TITAN PHARMACEUTICALS INC
Form 10-12G/A
March 31, 2010
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10/A

GENERAL FORM FOR REGISTRATION OF SECURITIES

Pursuant to Section 12(b) or (g) of The Securities Exchange Act of 1934

Titan Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**94-3171940**
State of other jurisdiction of	**I.R.S. Employer**
incorporation or organization	**Identification No.**
400 Oyster Point Blvd., Suite 505,	**94080**

South San Francisco, California
(Address of principal executive officer) **(Zip code)**
Registrant s telephone number, including area code: (650) 244-4990

Securities to be registered pursuant to Section 12(b) of the Act: none

Securities to be registered pursuant to Section 12(g) of the Act:

Common Stock, $ .001 par value

(Title of class)

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 smaller reporting company)	Smaller reporting company	x

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EXPLANATORY NOTE

Titan Pharmaceuticals, Inc. has 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 this registration statement on Form 10 to re-register under the Exchange Act. It is our intention to resume filing all periodic reports under the Exchange Act. In addition, we will seek to have our shares, which are currently quoted on the OTC Pink Sheets system, listed on the OTC Bulletin Board. Our board is taking these actions as part of an ongoing process to evaluate all of the strategic alternatives available to us with the goal of maximizing value for our stockholders.

References herein to we, us, Titan, and our company refer to Titan Pharmaceuticals, Inc. and its subsidiaries unless the context otherwise requires.

Probuphine®, Spheramine® and ProNeura are trademarks of our company. This Form 10 also includes trade names and trademarks of companies other than Titan.

SPECIAL NOTE REGARDING FORWARD-LOOKING INFORMATION

Statements in this Form 10 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:

- 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.

Item 1. Business

Overview

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

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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.

In September 2008, we were notified by Bayer Schering Pharma of the termination of the license agreement for the development and commercialization of Spheramine®, our proprietary cell therapy product in development for treating Parkinson s disease. Bayer Schering Pharma returned all rights for this product to us and, after further review and analysis of the information, we also decided to discontinue any further activities associated with this product candidate. Subsequently, we terminated our Spheramine license agreement with New York University (NYU) and returned all rights previously granted to us by NYU. Thereafter, to further conserve capital, we also terminated the license agreements for DITPA and gallium maltolate and returned all development and commercialization rights to the respective licensors, except for certain rights from the University of Iowa to potentially use gallium maltolate for the treatment of chronic bacterial infections.

Our Products

The following table provides a summary status of our products:

Product	Potential Indication(s)	Phase of Development	Marketing Rights
Iloperidone (Fanapt)	Schizophrenia, psychosis	Approved in U.S. for schizophrenia	Novartis U.S. and Canada Vanda - Rest of the world
Probuphine	Opioid addiction	Phase 3	Titan

Iloperidone (Fanapt) was approved by the FDA in May 2009 for the treatment of schizophrenia and Novartis has acquired the rights to commercialize it in the U.S. and Canada. Novartis announced that it commenced commercial launch of Fanapt in January 2010.

Probuphine is currently in Phase 3 clinical development and although it has demonstrated efficacy in one controlled Phase 3 study, additional development is necessary prior to registration and it may still not be successfully developed or commercialized. Titan has been awarded a $7.6 million grant by the NIH in partial support of the second controlled Phase 3 study, the total external cost of which is estimated at approximately $14.6 million. We will also require significant further capital, currently estimated at approximately $3.9 million, to support third party expenses related to manufacturing development, testing, and regulatory clearance activities prior to commercialization without giving effect to the cost of additional clinical studies, if any, that may be required by the FDA. We may experience unanticipated problems relating to product development and cannot predict whether we will successfully develop and commercialize any products.

