TITAN PHARMACEUTICALS INC
Form S-1/A
May 05, 2010
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As filed with the Securities and Exchange Commission on May 5, 2010

Registration No. 333-166351

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

AMENDMENT NO. 1

TO

FORM S-1

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

TITAN PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	94-3171940	2836
(State or Other Jurisdiction of Incorporation or Organization)	(IRS Employer Identification No.)	(Primary Standard Industrial Classification Code Number)

400 Oyster Point Blvd., Suite 505, South San Francisco, California 650-244-4990

(Address, including zip code, and Telephone Number, including area code, of Registrant s Principal Executive Offices)

Sunil Bhonsle, President

Titan Pharmaceuticals, Inc.

400 Oyster Point Blvd., Suite 505, South San Francisco, California

650-244-4990

(Name, Address, including zip code, and Telephone Number, including area code, of Agent for Service)

With a copy to:

Fran Stoller, Esq.

Loeb & Loeb LLP

345 Park Avenue

New York, New York 10154

Tel: (212) 407-4935

Fax: (212) 407-4990

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

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. x

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

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

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

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

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

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Amount of shares to be registered (1)	Proposed Maximum offering price per share (2)	Proposed maximum aggregate offering price	Amount of registration fee
common stock, par value $0.001 per share	3,515,000	$1.735	$6,098,525	$434.82
common stock, par value $0.00 per share	6,191,250	$1.735	$10,741,818.75	$765.89
Total (3)	9,706,250		$16,840,343.75	$1,200.71*

(1) Pursuant to Rule 416 under the Securities Act of 1933, as amended (the Securities Act), this registration statement includes an indeterminate number of shares as may become necessary to adjust the number of shares issued by the Registrant to the selling stockholders resulting from stock splits, stock dividends or similar transactions involving our common stock.

(2) Estimated solely for the purpose of calculating the registration fee in accordance with Rule 457(c) under the Securities Act based on the average of the high and low prices of our common stock reported on the OTC Pink Sheets on April 23, 2010.

(3) Pursuant to Rule 429 of the Securities Act, includes 9,406,250 shares previously included in the Registrant s registration statement on Form S-3 (file number 333-148757) declared effective by the Securities and Exchange Commission on February 1, 2008.

* Previously paid

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 which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 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. THE SELLING STOCKHOLDERS MAY NOT SELL THESE SECURITIES PUBLICLY UNTIL THE REGISTRATION STATEMENT FILED WITH THE SECURITIES AND EXCHANGE COMMISSION IS EFFECTIVE. THIS PROSPECTUS IS NOT AN OFFER TO SELL THESE SECURITIES AND IT IS NOT SOLICITING AN OFFER TO BUY THESE SECURITIES IN ANY STATE WHERE THE OFFER OR SALE IS NOT PERMITTED.

Subject to Completion, Dated May 5, 2010

Prospectus

TITAN PHARMACEUTICALS, INC.

9,706,250 Shares of Common Stock

This prospectus relates to the resale of 9,706,250 shares of our common stock, par value $.001 per share, being offered by the selling stockholders identified in this prospectus. The shares of common stock offered under this prospectus include 6,191,250 shares issuable upon exercise of outstanding warrants (the Warrants).

We will not receive any of the proceeds from the sale of the shares by the selling stockholders. To the extent the Warrants are exercised for cash, if at all, we will receive the exercise price for the Warrants. The selling stockholders may sell the shares as set forth herein under Plan of Distribution.

We have agreed to pay certain expenses in connection with the registration of the shares.

Our common stock is traded on the OTC Pink Sheets under the symbol TTNP.PK . The closing price for our common stock on May 4, 2010 was $1.22 per share. We are seeking to have our common stock listed on the OTC Bulletin Board.

Investing in our common stock involves risk. You should carefully consider the risk factors beginning on page 4 of this prospectus before purchasing shares of our common stock.

