the rights or privileges of existing holders of common stock except that the economic and voting interests

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of each stockholder will be diluted as a result of any such issuance. Although the number of shares of common stock that stockholders presently own will not decrease, these shares will represent a smaller percentage of our total shares that will be outstanding after any issuances of shares of common stock to Kingsbridge. If we draw down amounts under the CEFF when our share price is decreasing, we will need to issue more shares to raise the same amount than if our stock price was higher. Such issuances will have a dilutive effect and may further decrease our stock price.

Kingsbridge agreed in the common stock purchase agreement that during the term of the CEFF, neither Kingsbridge nor any of its affiliates, nor any entity managed or controlled by it, will enter into, execute, or cause or assist any other person to enter into or execute, any short sale of any of our securities, including our common stock, or engage, through related parties or otherwise, in derivative transactions directly related to shares of our common stock, except during the term of a draw down pricing period with respect to the shares that Kingsbridge purchased pursuant to the CEFF during that draw down pricing period. Subject to the foregoing restrictions, Kingsbridge has the right during any draw down pricing period to sell shares of our common stock equal in number to the aggregate number of shares of common stock purchased pursuant to the CEFF during that draw down pricing period.

In order for Kingsbridge to be obligated to buy any shares of our common stock pursuant to a draw down, the following conditions, none of which is in the control of Kingsbridge, must be met as of the date we notify Kingsbridge of our election to sell shares to Kingsbridge pursuant to the CEFF, and the date upon which each settlement of the purchase and sale of our common stock occurs with respect to such draw down:

Each of our representations and warranties in the common stock purchase agreement must be true and correct in all material respects as of the date when made as though made at that time, except for representations and warranties that are expressly made as of a particular date.

We must have performed, satisfied and complied in all material respects with all covenants, agreements and conditions required by the common stock purchase agreement, the registration rights agreement and the warrant to be performed, satisfied or complied with by us.

We must have complied in all respects with all applicable federal, state and local governmental laws, rules, regulations and ordinances in connection with the execution, delivery and performance of the common stock purchase agreement and the consummation of the transactions contemplated by it, except for such failures to comply as would not have a material adverse effect on the business, operations, properties or financial condition of us and our subsidiaries as a whole or prohibit or otherwise interfere with our ability to perform any of our obligations under the common stock purchase agreement, registration rights agreement or warrant.

The registration statement, which includes this prospectus, shall have previously become effective and must remain effective.

We must not have knowledge of any event that could reasonably be expected to have the effect of causing the registration statement applicable to the resale of shares of our common stock by Kingsbridge to be suspended or otherwise ineffective.

Trading in our common stock must not have been suspended by the Securities and Exchange Commission, or the SEC, the NASDAQ Global Market or the Financial Industry Regulatory Authority and trading in securities generally on the NASDAQ Global Market must not have been suspended or limited.

No statute, rule, regulation, order, decree, writ, ruling or injunction shall have been enacted, entered, promulgated, endorsed or, to our knowledge, threatened by any court or governmental authority which prohibits the consummation of or would materially modify or delay any of the transactions contemplated by the common stock purchase agreement.

No action, suit or proceeding before any arbitrator or any governmental authority shall be pending, and, to our knowledge, no investigation by any governmental authority shall be threatened, against us, any of our subsidiaries or any of our or our subsidiaries officers, directors or affiliates seeking to enjoin, prevent or change the transactions contemplated by the common stock purchase agreement or seeking material damages in connection with such transactions.

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We must have sufficient shares of common stock, calculated using the closing trade price of the common stock as of the trading day immediately preceding the date we notify Kingsbridge of our election to sell shares to Kingsbridge pursuant to the CEFF, registered under the registration statement to issue and sell such shares in accordance with such draw down.

We must not be in default in any material aspect under the warrant we issued to Kingsbridge.

There is no guarantee that we will be able to meet the foregoing conditions or any other conditions under the common stock purchase agreement or that we will be able to draw down any portion of the amounts available under the CEFF.

The warrant that we issued to Kingsbridge may be exercised for cash or, or under certain circumstances, on a cashless basis, in which case we will deliver, upon exercise, the number of shares with respect to which the warrant is being exercised reduced by a number of shares having a value equal to the aggregate exercise price of the shares with respect to which the warrant is being exercised. The exercise price and number of shares of common stock issuable upon exercise of the warrant may be adjusted in certain circumstances, including subdivisions and stock splits, stock dividends, reorganizations, reclassifications, consolidations, mergers or sales of assets and upon the issuance of certain assets or securities to holders of our common stock, as applicable. We may, under certain circumstances involving a failure by Kingsbridge to accept a draw down, have the right to demand the surrender of the warrant (or any remaining portion thereof), shares of common stock issued upon any exercise of the warrant and/or cash proceeds from the sale of any such shares.