Iloperidone (Fanapt)

Iloperidone (Fanapt) is our novel, proprietary product approved in the U.S. on May 6, 2009 for the treatment of adult patients with schizophrenia. The Phase 3 clinical development was conducted initially by our sub-licensee, Novartis, and completed by Novartis sub-licensee, Vanda. In July 2008, Vanda received a non-approval letter from the FDA requesting additional information about the product. Vanda addressed the questions asked by the FDA and provided additional clarification following which the FDA granted marketing approval as noted above. The approval was supported by two placebo-controlled Phase 3 clinical studies comparing Fanapt to placebo and active control in patients with schizophrenia, as well as safety data from more than 3,000 patients. Fanapt , a mixed dopamine D2 / serotonin 5HT2A receptor antagonist belonging to the class of atypical antipsychotics, will be commercialized in the U.S. and Canada by Novartis and the development of a depot formulation will also be pursued by Novartis. Vanda has commercialization rights for the rest of the world for the oral formulation and the

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depot formulations, although Novartis has the first option to negotiate an agreement to co-market both these products in the rest of the world. Based on the terms of our sub-license agreement with Novartis we are entitled to royalty revenue of 8% of annual worldwide net sales up to $200 million and 10% of annual worldwide net sales above $200 million. We do not incur any expenses associated with this product.

Probuphine

We are developing Probuphine for the treatment of opioid addiction. Probuphine is the first product to utilize our novel, proprietary, long-term drug delivery technology. See Continuous Drug Delivery Technology below. Probuphine is designed to provide continuous, long-term therapeutic levels of the drug buprenorphine, an approved agent for the treatment of opioid addiction. Probuphine has been shown to be effective with an acceptable safety profile in the three Phase 3 studies that have been completed to date, specifically:

A six-month, double-blind, placebo-controlled safety and efficacy trial;

A six-month, open-label re-treatment safety trial; and

A pharmacokinetic safety study.

The goal of any therapy for an addictive disorder is to reduce the use of the illicit substance over time and to engage the patient in treatment long enough for therapeutic gains to be consolidated. In a clinical study, the effectiveness of a treatment for opioid addiction is evaluated by testing a patient s urine samples for the presence of illicit opioids over the treatment period. In the placebo controlled Phase 3 study of Probuphine, every participant was required to provide urine samples three times a week, essentially on alternate days. Any missed sample was considered a positive result (i.e. urine testing positive for illicit opioid). In the study, the primary effectiveness of the treatment with Probuphine was established by comparing the negative urine results (i.e. urine testing negative for illicit opioid) between the Probuphine and placebo arms using a statistical technique, specifically the continuous distribution function of negative urines , which basically performs a comparative analysis of the urine testing results over the time period of treatment. The patients in the Probuphine arm showed clinically meaningful and a statistically significant difference in the negative urines as compared to the placebo arm, i.e. the Probuphine patients had statistically more negative results than the placebo arm, demonstrating that the treatment with Probuphine was successful in reducing their usage of illicit opioids as compared to the treatment with placebo. These favorable results for Probuphine were also confirmed by a significant difference over the placebo arm in other secondary measures such as retention in treatment, withdrawal symptoms and craving for opioids, all of which are monitored by clinicians to see if a treatment is providing clinically meaningful benefit to the patients. Results for the first double-blind, placebo-controlled safety and efficacy study were initially released in July 2008. Treatment with Probuphine was well tolerated in this clinical study.

Patients who completed the first controlled study were eligible for enrollment in the six month re-treatment study, which provided data on one full year of treatment. The pharmacokinetic safety study has provided important data on the level of buprenorphine in the blood during the treatment period and gives a good profile of the safety of Probuphine. Data from all of these studies have been presented at the International Society of Addiction Medicine 2008 Annual Meeting in November 2008, and the American Society of Addiction Medicine 2009 Annual Meeting in May 2009.