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES, OR PASSED UPON THE ADEQUACY OR ACCURACY OF THIS PROSPECTUS. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

The date of this prospectus is May , 2010

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SUMMARY

This summary highlights material information about us that is described more fully elsewhere in this prospectus. It may not contain all of the information that you find important. You should carefully read this entire document, including the Risk Factors section beginning on page 4 of this prospectus and the consolidated financial statements and related notes to those statements appearing elsewhere in this prospectus before making a decision to invest in our common stock.

Unless otherwise indicated in this prospectus or the context otherwise requires, all references to we, us, our, the Company and Titan refers to Titan Pharmaceuticals, Inc. and all of its subsidiaries. References to the SEC or Commission refers to the U.S. Securities and Exchange Commission.

Probuphine® , Spheramine® and ProNeura are trademarks of our company. This Form S-1 also includes trade names and trademarks of companies other than Titan.

OUR COMPANY

We are a biopharmaceutical company developing proprietary therapeutics primarily for the treatment of central nervous system (CNS) disorders. We currently have two key assets as described below:

Iloperidone (Fanapt): An atypical antipsychotic approved by the U.S. Food and Drug Administration (FDA) for the treatment of schizophrenia. Novartis Pharma AG (Novartis) has acquired the U.S. and Canadian rights to further develop and commercialize the approved oral formulation, and also further develop and potentially commercialize an injectible form of the drug, known as a depot formulation, that will provide medication over a prolonged period of several weeks following a single treatment. Vanda Pharmaceuticals, Inc. (Vanda) has the development and commercialization rights to the oral and depot formulations of this product for the rest of the world. We are entitled to a royalty of 8-10% on worldwide net sales for several years based on the remaining life of certain patents (through September 2016 for the oral formulation in the U.S. including a patent extension requested under the Hatch Waxman Act), and we anticipate commencement of royalty revenues from sales in the United States during the first half of 2010.

Probuphine: An implant formulation of buprenorphine in Phase 3 clinical development for the treatment of opioid addiction that is capable of maintaining a stable blood level of the drug in patients for six months following a single treatment. We announced positive safety and efficacy results of this product in a placebo controlled Phase 3 study during 2008 and we have now completed approximately half of the overall clinical development program required for registration and potential approval of Probuphine. Recently we have been awarded a $7.6 million grant from the National Institutes of Health (NIH) that will partially fund the second Phase 3 controlled safety and efficacy study required by the FDA for product registration.

We have been publicly-traded since our company s initial public offering in January 1996. In December 2008, as part of our efforts to conserve cash, we announced our decision to voluntarily delist from the NYSE Amex (formerly the American Stock Exchange) and terminate our obligation to file reports under the Securities Exchange Act of 1934 (the Exchange Act). In light of recent favorable developments, in particular the U.S. Food and Drug Administration s approval of Fanapt and our receipt of a grant from the National Institutes for Health for our Probuphine program, our board of directors made a determination to file a registration statement on Form 10 to re-register under the Exchange Act. On March 15, 2010, our reporting obligations under the Exchange Act resumed. On April 26, 2010, we were informed that the SEC has completed its review of the Form 10. Our executive offices are located 400 Oyster Point Blvd., Suite 505, South San Francisco, California. Our telephone number is 650-244-4990. Our website address is www.titanpharm.com.

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NOTE REGARDING FORWARD-LOOKING STATEMENTS

Statements in this Form S-1 or in the documents incorporated by reference herein that are not descriptions of historical facts are forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Reference is made in particular to the description of our plans and objectives for future operations, assumptions underlying such plans and objectives and other forward-looking terminology such as may, expects, believes, anticipates, intends, expects, projects, or similar terms, variations of such the negative of such terms. Forward-looking statements are based on management s current expectations. Actual results could differ materially from those currently anticipated due to a number of factors, including those set forth under Risk Factors including, in particular, risks relating to:

- sales of Fanapt;
- the results of ongoing research and development activities;
- uncertainties relating to preclinical and clinical testing, financing and strategic agreements and relationships;
- the early stage of products under development;
- government regulation;
- patent matters; and
- competition.

