TITAN PHARMACEUTICALS INC
Form 10-K
March 12, 2008

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2007

Or

¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to .

Commission file number 001-13341

TITAN PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**94-3171940**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer identification number)**

400 Oyster Point Blvd., Suite 505,

South San Francisco, California	**94080**
(Address of principal executive offices)	**(Zip code)**

Registrant s telephone number, including area code: (650) 244-4990

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

Title of each class	**Name of each exchange on which registered**
Common Stock, $.001 par value	**The American Stock Exchange**

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer as defined in Rule 405 of the Securities Act. Yes ¨ No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes ¨ No x

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to the filing requirements for the past 90 days. Yes x No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition or accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ¨ Accelerated filer x Non-accelerated filer ¨ Small Reporting Company ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x

The aggregate market value of the 43,488,626 shares of voting and non-voting common equity held by non-affiliates of the registrant based on the closing price on June 29, 2007 was $94.4 million.

As of March 7, 2008, 58,281,460 shares of common stock, $.001 par value, of the registrant were issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE: NONE

PART I

Statements in this Form 10-K that are not descriptions of historical facts are forward-looking statements that are subject to risks and uncertainties. Actual results could differ materially from those currently anticipated due to a number of factors, including those set forth under Risk Factors including, but not limited to, the results of research and development efforts, the results of pre-clinical and clinical testing, the effect of regulation by the United States Food and Drug Administration (FDA) and other agencies, the impact of competitive products, product development, commercialization and technological difficulties, the Company s ability to obtain additional financing, the effect of our accounting policies, and other risks detailed in our Securities and Exchange Commission filings.

Probuphine®, Spheramine®, ProNeura and CCM are trademarks of Titan Pharmaceuticals, Inc. This Form 10-K also includes other trade names and trademarks of companies other than Titan Pharmaceuticals, Inc.

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

Item1. Business

(a) General Development of Business

We are a biopharmaceutical company developing proprietary therapeutics primarily for the treatment of central nervous system (CNS) disorders. Our product development programs focus primarily on large pharmaceutical markets with significant unmet medical needs and commercial potential. We are focused primarily on clinical development of the following products:

Probuphine: for the treatment of opioid addiction

Iloperidone: for the treatment of schizophrenia and related psychotic disorders (partnered with Vanda Pharmaceuticals, Inc.)

Spheramine: for the treatment of advanced Parkinson s disease (partnered with Bayer Schering Pharma AG)

We are directly developing our product candidates and also utilizing corporate partnerships, including a collaboration with (i) Bayer Schering Pharma AG, Germany (Bayer Schering) for the development of Spheramine to treat Parkinson s disease, and (ii) Vanda Pharmaceuticals, Inc. (Vanda) for the development of iloperidone for the treatment of schizophrenia and related psychotic disorders. We also utilize grants from government agencies to fund development of our product candidates.

Our resources are focused primarily on the development of Probuphine; and while we also have rights to the following compounds 3,5 diiodothyropropionic acid, or DITPA, a proprietary product with potential for the treatment of cardiovascular disease and gallium maltolate, a novel oral agent for the potential treatment of chronic bacterial infections, bone disease and cancer, there will be minimal expenses associated with these compounds, while we evaluate further activities in these programs.

(b) Financial Information About Industry Segments

We operate in only one business segment, the development of pharmaceutical products.

(c) Narrative Description of Business

Product Development Programs

The following table provides summary status of our products in development:

Product	Potential Indication(s)	Phase of Development	Marketing Rights
Probuphine	Opioid addiction	Phase III	Titan
Iloperidone	Schizophrenia, psychosis	NDA Filed	Vanda Pharmaceuticals, Inc.
Spheramine	Parkinson s disease	Phase IIb	Bayer Schering Pharma AG

Our products are at various stages of development and may not be successfully developed or commercialized. We do not currently have any products being commercially sold. Our proposed products will require significant further capital expenditures, development, testing, and regulatory clearances prior to commercialization. We may experience unanticipated problems relating to product development and cannot predict whether we will successfully develop and commercialize any products.

Probuphine

We are developing Probuphine for the treatment of opioid addiction. Probuphine is the first product to utilize our novel, proprietary ProNeura long-term drug delivery technology (See ProNeura 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.

In December 2007, we completed enrollment in a randomized, double-blind, placebo-controlled, multi-center Phase III clinical study of Probuphine in the treatment of opioid addiction. This 150 patient study, which is being conducted in the U.S., will evaluate the safety and effectiveness of treatment with Probuphine versus placebo in reducing opioid addiction over 24 weeks of treatment. Results of this study are expected in the second half of 2008.