These studies are part of a registration directed program intended to obtain marketing approval of Probuphine for the treatment of opioid addiction in Europe and the U.S. The Phase 3 program includes additional clinical studies, including a second controlled Phase 3 study which has received a $7.6 million award from the NIH. This NIH grant will support approximately half of the expenses associated with this study and we will need additional funding to complete this clinical study and the overall development program. This confirmatory Phase 3 study will be conducted at approximately 23 sites in the U.S. and about one-third of those sites have been initiated and are currently in the process of recruiting patients. Completion of patient enrollment is targeted for the end of 2010 with study completion and results available in the third quarter of 2011. We continue to have discussions with the FDA relating to finalizing the Probuphine clinical development program and the chemistry and manufacturing controls (CMC) which is necessary prior to any product registration.

In June 2004, we announced final results from a pilot clinical study that evaluated the safety, pharmacokinetics and preliminary efficacy of Probuphine in the treatment of opioid-addicted patients. The results were presented at the Annual Meeting of the International Society of Addiction Medicine in Helsinki, and demonstrated that all 12 patients switched from daily sublingual buprenorphine therapy to Probuphine, had maintenance of therapeutic benefit for a period of six months following a single treatment of Probuphine. Treatment with Probuphine was well tolerated in this clinical study, with no significant adverse events.

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Continuous Drug Delivery Technology

Our continuous drug delivery system consists of a small, solid rod made from a mixture of ethylene-vinyl acetate (EVA) and a drug substance. The resulting product is a solid matrix that is placed subcutaneously, normally in the upper arm in a simple office procedure, and is removed in a similar manner at the end of the treatment period. The drug substance is released slowly, at continuous levels, through the process of diffusion. This results in a constant rate of release similar to intravenous administration. We believe that such long-term, linear release characteristics are desirable by avoiding peak and trough level dosing that poses problems for many CNS and other therapeutic agents.

Our continuous drug delivery technology was developed to address the need for a simple, practical method to achieve continuous long-term drug delivery, and potentially can provide controlled drug release on an outpatient basis over extended periods of up to 6 12 months. In addition to Probuphine, which is our first product in clinical testing to utilize our proprietary continuous drug delivery technology, we continue to seek opportunities to develop this drug delivery technology for other potential treatment applications in which conventional treatment is limited by variability in blood drug levels and poor patient compliance.

License Agreements

We are a party to several agreements with companies and universities for the performance of research and development activities and for the acquisition of licenses relating to such activities. Expenses under these agreements totaled approximately $86,000, $239,000 and $378,000 in the years ended December 31, 2009, 2008 and 2007, respectively.

In January 1997, we acquired an exclusive worldwide license under U.S. and foreign patents and patent applications relating to the use of iloperidone for the treatment of psychiatric and psychotic disorders and analgesia from Sanofi-Aventis SA (Sanofi-Aventis) (formerly Hoechst Marion Roussel, Inc.). The Sanofi-Aventis agreement provides for the payment of royalties on future net sales and requires us to satisfy certain other terms and conditions, specifically continued diligent product development and commercialization efforts standard for these types of agreements, in order to retain our rights, all of which have been met to date.

In November 1997, we granted a worldwide sublicense, except Japan, to Novartis under which Novartis continued, at its expense, all further development of iloperidone. In April 2001, that sublicense was extended to include Japan. Novartis will make our milestone and royalty payments to Sanofi-Aventis during the life of the Novartis agreement, and will also pay Titan a royalty on future net sales of the product.

In June 2004, Vanda acquired from Novartis the worldwide rights to develop and commercialize iloperidone. Under its agreement with Novartis, Vanda proceeded with and funded the iloperidone Phase III development program. All of our rights and economic interests in iloperidone, including royalties on sales of iloperidone, remained essentially unchanged under the agreement.

In October 2009, Vanda and Novartis amended and restated their sub-license agreement whereby Novartis acquired the U.S. and Canadian rights to commercialize Fanapt, the oral formulation of iIloperidone approved in the U.S. Novartis also acquired the U.S. and Canadian development and commercialization rights to the depot formulation previously under development by Vanda and agreed to fund and continue the development of this formulation. Further, Novartis has also retained the right of first negotiation to co-market Fanapt and the depot formulation in the rest of the world. Our royalty interest in iloperidone remains unchanged, and Titan is entitled to royalty revenue of 8% of annual worldwide net sales up to $200 million and 10% of annual worldwide net sales above $200 million for several years based on the remaining life of certain patents. We anticipate commencement of royalty revenues from U.S. sales during the first half of 2010.