We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations or any changes in events, conditions or circumstances on which any such statement is based.

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THE OFFERING

This prospectus relates to the resale of 9,706,250 shares of our common stock, par value $.001 per share being offered by the selling stockholders identified in this prospectus.

Common stock being offered by selling stockholders	9,706,250 shares
Common stock outstanding	59,247,742 shares as of the date of this Prospectus
Common stock outstanding after the offering (assuming full exercise of the Warrants)	65,438,992 shares
Use of Proceeds	We will not receive any proceeds from the sale of the shares by the selling stockholders. However, to the extent that the Warrants are exercised for cash, we will receive proceeds from any exercise of the Warrants up to an aggregate of approximately $12.4 million. We intend to use any proceeds received from the exercise of the Warrants for working capital and other general corporate purposes.
Trading	Our common stock is listed on the OTC Pink Sheets under the symbol TTNP.PK.
Risk Factors	The securities offered by this prospectus are speculative and involve a high degree of risk and investors purchasing securities should not purchase the securities unless they can afford the loss of their entire investment. See Risk Factors beginning on page 4.

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RISK FACTORS

An investment in our common stock is speculative and involves a high degree of risk and uncertainty. You should carefully consider the risks described below, together with the other information contained in this prospectus, including the consolidated financial statements and notes thereto, before deciding to invest in our common stock. Additional risks not presently known to us or that we presently consider immaterial may also adversely affect our company. If any of the following risks occur, our business, financial condition and results of operations and the value of our common stock could be materially and adversely affected.

The timing and amount of royalty revenues from iloperidone (Fanapt) will be wholly dependent on the efforts of third parties.

We do not have any role in the marketing, manufacture or commercialization of iloperidone (Fanapt). The timing and amount of royalty revenues we receive from the sale of this product will be wholly dependent upon the ability of Novartis to successfully launch and commercialize this product in the United States and Canada and on the ability of Vanda or others to sell this product in other countries. Similarly, our ability to realize any royalty revenue relating to the depot formulation of the product will depend on the ability of Novartis to successfully complete the development and regulatory approval process and implement the marketing program necessary to commercialize this product. While Novartis has announced that it launched commercial sales of Fanapt in January 2010, which would result in royalty payments to us during the following quarter, Novartis may experience unanticipated problems that delay, perhaps materially, product sales and our receipt of revenues.

Our available capital is sufficient to fund our operations only through September 2010 and we do not have the funds needed to continue the Probuphine program.

At December 31, 2009, we had cash and cash equivalents of $3.3 million, which we believe is sufficient, together with the $7.6 million NIH grant, to sustain our planned operations through September 2010, at which time we expect to be generating revenues from royalties on the sale of Fanapt. We do not currently have sufficient capital to fully fund the Probuphine program, external costs of which are currently estimated at approximately $18.5 million exclusive of any additional clinical trials the FDA may require, and we cannot be certain that the requisite funds will be available, from royalty revenues or otherwise, to continue that program.

Probuphine is in the development stage and may not be successfully developed or commercialized.

Probuphine, which is in Phase 3 clinical development, will require significant further capital expenditures, development, testing, and regulatory clearances prior to commercialization. Even if we are able to obtain the requisite funding to continue this program, the results of preclinical and clinical studies to date are not necessarily indicative of whether a product will demonstrate safety and efficacy in large patient populations to the satisfaction of the regulatory authorities in the U.S. and elsewhere. Of the large number of drugs in development, only a small percentage successfully complete the FDA regulatory approval process and are commercialized.

To date, we have experienced setbacks in some of our other product development efforts. For example, the results of a study evaluating the EKG profile of patients taking iloperidone led to a significant delay in the development of that product, a vaccine product formerly under development failed to meet the study s primary endpoint, and a study of one of our products in a combination treatment was discontinued as a result of an interim safety analysis. We may continue to experience unanticipated problems relating to product development, testing, regulatory compliance, manufacturing, marketing and competition, and our costs and expenses could exceed current estimates. We cannot predict whether we will successfully develop and commercialize Probuphine or any other product.