We also entered into a registration rights agreement with Kingsbridge. Pursuant to the registration rights agreement, as amended, we have filed a registration statement, which includes this prospectus, with the SEC relating to the resale by Kingsbridge of any shares of common stock purchased by Kingsbridge under the common stock purchase agreement or issued to Kingsbridge as a result of the exercise of the Kingsbridge warrant. We agreed to use our commercially reasonable efforts to have the registration statement be declared effective by the SEC no later than April 30, 2010 and to ensure that it remains effective for up to one year following the termination of the CEFF. The effectiveness of this registration statement is a condition precedent to our ability to sell common stock to Kingsbridge under the common stock purchase agreement. We are entitled in certain circumstances, including the existence of certain kinds of material nonpublic information, to deliver a blackout notice to Kingsbridge to suspend the use of this prospectus and prohibit Kingsbridge from selling shares under this prospectus for a period of not more than thirty days. If we deliver a blackout notice in the ten trading days following a settlement of a draw down (or 15 trading days if we convert this registration statement from a registration statement on Form S-1 under the Securities Act to a registration statement on Form S-3 under the Securities Act), or if the registration statement of which this prospectus is a part is not effective in circumstances not permitted by the registration rights agreement, then we must pay certain amounts to Kingsbridge (or issue Kingsbridge additional shares in lieu of payment) as liquidated damages.

The foregoing summary of the CEFF does not purport to be complete and is qualified by reference to the common stock purchase agreement, the registration rights agreement, the warrant and the November 2009 amendment agreement, copies of which have been filed as exhibits to the registration statement of which this prospectus is a part.

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RISK FACTORS

Investing in our common stock involves a high degree of risk. You should consider carefully the risk factors described below, and all other information contained in or incorporated by reference in this prospectus (as supplemented and amended), before deciding whether to buy our common stock. If any of the following risks actually occur, the market price of our common stock could decline, and you could lose all or part of your investment. Additional risks not presently known to us or that we currently believe are immaterial may also significantly impair our business operations and could result in a complete loss of your investment.

Risks Relating to Our Business

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

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

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

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

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

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

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

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

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

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

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

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

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

The DEA limits the quantity of certain Schedule I controlled substances that may be produced in the U.S. in any given calendar year through a quota system. Because the active pharmaceutical ingredient of Xyrem and JZP-6, sodium oxybate, is a Schedule I controlled substance, our supplier of the active pharmaceutical ingredient and our product manufacturers must obtain DEA quotas in order to supply us with sodium oxybate, Xyrem and JZP-6. Since the DEA typically grants quotas on an annual basis and requires a detailed submission and justification for each request, obtaining a DEA quota is a difficult and time consuming process. If our commercial or clinical requirements for sodium oxybate, Xyrem or JZP-6 exceed our supplier s and contract manufacturer s DEA quotas, our supplier and contract manufacturer would need quota increases from the DEA, which could be difficult and time consuming to obtain and might not ultimately be obtained on a timely basis, or at all. We believe, although we cannot assure you, that our quota for 2009 will be sufficient to meet our commercial, clinical and development needs. The DEA has issued a preliminary quota for 2010 that is the same as that issued for 2009 but that is substantially less than the quota we believe we will need both to provide commercial supplies of Xyrem and to prepare for the commercial launch of JZP-6. We are in discussion with the DEA concerning the 2010 quota; however, if we are not successful in changing the quota before it becomes final we would have to petition for a change to the quota which could delay the potential commercial launch of JZP-6. In the future and in cooperation with our procurement and manufacturing partners, we will continue to seek increased quotas to satisfy our clinical and commercial needs. However, we may not be successful in obtaining increased quotas from the DEA, and without sufficient DEA quotas, there could be shortages of Xyrem, JZP-6 or sodium oxybate for the marketplace or for use in our clinical studies, or both.

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

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

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

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

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

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

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

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

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

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

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

- the clinical indications for which a product is approved, including any potential additional restrictions placed upon the product in connection with its approval;
- prevalence of the disease or condition for which the product is approved and the severity of side effects;
- acceptance by physicians and patients of each product as a safe and effective treatment;
- perceived advantages over alternative treatments;
- relative convenience and ease of administration;
- the cost of treatment in relation to alternative treatments, including generic products;
- the extent to which the product is approved for inclusion on formularies of hospitals and managed care organizations; and
- the availability of adequate reimbursement by third parties.

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

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

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

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

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;

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- 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;
- varying interpretation of data by the FDA or foreign regulatory agencies; and
- insufficient funds to complete the trials.

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

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

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

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

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

If third parties do not successfully carry out their duties under their agreements with us, if the quality or accuracy of the data they obtain is compromised due to failure to adhere to our clinical protocols or regulatory

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requirements, or if they otherwise fail to comply with clinical trial protocols or meet expected deadlines, our clinical trials may not meet regulatory requirements. If our clinical trials do not meet regulatory requirements or if these third parties need to be replaced, our clinical trials may be extended, delayed, suspended or terminated. If any of these events occur, we may not be able to obtain regulatory approval of our product candidates.

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

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

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

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

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

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

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

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

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

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

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

We are marketing Luvox CR in the U.S. for the treatment of obsessive compulsive disorder and social anxiety disorder. Selective serotonin reuptake inhibitors are the standard treatment for anxiety disorders, including obsessive compulsive disorder and social anxiety disorder. Six other branded products are currently approved by the FDA for the treatment of obsessive compulsive disorder, including five selective serotonin reuptake inhibitors: Paxil, which is marketed by GlaxoSmithKline, Zoloft, which is marketed by Pfizer, Prozac, which is marketed by Eli Lilly, Pexeva, whic