This study is 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 III program includes additional clinical studies to be conducted later in the U.S. and Europe. We continue to have discussions with the U.S. Food and Drug Administration (FDA) relating to finalizing the Probuphine development program.

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.

Iloperidone

Iloperidone is our novel, proprietary product in development for the treatment of schizophrenia and related psychotic disorders. Iloperidone was evaluated in a Phase III program comprising over 3,500 patients at more than 200 sites in 24 countries, administered and funded by Novartis Pharma AG (Novartis). In three completed efficacy studies conducted by Novartis, iloperidone statistically significantly reduced the symptoms of schizophrenia compared to placebo. Iloperidone has also been investigated in three 12-month safety studies, which confirm safety and tolerability. A dose dependent increase in the QTc interval was observed and investigated further in a clinical study, and no clinically significant adverse events were observed.

In June 2004, Vanda Pharmaceuticals, Inc. (Vanda) acquired from Novartis the worldwide rights to develop and commercialize iloperidone. Vanda was founded by Dr. Argeris N. Karabelas, former CEO of Novartis Pharmaceuticals, and Dr. Mihael Polymeropoulos, former Vice President of Pharmacogenetics at Novartis Pharmaceuticals. All of our rights and economic interests in iloperidone, including royalties on sales of iloperidone, remain essentially unchanged under the agreement.

In September 2007, Vanda submitted a New Drug Application (NDA) with the FDA for iloperidone. The NDA for iloperidone was officially accepted for review by the FDA in November 2007, with the potential for approval of the product in the second half of 2008.

In December 2006, Vanda announced positive results from a Phase III clinical trial evaluating iloperidone in patients with schizophrenia. In this study, iloperidone demonstrated statistically significant improvement compared to placebo on the Positive and Negative Symptom Scale (PANSS), the trial s primary endpoint. Iloperidone also achieved significant efficacy on the positive and negative symptom subscales of PANSS. The Phase III trial was a randomized, double-blind, placebo-controlled, multi-center, 4 week study that enrolled 604 patients with schizophrenia. The trial evaluated 12 mg of iloperidone dosed twice-daily (24 mg per day). The primary endpoint was efficacy vs. placebo in PANSS (total) and was determined using the Mixed Method Repeated Measures (MMRM) methodology. The safety profile of iloperidone was consistent with what has been observed in previous iloperidone Phase III trials.

Iloperidone s efficacy and safety was also evaluated in this study in patients with specific genetic profiles using pharmacogenetics, in order to potentially give physicians and patients information to potentially help individualize their antipsychotic therapy. It had been previously identified that a certain polymorphism in a gene, occurring in approximately 70% of patients, may be associated with the pathogenesis of schizophrenia and appeared to correlate with iloperidone response. Iloperidone achieved statistical significance vs. placebo on the PANSS scale in these patients, with a magnitude of response greater than that seen in the overall iloperidone population.

Spheramine

Spheramine is a cell-based therapeutic being developed for the treatment of advanced Parkinson s disease. It utilizes our proprietary cell-coated microcarrier (CCM) technology, which enables the development of cell-based therapies for minimally-invasive, site-specific delivery to the central nervous system of therapeutic factors precisely where they are needed.

Spheramine consists of microcarriers coated with human retinal pigment epithelial cells that are intended to enhance brain levels of dopamine, a neurotransmitter deficient in certain brain regions in Parkinson s disease, leading to movement disorders. Preclinical studies have demonstrated the preliminary efficacy and safety of Spheramine, including blinded studies in a primate model of Parkinson s disease. Positron emission tomography (PET) imaging studies in primates have confirmed the presence of increased dopamine signals in regions treated with Spheramine. A pilot clinical study of Spheramine performed by Titan in six patients with advanced Parkinson s disease demonstrated substantial improvement (average 48%) in motor function at one-year post treatment with no significant adverse events. These results were first reported at the American Academy of Neurology (AAN) annual meeting in 2002. In June 2005, Bayer Schering sponsored a symposium on Spheramine at the International Congress on Parkinson s Disease and Related Disorders in Berlin. In the keynote address, Ray Watts, M.D., Professor and Chairman, Department of Neurology, University of Alabama Birmingham, presented 48-month follow-up data for the six patients in our pilot clinical study of Spheramine. The data presented indicate that Spheramine is well tolerated and that patients continued to demonstrate 43% average improvement in motor function over baseline, four years after treatment.