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We must comply with extensive government regulations.

The research, development, manufacture and marketing of pharmaceutical products are subject to an extensive regulatory approval process by the FDA and other regulatory agencies in the U.S. and other countries. The process of obtaining required regulatory approvals for drugs, including conducting preclinical and clinical testing to determine safety and efficacy, is lengthy, expensive and uncertain. Even after such time and expenditures, we may not obtain necessary regulatory approvals for clinical testing or for the manufacturing or marketing of any products. We have limited experience in obtaining FDA approval. Regulatory approval may entail limitations on the indicated usage of a drug, which may reduce the drug s market potential. Even if regulatory clearance is obtained, post-market evaluation of the products, if required, could result in restrictions on a product s marketing or withdrawal of the product from the market, as well as possible civil and criminal sanctions. Our business will be seriously harmed if our regulatory submissions are delayed or we cancel plans to make submissions for proposed products for any of the following reasons:

unanticipated preclinical testing or clinical trial reports;

failure to reach agreement with the FDA regarding study protocols or endpoints;

changes in regulations or the adoption of new regulations;

unanticipated enforcement of existing regulations;

unexpected technological developments; and

developments by our competitors.

We face risks associated with third parties conducting preclinical studies and clinical trials of our products as well as our dependence on third parties to manufacture any products that we may successfully develop.

We depend on third-party laboratories and medical institutions to conduct preclinical studies and clinical trials for our products and other third-party organizations to perform data collection and analysis, all of which must maintain both good laboratory and good clinical practices. We will also depend upon third party manufacturers for the production of any products we may successfully develop to comply with current Good Manufacturing Practices of the FDA, which are similarly outside our direct control. If third party laboratories and medical institutions conducting studies of our products fail to maintain both good laboratory and clinical practices, the studies could be delayed or have to be repeated. Similarly, if the manufacturers of any products we develop in the future fail to comply with current Good Manufacturing Practices of the FDA, we may be forced to cease manufacturing such product until we have found another third party to manufacture the product.

We face risks associated with clinical trial liability claims in the event that the use or misuse of our product candidates results in personal injury or death.

We face an inherent risk of clinical trial liability claims in the event that the use or misuse of our product candidates results in personal injury or death. Our clinical liability insurance coverage may not be sufficient to cover claims that may be made against us. Any claims against us, regardless of their merit, could severely harm our financial condition, strain our management and other resources or destroy the prospects for commercialization of the product which is the subject of any such claim.

We may be unable to protect our patents and proprietary rights.

Our future success will depend to a significant extent on our ability to:

obtain and keep patent protection for our products and technologies on an international basis;

enforce our patents to prevent others from using our inventions;

maintain and prevent others from using our trade secrets; and

operate and commercialize products without infringing on the patents or proprietary rights of others.

We cannot assure you that our patent rights will afford any competitive advantages, and these rights may be challenged or circumvented by third parties. Further, patents may not be issued on any of our pending patent applications in the U.S. or abroad. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that before a potential product can be commercialized, any related patent

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may expire or remain in existence for only a short period following commercialization, reducing or eliminating any advantage of the patent. For example, the two U.S. patents licensed by Titan under the MIT license have already expired, and we must rely on the method of use patent application for Probuphine to get patent protection and market exclusivity. If we sue others for infringing our patents, a court may determine that such patents are invalid or unenforceable. Even if the validity of our patent rights is upheld by a court, a court may not prevent the alleged infringement of our patent rights on the grounds that such activity is not covered by our patent claims.

In addition, third parties may sue us for infringing their patents. In the event of a successful claim of infringement against us, we may be required to:

- pay substantial damages;
- stop using our technologies and methods;
- stop certain research and development efforts;
- develop non-infringing products or methods; and
- obtain one or more licenses from third parties.