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In October 1995, we acquired from the Massachusetts Institute of Technology (MIT) an exclusive worldwide license to certain U.S. and foreign patents relating to our continuous drug delivery system. The exclusive nature of the MIT license is subject to our continued diligent product development activities. The agreement provides for the payment of a 2% royalty based on sales of products and processes incorporating the licensed technology, as well as 25% of other income (excluding research expense reimbursement) derived from sublicenses of the licensed technology.

In August 2000, through the acquisition of GeoMed, Inc., we acquired an exclusive worldwide license to make, use and sell products developed under the patent rights to the compositions and application of gallium complexes. We subsequently acquired additional rights to gallium; however, between December 2008 and March 2009, as part of our ongoing efforts to conserve cash, we terminated all of the license agreements with the exception of an agreement we entered into in July 2005 with the University of Iowa Research Foundation. Under this agreement, we received an exclusive worldwide license to patent rights held by the University of Iowa Research Foundation covering the methods of treating biofilm formation, pseudomoras aeruginosa growth, human deficiency virus, and intracellular pathogens and pathogens causing chronic pulmonary infection using gallium maltolate. Under this agreement, we are required to pay a license issuance fee and certain minimum annual royalty payments. In addition, we are required to pay royalties based on net sales of products and processes incorporating the licensed technology.

Patents and Proprietary Rights

We hold a license from Sanofi-Aventis under certain issued U.S. patents and certain issued foreign patents relating to iloperidone and its methods of use. Our license is exclusive for use in the treatment of psychiatric disorders, psychotic disorders and analgesia. The term of the U.S. patent that covers certain aspects of our iloperidone product expires in 2011, however it is anticipated that based on provisions of the Hatch-Waxman Act pertaining to the approval by the FDA of new molecules for medical treatment, the market exclusivity period for Fanapt will be extended by five years to 2016. The method of use patent in the U.S. covering the depot formulation will expire in 2020 assuming no further extensions. The issued foreign patents cover major countries in Europe, Asia, North and South America and Africa with expiration dates ranging from 2010 to 2015 (does not include any market exclusivity periods or patent extension periods that may be available in these countries). Prosecution of various divisional and continuation applications and their foreign counterparts continues satisfactorily, although it is uncertain whether additional patents will be granted.

We are the exclusive licensee under the MIT license to two U.S. patents and their European counterparts relating to a long-term drug delivery system. The U.S. patent terms have already expired and European patent terms will expire in 2010. These dates do not include possible term extensions. Four additional patent applications have been filed which incorporate the use of specific compounds with the continuous delivery technology, including two applications related to Probuphine for the potential treatment of opioid addiction and chronic pain. Patents have issued in Australia, India, Mexico and New Zealand and we have received a Notice of Allowance from the United States Patent and Trademark Office (PTO) for certain claims regarding the use of Probuphine for the treatment of opioid addiction. Further prosecution of these applications is currently proceeding at the PTO and corresponding agencies in Europe, Canada, Japan, India and Hong Kong. The U.S. patent related to the use of Probuphine for the treatment of opioid addiction, if issued, will provide market exclusivity up to 2023.

We are the licensee from the University of Iowa Research Foundation (UIRF) of two issued U.S. patents (expiring 2016) relating to methods of use of gallium compounds to inhibit the growth of P. aeruginosa, and the treatment of infections by pathogens causing chronic pulmonary infection. We are also the licensee from UIRF of certain rights to patent applications covering the use of gallium complexes in preventing and also treating bacterial biofilm-based infections, for which patents have issued in South Africa and Mexico and prosecution in the U.S., Canada, Europe, Australia, New Zealand and some Asian countries continues.