In June 2007, enrollment was completed in a current multi-center, randomized, double-blind, placebo-controlled clinical trial of Spheramine in Parkinson s disease. This Phase IIb clinical study enrolled 71 patients

with advanced Parkinson s disease (Hoehn and Yahr Stages III and IV) to further evaluate the efficacy, safety, and tolerability of Spheramine. The results from this study are expected to be available in the second half of 2008.

Bayer Schering, our corporate partner for worldwide development and commercialization of Spheramine, is funding the clinical development program for Spheramine. Under this agreement, Bayer Schering received exclusive, worldwide development, manufacturing and commercialization rights, and, in addition to the clinical and manufacturing development funding and milestone payments, Bayer Schering will pay us a royalty on future product sales. The Investigational New Drug application (IND) filed by Titan with the FDA was transferred to Bayer Schering in November 2005.

In July 2004, we announced that the FDA had granted a Fast Track designation for Spheramine for the treatment of advanced Parkinson s disease. The Fast Track Program is designed by the FDA to facilitate the development and expedite the review of drug candidates that demonstrate the potential to treat serious or life-threatening diseases and address unmet medical needs. The FDA had previously approved Orphan Drug designation for Spheramine for the treatment of advanced Parkinson s disease.

ProNeura Continuous Drug Delivery Technology

Our ProNeura 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.

In addition to Probuphine, which is our first product in clinical testing to utilize our proprietary ProNeura long term drug delivery technology, we are planning to develop our ProNeura sustained drug delivery technology for other potential treatment applications in which conventional treatment is limited by variability in blood drug levels and poor patient compliance. ProNeura 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.

Sponsored Research and License Agreements

We are a party to several agreements with research institutions, companies, universities and other entities for the performance of research and development activities and for the acquisition of licenses relating to such activities. Expenses under these agreements totaled approximately $378,000, $690,000, and $700,000 in the years ended December 31, 2007, 2006, and 2005, respectively.

Iloperidone

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 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 will continue, 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 is proceeding with and now funding the iloperidone Phase III development program. All of our rights and economic interests in iloperidone, including royalties on sales of iloperidone, remain essentially unchanged under the agreement.

Spheramine and Other Cell Therapy Products

In November 1992, we acquired an exclusive, worldwide license under certain U.S. and foreign patent applications relating to the CCM technology pursuant to a research and license agreement with New York University (NYU). The NYU agreement provides for the payment of royalties based on future net sales of products and processes incorporating the licensed technology, as well as a percentage of any income we receive from any sublicense thereof. We are also obligated to reimburse NYU for all costs and expenses incurred by NYU in filing, prosecuting and maintaining the licensed patents and patent applications. We must satisfy certain other terms and conditions of the NYU agreement in order to retain our license rights. These include, but are not limited to, the use of best efforts to bring licensed products to market as soon as commercially practicable and to diligently commercialize such products thereafter.

In January 2000, we entered into a sublicense agreement with Bayer Schering granting Bayer Schering exclusive worldwide commercialization rights to Spheramine. Under the agreement, we will collaborate with Bayer Schering on manufacturing and clinical development of cell therapy for the treatment of Parkinson s disease. We will receive funding for development activities, as well as potential reimbursement of certain prior research and development expenses. Bayer Schering will fully fund, and manage in collaboration with us, all future pilot and pivotal clinical studies, and manufacturing and development activities. Under the agreement, Bayer Schering will pay us a royalty on net sales of Spheramine.

ProNeura Long-term Drug Delivery System

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 the long-term drug delivery system. The exclusive nature of the MIT license is subject to certain conditions regarding timely performance of product development activities. We must also satisfy certain other usual terms and conditions set forth in the MIT license in order to retain our license rights, including payments of royalties based on sales of products and processes incorporating the licensed technology, as well as a percentage of income derived from sublicenses of the licensed technology.

DITPA

In October 2003, through the acquisition of Developmental Therapeutics, Inc. (DTI), we acquired an exclusive worldwide license to an issued U.S. patent and pending international patent applications covering DITPA. Under this license agreement, we made an initial stock payment of 1,187,500 shares of our common stock and a cash payment of $171,250 to the University of Arizona, the licensor of the technology, and will also make an additional payment of 712,500 shares of our common stock upon the achievement of positive pivotal study results or certain other substantial milestones within five years. A cash payment of $102,750 or, alternatively, an additional payment of 37,500 shares of our common stock, will also be made to the licensor of the technology upon achievement of such study results or such other substantial milestones within five years. Also under this agreement, we are required to make royalty payments to the licensor based on net sales of products and processes incorporating the licensed technology, subject to minimum annual amounts commencing in the first year following the commercial sale of the product, as well as a percentage of any income derived from any sublicense of the licensed technology. In addition, we are required to make milestone payments to the licensor upon the achievement of certain clinical or regulatory milestones.