If required, we cannot assure you that we will be able to obtain such licenses on acceptable terms, or at all. If we are sued for infringement, we could encounter substantial delays in development, manufacture and commercialization of our product candidates. Any litigation, whether to enforce our patent rights or to defend against allegations that we infringe third party rights, will be costly, time consuming, and may distract management from other important tasks.

We also rely in our business on trade secrets, know-how and other proprietary information. We seek to protect this information, in part, through the use of confidentiality agreements with employees, consultants, advisors and others. Nonetheless, we cannot assure you that those agreements will provide adequate protection for our trade secrets, know-how or other proprietary information and prevent their unauthorized use or disclosure. To the extent that consultants, key employees or other third parties apply technological information independently developed by them or by others to our proposed products, disputes may arise as to the proprietary rights to such information, which may not be resolved in our favor.

We face intense competition.

Competition in the pharmaceutical and biotechnology industries is intense. We face, and will continue to face, competition from numerous companies that currently market, or are developing, products for the treatment of the diseases and disorders we have targeted. Many of these entities have significantly greater research and development capabilities, experience in obtaining regulatory approvals and manufacturing, marketing, financial and managerial resources than we have. We also compete with universities and other research institutions in the development of products, technologies and processes, as well as the recruitment of highly qualified personnel. Our competitors may succeed in developing technologies or products that are more effective than the ones we have under development or that render our proposed products or technologies noncompetitive or obsolete. In addition, our competitors may achieve product commercialization or patent protection earlier than we will.

Healthcare reform and restrictions on reimbursements may limit our financial returns.

Our ability or the ability of our collaborators to commercialize drug products, if any, may depend in part on the extent to which government health administration authorities, private health insurers and other organizations will reimburse consumers for the cost of these products. These third parties are increasingly challenging both the need for and the price of new drug products. Significant uncertainty exists as to the reimbursement status of newly approved therapeutics. Adequate third party reimbursement may not be available for our own or our collaborator s drug products to enable us or them to maintain price levels sufficient to realize an appropriate return on their and our investments in research and product development.

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We may not be able to retain our key management and scientific personnel.

As a company with a limited number of personnel, we are highly dependent on the services of our executive management and scientific staff, in particular Sunil Bhonsle and Marc Rubin, our President and Executive Chairman, respectively, and our Senior Vice President Clinical Development and Medical Affairs, all of whom are parties to employment agreements with us. The loss of one or more of such individuals could substantially impair ongoing research and development programs and could hinder our ability to obtain corporate partners. Our success depends in large part upon our ability to attract and retain highly qualified personnel. We compete in our hiring efforts with other pharmaceutical and biotechnology companies, as well as universities and nonprofit research organizations, and we may not be successful in our efforts to attract and retain personnel.

Our shares are currently quoted on the OTC Pink Sheets and we cannot predict whether our shares will ever trade on the OTC Bulletin Board or any national securities exchange.

Our shares are currently quoted on the OTC Pink Sheets. Many institutional investors have investment policies which prohibit them from trading in stocks on the OTC Pink Sheets. As a result, shares quoted on the OTC Pink Sheets generally have limited trading volume and exhibit a wide spread between the bid/ask quotations than stock traded on national exchanges. A registered broker-dealer has filed a Form 211 with the Financial Industry Regulatory Authority that would permit our common stock to be quoted for trading on the OTC Bulletin Board, but we cannot be sure that such an effort would be successful. As a result, an investment in our common stock may be illiquid and investors may not be able to liquidate their investment readily or at all when they desire to sell.

Our stock price has been and will likely continue to be volatile.

Our stock price has experienced substantial fluctuations and could continue to fluctuate significantly due to a number of factors, including:

- variations in our anticipated or actual operating results;
- sales of substantial amounts of our common stock;
- announcements about us or about our competitors, including introductions of new products;
- litigation and other developments relating to our patents or other proprietary rights or those of our competitors;
- conditions in the pharmaceutical or biotechnology industries;
- governmental regulation and legislation; and
- change in securities analysts estimates of our performance, or our failure to meet analysts expectations.