Competition

The pharmaceutical and biotechnology industries are characterized by rapidly evolving technology and intense competition. Many companies of all sizes, including major pharmaceutical companies and specialized biotechnology companies, are engaged in the development and commercialization of therapeutic agents designed for the treatment of the same diseases and disorders that we target. Many of our competitors have substantially greater

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financial and other resources, larger research and development staff and more experience in the regulatory approval process. Moreover, potential competitors have or may have patents or other rights that conflict with patents covering our technologies. For risks we face with respect to competition, see Risk Factors We face intense competition.

With respect to Probuphine, Reckitt & Benckiser, Inc. received FDA approval in 2002 for a sublingual buprenorphine product for the treatment of opioid addiction. This product, to be administered daily, will compete with our six-month implantable product for opioid addiction. The FDA previously approved Orphan Drug designation, expiring in 2009, for Reckitt Benckiser s sublingual buprenorphine for the treatment of opioid addiction. Other forms of buprenorphine are also in development by other companies, including intramuscular injections and intranasally delivered buprenorphine, which also might compete with our product.

Several products categorized as atypical antipsychotics that will compete with Fanapt are already on the market. These products include Risperdal sold by Janssen Pharmaceuticals, Zyprexa sold by Eli Lilly, Clozaril sold by Novartis, Seroquel sold by AstraZeneca, Geodon sold by Pfizer, and Abilify sold by Bristol-Myers Squibb. Competition among these companies is already intense and iloperidone will face significant competition. The success of Fanapt will depend on how it can be differentiated from products already on the market on the basis of efficacy, side-effect profile, cost, availability of formulations and dose requirements, among other things.

Manufacturing

We utilize contract manufacturing organizations to manufacture our products for pre-clinical studies and clinical trials. While we have not introduced any products on the commercial market to date, at such time as we are ready to do so we will need to allocate additional resources to the manufacture of these products. We do not have the facilities to manufacture these products in-house nor do we intend to establish our own manufacturing operation at this time. We currently plan to pursue collaborative arrangements regarding the manufacture of any products that we may successfully develop.

Government Regulation

In order to obtain FDA approval of a new drug, a company generally must submit proof of purity, potency, safety and efficacy, among other regulatory standards. In most cases, such proof entails extensive clinical and pre-clinical laboratory tests.

The procedure for obtaining FDA approval to market a new drug involves several steps. Initially, the manufacturer must conduct pre-clinical animal testing to demonstrate that the product does not pose an unreasonable risk to human subjects in clinical studies. Upon completion of such animal testing, an Investigational New Drug application, or IND, must be filed with the FDA before clinical studies may begin. An IND application consists of, among other things, information about the proposed clinical trials. Among the conditions for clinical studies and IND approval is the requirement that the prospective manufacturer s quality control and manufacturing procedures conform to current Good Manufacturing Practices (cGMP), which must be followed at all times. Once the IND is approved (or if the FDA does not respond within 30 days), the clinical trials may begin.

The results of the pre-clinical and clinical testing on new drugs, if successful, are submitted to the FDA in the form of a New Drug Application (NDA). The NDA approval process requires substantial time and effort and there can be no assurance that any approval will be granted on a timely basis, if at all. The FDA may refuse to approve an NDA if applicable regulatory requirements are not satisfied. Product approvals, if granted, may be withdrawn if compliance with regulatory standards is not maintained or problems occur following initial marketing.

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The FDA may also require post-marketing testing and surveillance of approved products, or place other conditions on their approvals. These requirements could cause it to be more difficult or expensive to sell the products, and could therefore restrict the commercial applications of such products. Product approvals may be withdrawn if compliance with regulatory standards is not maintained or if problems occur following initial marketing. With respect to patented products or technologies, delays imposed by the governmental approval process may materially reduce the period during which we will have the exclusive right to exploit such technologies.

We believe we are in compliance with all material applicable regulatory requirements. However, see Risk Factors We must comply with extensive government regulations for additional risks we face regarding regulatory requirements and compliance.

