

JAZZ PHARMACEUTICALS INC  
Form S-1/A  
May 24, 2007  
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As filed with the Securities and Exchange Commission on May 24, 2007

Registration No. 333 -141164

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

Washington, D.C. 20549

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**AMENDMENT NO. 4**

**TO**

**FORM S-1**

**REGISTRATION STATEMENT**

*UNDER*

*THE SECURITIES ACT OF 1933*

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**JAZZ PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

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

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

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

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**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)

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**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. "

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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. "

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**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*

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*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.*

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

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*Investing in the common stock involves risks. See Risk Factors beginning on page 9.*

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*PRICE \$                      A SHARE*

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	<i>Underwriting</i>		
	<i>Price to</i>	<i>Discounts and</i>	
<i>Per Share</i>	<i>Public</i>	<i>Commissions</i>	<i>Proceeds to</i>
<i>Total</i>	\$	\$	<i>Jazz Pharmaceuticals</i>
	\$	\$	\$

*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.



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**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



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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

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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

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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.

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#### **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.

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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.

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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](http://www.jazzpharmaceuticals.com). Information contained in, or accessible through, our website does not constitute a part of this prospectus.

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

**Market Data**

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



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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.



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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)				
<b>Consolidated Statements of Operations Data:</b>					
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)

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Loss per share attributable to common stockholders, basic and diluted	\$ (1,550.25)	\$ (14,192.67)	\$ (6,254.69)	\$ (2,875.56)	\$ (851.48)
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Weighted-average common shares used in computing loss per share attributable to common stockholders, basic and diluted