Our common stock is deemed to be a penny stock, which may make it more difficult for investors to sell their shares due to suitability requirements.

Our common stock is subject to Rule 15g-1 through 15g-9 under the Exchange Act, which imposes certain sales practice requirements on broker-dealers which sell our common stock to persons other than established customers and accredited investors (generally, individuals with a net worth in excess of $1,000,000 or annual incomes exceeding $200,000 (or $300,000 together with their spouses)). For transactions covered by this rule, a broker-dealer must make a special suitability determination for the purchaser and have received the purchaser s written consent to the transaction prior to the sale. This rule adversely affects the ability of broker-dealers to sell our common stock and the ability of our stockholders to sell their shares of common stock.

Additionally, our common stock is subject to the SEC regulations for penny stock. Penny stock includes any equity security that is not listed on a national exchange and has a market price of less than $5.00 per share, subject to certain exceptions. The regulations require that prior to any non-exempt buy/sell transaction in a penny stock, a disclosure schedule set forth by the SEC relating to the penny stock market must be delivered to the purchaser of such penny stock. This disclosure must include the amount of commissions payable to both the broker-

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dealer and the registered representative and current price quotations for the common stock. The regulations also require that monthly statements be sent to holders of penny stock that disclose recent price information for the penny stock and information of the limited market for penny stocks. These requirements adversely affect the market liquidity of our common stock.

As a result of the de-registration of our securities, we are currently ineligible to use Form S-3 to register securities, which may adversely affect our cost of future capital.

We are currently ineligible to use Form S-3 to register securities for sale by us or for resale by other security holders and will not be eligible until we have timely filed all periodic reports under the Exchange Act for at least 12 calendar months. In the meantime, we would need to use Form S-1 to register securities with the SEC for capital raising transactions or issue such securities in private placements, in either case, increasing the costs of raising capital during this period.

Our net operating losses and research and development tax credits may not be available to reduce future federal and state income tax payments.

At December 31, 2009, we had federal net operating loss and tax credit carryforwards of $227.8 million and $7.0 million, respectively, and state net operating loss and tax credit carryforwards of $123.4 million and $6.5 million, respectively. Current federal and state tax laws include substantial restrictions on the utilization of net operating loss and tax credits in the event of an ownership change. We have not performed a change of ownership analysis since 1999 and, accordingly, some or all of our net operating loss and tax credit carryforwards may not be available to offset future taxable income, if any. Even if the carryforwards are available, they may be subject to annual limitations, lack of future taxable income, or future ownership changes that could result in the expiration of the carryforwards before they are utilized.

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USE OF PROCEEDS

We will not receive any of the proceeds from the sale of the Shares being offered by the selling stockholders. However, to the extent that the Warrants are exercised for cash, we will receive proceeds from any exercise of the Warrant up to an aggregate of approximately $12.4 million. We intend to use any proceeds received from the exercise of the Warrants for working capital and other general corporate purposes.

SELECTED CONSOLIDATED FINANCIAL DATA

The following selected historical financial information should be read in conjunction with our financial statements and related notes included as part of this prospectus as well as and the information contained in the section of this prospectus captioned Management s Discussion and Analysis of Financial Condition and Results of Operations. The selected consolidated statement of income data for the fiscal years ended December 31, 2007, 2008 and 2009 and the consolidated balance sheet data as of December 31, 2008 and 2009 have been derived from our audited consolidated financial statements of included elsewhere in this prospectus. The results of operations for past accounting periods are not necessarily indicative of the results to be expected for any future periods.