Foreign Regulatory Issues

Sales of pharmaceutical products outside the United States are subject to foreign regulatory requirements that vary widely from country to country. Whether or not FDA approval has been obtained, approval of a product by a comparable regulatory authority of a foreign country must generally be obtained prior to the commencement of marketing in that country. Although the time required to obtain such approval may be longer or shorter than that required for FDA approval, the requirements for FDA approval are among the most detailed in the world and FDA approval generally takes longer than foreign regulatory approvals.

Employees

At December 31, 2009, we had three full-time employees, one part-time employee and several consultants. See Risk Factors We may not be able to retain our key management and scientific personnel.

Item 1A. Risk Factors

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 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.

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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.

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.

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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 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

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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.

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 in 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 in 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. We anticipate having a registered broker-dealer file 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.

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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-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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Item 2. Financial Information
Management s Discussion and Analysis of Financial Condition and Results of Operations.

Forward-Looking Statements

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 Special Note Regarding Forward Looking Statements at the beginning of this Form 10.

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 10.

Overview

We are a biopharmaceutical company engaged in the development of proprietary therapeutics primarily for the treatment of central nervous system (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.

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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, Vanda and Novartis announced their agreement regarding the marketing and commercialization of this product and later that month we received a $7.6 million grant from the NIH for the clinical development of Probuphine. 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.

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.

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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 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. See Item 1. Business License Agreements.

Net cash provided by investing activities of approximately $2,000 during the year ended December 31, 2009 consisted of purchases of furniture and equipment of approximately $7,000. This was offset in part by net proceeds from the sale of an investment of approximately $9,000.

Net cash provided by financing activities during the year ended December 31, 2009 was approximately $4.0 million, which consisted primarily of proceeds from the following: In September and October 2009, our directors exercised options to purchase our common stock providing net proceeds of approximately $555,000. In December 2009, we completed the sale of 300,000 shares of common stock for aggregate net proceeds of approximately $478,000. Also in December 2009, we entered into a financing agreement with Oxford Capital Financing (Oxford) pursuant to which we received a three-year term loan in the principal amount of $3.0 million that bears interest at the rate of 13% per annum. We paid Oxford an initial facility fee of $60,000 and are obligated to make a final payment fee of $180,000. The loan is secured by our assets and has a provision for pre-payment. Oxford received five-year warrants to purchase 42,254 shares of our common stock at an exercise price of $2.13 per share.

We expect to continue to incur substantial additional operating losses from costs related to the continuation of product and technology development, clinical trials, and administrative activities. We believe that our working capital at December 31, 2009, together with proceeds from the NIH grant, is sufficient to sustain our planned operations through September 2010, at which time we expect to be generating royalty

revenues from sales of Fanapt that we believe will enable us to fund our operations at least through December 2010.

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The following table sets forth the aggregate contractual cash obligations as of December 31, 2009 (in thousands):

		Payments Due by Period			
Contractual obligations	**Total**	**< 1 year**	**1-3 years**	**3-5 years**	**5 years+**
Operating leases	$ 289	$ 274	$ 15	$	$
License agreements	78	61	7	5	5
Debt obligation	$ 3,905	$ 901	$ 3,004	$ 0	
Total contractual cash obligations	$ 4,272	$ 1,236	$ 3,026	$ 5	$ 5

For a full discussion of risks and uncertainties regarding our need for additional financing, see Risk Factors 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.

Results of Operations

Year Ended December 31, 2009 Compared to Year Ended December 31, 2008

Revenues in 2009 were approximately $79,000 compared to approximately $73,000 in 2008, an increase of approximately $6,000. Our revenues during 2009 and 2008 were derived from fees received under various licensing agreements.