	Years Ended December 31,		
	2009	2008	2007
	(in thousands, except per share data)		
Statement of Operations Data:			
Total revenue	$ 79	$ 73	$ 24
Operating expenses:			
Research and development	2,456	16,235	12,244
General and administrative	3,438	9,756	6,213
Other income (expense), net	(71)	484	786
Net loss	$ (5,886)	$ (25,434)	$ (17,647)
Basic and diluted net loss per share	$ (0.10)	$ (0.44)	$ (0.41)
Shares used in computing:			
Basic and diluted net loss per share	58,473	58,285	42,998

	As of December 31,		
	2009	2008	2007
	(in thousands)		
Balance Sheet Data:			
Cash, cash equivalents, and marketable securities	$ 3,300	$ 4,672	$ 30,016
Working capital	2,069	2,759	26,200
Total assets	3,726	5,668	30,844
Total stockholders equity (deficit)	(1,448)	1,793	25,347

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MANAGEMENT S DISCUSSION AND ANALYSIS OF

FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Statements in the following discussion and throughout this report that are not historical in nature are forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act. You can identify forward-looking statements by the use of words such as expect, anticipate, estimate, may, will, should, intend, believe, and similar expressions. Although we believe the exp reflected in these forward-looking statements are reasonable, such statements are inherently subject to risk and we can give no assurances that our expectations will prove to be correct. Actual results could differ from those described in this report because of numerous factors, many of which are beyond our control. These factors include, without limitation, those described under Item 1A Risk Factors. We undertake no obligation to update these forward-looking statements to reflect events or circumstances after the date of this report or to reflect actual outcomes. Please see Note Regarding Forward Looking Statements at the beginning of this Form S-1.

The following discussion of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and the related notes thereto and other financial information appearing elsewhere in this Form S-1.

Overview

We are a biopharmaceutical company engaged in the development of proprietary therapeutics primarily for the treatment of CNS disorders. We commenced operations in 1992 and completed an initial public offering in January 1996. At the end of 2007, we had three late stage product development programs: (i) iloperidone-NDA filed with the FDA by Vanda seeking U.S. marketing approval for treatment of schizophrenia, (ii) Probuphine-controlled Phase 3 study being conducted by Titan to evaluate safety and efficacy for the treatment of opioid addiction, and (iii) Spheramine-controlled Phase 2b study being conducted by Bayer Schering Pharma for the treatment of advanced Parkinsons disease. In July 2008, we learned that Vanda, the licensee of iloperidone, had received a non-approval letter from the FDA. In July 2008, we announced positive results in the Phase 3 study of Probuphine for the treatment of opioid addiction. In September 2008, we were advised by the licensee of Spheramine that it was ending its development program and terminating its license agreement with us. After further review and analysis of the information on which such licensee s decision was based, we also decided to discontinue any further activities associated with this product candidate. As a result of these adverse events with respect to two of our three principal product candidates, we were forced to undertake substantial cost cutting measures that included an almost complete reduction in our workforce and a phased suspension of all of our development activities, and focus our efforts on maximizing value for our stockholders either through the sale of assets or the establishment of a corporate partnering arrangement for Probuphine.

In May 2009, the FDA, after reviewing additional material provided by Vanda, reconsidered its decision and granted approval for iloperidone (Fanapt). Later that month, we announced that we had re-engaged three of our prior executives, including our two current executive officers. In October 2009, we received a $7.6 million grant from the NIH for the clinical development of Probuphine and later that month Vanda and Novartis announced their agreement regarding the marketing and commercialization of Fanapt . Our board of directors is currently in the process of evaluating all of the strategic alternatives available to us to maximize shareholder value, including possible monetization of the Fanapt royalty stream, continuation of the Probuphine program, a merger or other business combination, among others.

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Critical Accounting Policies and the Use of Estimates

The preparation of our financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in our consolidated financial statements and accompanying notes. Actual results could differ materially from those estimates. We believe the following accounting policies for the years ended December 31, 2009 and 2008 to be applicable:

Share-Based Payments

Effective January 1, 2006, we adopted the fair value recognition provisions of ASC 718, Compensation-Stock Compensation (formerly SFAS No. 123(R)), using the modified-prospective transition method. Under the fair value recognition provisions of ASC 718, share-based compensation cost is estimated at the grant date based on the fair value of the award and is recognized as expense, net of estimated pre-vesting forfeitures, ratably over the vesting period of the award. We selected the Black-Scholes option pricing model as the most appropriate fair value method for our awards. Calculating share-based compensation expense requires the input of highly subjective assumptions, including the expected term of the share-based awards, stock price volatility, and pre-vesting forfeitures. We estimated the expected term of stock options granted for the years ended December 31, 2009 and 2008 based on the historical experience of similar awards, giving consideration to the contractual terms of the share-based awards, vesting schedules and the expectations of future employee behavior. We estimated the expected term of stock options granted for the year ended December 31, 2007 based on the simplified method provided in Staff Accounting Bulletin No. 107, Share-Based Payment. We estimated the volatility of our common stock at the date of grant based on the historical volatility of our common stock. The assumptions used in calculating the fair value of share-based awards represent our best estimates, but these estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and we use different assumptions, our share-based compensation expense could be materially different in the future. In addition, we are required to estimate the expected pre-vesting forfeiture rate and only recognize expense for those shares expected to vest. We estimate the pre-vesting forfeiture rate based on historical experience. If our actual forfeiture rate is materially different from our estimate, our share-based compensation expense could be significantly different from what we have recorded in the current period.

Income Taxes

We make certain estimates and judgments in determining income tax expense for financial statement purposes. These estimates and judgments occur in the calculation of certain tax assets and liabilities, which arise from differences in the timing of recognition of revenue and expense for tax and financial statement purposes. As part of the process of preparing our consolidated financial statements, we are required to estimate our income taxes in each of the jurisdictions in which we operate. This process involves us estimating our current tax exposure under the most recent tax laws and assessing temporary differences resulting from differing treatment of items for tax and accounting purposes. We assess the likelihood that we will be able to recover our deferred tax assets. We consider all available evidence, both positive and negative, expectations and risks associated with estimates of future taxable income and ongoing prudent and feasible tax planning strategies in assessing the need for a valuation allowance. If it is not more likely than not that we will recover our deferred tax assets, we will increase our provision for taxes by recording a valuation allowance against the deferred tax assets that we estimate will not ultimately be recoverable.

Clinical Trial Accrual

We also record accruals for estimated ongoing clinical trial costs. Clinical trial costs represent costs incurred by clinical research organizations, (CROs), and clinical sites. These costs are recorded as a component of research and development expenses. Under our agreements, progress payments are typically made to investigators, clinical sites and CROs. We analyze the progress of the clinical trials, including levels of patient enrollment, invoices received and contracted costs when evaluating the adequacy of accrued liabilities. Significant judgments and estimates must be made and used in determining the accrued balance in any accounting period. Actual results could differ from those estimates under different assumptions. Revisions are charged to expense in the period in which the facts that give rise to the revision become known. The actual clinical trial costs for the Probuphine studies conducted in the past three years have not differed materially from the estimated projection of expenses.

Liquidity and Capital Resources

We have funded our operations since inception primarily through sales of our securities, as well as with proceeds from warrant and option exercises, corporate licensing and collaborative agreements, and government-sponsored research grants. At December 31, 2009, we had approximately $3.3 million of cash and cash equivalents compared to approximately $4.7 million at December 31, 2008. Our operating activities used approximately $5.5 million during the year ended December 31, 2009. This consisted primarily of the net loss for the period of

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approximately $5.9 million and $1.3 million related to net changes in operating assets and liabilities. This was offset in part by non-cash charges of approximately $0.2 million related to depreciation, and approximately $1.5 million related to share-based compensation expenses. Uses of cash in operating activities were primarily to fund product development programs and administrative expenses. The license agreements with Sanofi-Aventis and MIT require us to pay royalties on future product sales, if any. In addition, in order to maintain license and other rights while products are under development, we must comply with customary licensee obligations, including the payment of patent-related costs, annual minimum license fees, meeting project-funding milestones and diligent efforts in product development. The aggregate commitments we have under these agreements, including minimum license payments, for the next 12 months is approximately $100,000.

Net cash provided by investing activities of approximately $2,000 during the year ended December 31, 2009 consisted of purchas