Research and development expenses for 2009 were approximately $2.5 million compared to approximately $16.2 million in 2008, a decrease of approximately $13.7 million, or 85%. The decrease in research and development costs was primarily associated with the phased suspension of activities associated with clinical trials related to our Probuphine product, resulting in reductions in employee-related costs of approximately $3.8 million, internal research and development expenses of approximately $1.1 million and external research and development expenses of approximately $8.6 million. External research and development expenses include direct expenses such as clinical research organization charges, investigator and review board fees, patient expense reimbursements and contract manufacturing expenses. During 2009, our external research and development expenses relating to our Probuphine product development program were approximately $0.7 million compared to approximately $9.3 million for 2008. Other research and development expenses include internal operating costs such as clinical research and development personnel-related expenses, clinical trials-related travel expenses, and allocation of facility and corporate costs. As a result of the risks and uncertainties inherently associated with pharmaceutical research and development activities described elsewhere in this report, we are unable to estimate the specific timing and future costs of our clinical development programs or the timing of material cash inflows, if any, from our products or product candidates.

General and administrative expenses for 2009 were approximately $3.4 million, compared to approximately $9.8 million in 2008, a decrease of approximately $6.4 million, or 65%. The decrease in general and administrative expenses was primarily related to reductions in employee-related costs of approximately $3.9 million, non-cash stock compensation costs of approximately $0.3 million, marketing and product positioning costs of approximately $1.0 million, legal fees of approximately $0.3 million, travel-related expenses of approximately $0.3 million, consulting and professional fees of approximately $0.2 million, Board of Directors fees of approximately $0.2 million, and other general and administrative costs of approximately $0.1 million.

Net other expense for 2009 was approximately $71,000 compared to net other income of approximately $484,000 in 2008. Net other expense in 2009, consisted primarily of financing related expenses of approximately $60,000, interest expense of approximately $9,000 and tax-related expenses of approximately $10,000 offset by interest income of approximately $2,000 and net gain of approximately $6,000 resulting from the sale of certain assets. Net other income during 2008, consisted primarily of interest income on investments of approximately $0.5 million and gains of approximately $0.1 million resulting from the sale of certain investments offset by other expenses of approximately $0.1 million.

As a result of the foregoing, we had a net loss of approximately $5.9 million in 2009 compared to a net loss of approximately $25.4 million in 2008.

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Year Ended December 31, 2008 Compared to Year Ended December 31, 2007

Revenues in 2008 were $73,000 compared to $24,000 for 2007, an increase of $49,000. Our revenues during 2008 and 2007 were derived from fees received under various licensing agreements.

Research and development expenses for 2008 were $16.2 million compared to $12.2 million for 2007, an increase of $4.0 million. The increase in research and development expense was primarily associated with the initiation of certain clinical study-related activities in 2007. Of our 2008 research and development expenses, approximately 57%, or $9.3 million, were attributable to external research and development expenses related to our Probuphine project. External research and development expenses include direct expenses such as clinical research organization charges, investigator and review board fees, patient expense reimbursements, pre-clinical activities and contract manufacturing expenses. Remaining research and development expenses were attributable to internal operating costs, which include clinical research and development personnel salaries and employee-related expenses, clinical trials related travel expenses, and allocation of facility and corporate costs.

General and administrative expenses for 2008 were $9.8 million compared to $6.2 million for 2007, an increase of $3.6 million. The increase in general and administrative expenses was primarily related to increases in employee-related costs of approximately $1.9 million, non-cash stock compensation costs of approximately $0.5 million, marketing and product positioning costs of approximately $0.6 million, legal fees of approximately $0.2 million, travel-related expenses of approximately $0.1 million, and other general and administrative costs of approximately $0.3 million. This was offset by a decrease in consulting and professional fees of approximately $0.1 million.

Other income, net, for 2008 was $484,000 compared to $786,000 for 2007, a decrease of $302,000. The decrease in other income, net, consisted primarily of a decrease in interest income on investments of approximately $0.2 million and a decrease in gains on the sale of investments of approximately $0.2 million. This was offset by a decrease in other expense of approximately $0.1 million.

As a result of the foregoing, we had a net loss of $25.4 million in 2008 compared to a net loss of $17.7 million in 2007.

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