Gallium Complexes

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. Under this license agreement, we are required to make an annual license payment to Dr. Lawrence Bernstein, technology inventor, of $75,000, as well as royalty payments based on future net sales of products and processes incorporating the licensed technology. We must also pay all costs and expenses incurred in patent prosecution and maintenance.

In February 2004, we executed an agreement giving us an exclusive worldwide license to patent rights held by The Ohio State University covering the methods of treating arthritis using gallium compounds. 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.

In July 2005, we executed an agreement giving us 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.

In September 2006, we executed an agreement giving us an exclusive worldwide license to certain patent applications held by The MCW Research Foundation, Inc. covering the methods of treating cancer using novel gallium containing compounds in the field of human therapeutic treatment of lymphoma. Under this agreement, we are required to pay a one time license fee and royalties based on net sales of products and processes incorporating the licensed technology.

Patents and Proprietary Rights

We have obtained rights to certain patents and patent applications relating to our proposed products and may, in the future, seek rights from third parties to additional patents and patent applications. We also rely on trade secrets and proprietary know-how, which we seek to protect, in part, by confidentiality agreements with employees, consultants, advisors, and others. For risks we face with respect to patents and proprietary rights, see Risk Factors We may be unable to protect our patents and proprietary rights.

Iloperidone

We hold a license from Sanofi-Aventis under one issued U.S. patent and certain 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. This does not include possible term extensions. Prosecution of various divisional and continuation applications and their foreign counterparts continues satisfactorily, although it is uncertain whether additional patents will be granted.

Spheramine and Other Cell Therapy Products

We are the exclusive licensee under a license agreement with NYU of certain U.S. and foreign patents and patent applications relating to our CCM technology. The U.S. Patent and Trademark Office has issued four U.S. patents on the core subject matter underlying the NYU license and an additional two patents relating to uses in delivery of gene therapy to the central nervous system. Prosecution of various foreign counterparts continues satisfactorily, although it is uncertain whether additional patents will be granted.

Patents have issued that cover certain aspects of our Spheramine product and its use, including four U.S. patents with patent terms expiring in 2010, 2014, 2015 and 2017, and one European patent, which has been unbundled as 13 national patents in various European countries, one Australian, two Japanese, one Hong Kong and one Canadian patent, all of which have patent terms expiring in 2011. Patents have issued relating to aspects of our gene transfer technology, including two U.S. patents with patent terms expiring in 2016, one European patent, one Canadian patent, two Australian patents, one South African patent, and one Taiwanese patent, all of which have patent terms expiring in 2017, and one Philippine patent with a patent term expiring in 2019. These dates do not include possible term extensions.

We are the owners of certain U.S. and foreign patents and patent applications relating to our CCM technology. Prosecution of patent applications relating to these technologies is continuing, and prosecution of some of their foreign counterparts is still being continued, although it is uncertain whether additional patents will be granted. Two foreign patents have issued that cover certain aspects of the use of our Spheramine product and other CCM technology, including one Australian and one New Zealand patent, both of which have patent terms expiring in 2018. We also are the owners of certain U.S. and foreign patents and patent applications relating to the application of our CCM technology to treat schizophrenia, including one U.S. patent, which has a patent term expiring in 2019, and one European patent, one New Zealand patent, one Australian patent, one Mexican patent, and one South African patent, which have patent terms expiring in 2020. These dates do not include possible term extensions.

ProNeura Long-term Drug Delivery System

We are the exclusive licensee under the MIT license to two U.S. patents relating to a long-term drug delivery system, with patent terms expiring in 2009, and certain European patents with patent terms expiring in 2008 and 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 ProNeura technology, including two applications related to Probuphine for the potential treatment of opioid addiction and chronic pain. These applications are currently in process at the U.S. Patent and Trademark Office.

Other Compounds

We hold an exclusive license to two issued U.S. patents with patent terms expiring in 2021, one pending U.S. patent application, one issued Mexican patent with a term expiring in 2022, and related pending foreign patent applications relating to the use of 3,5-diiodothyroproprionic acid (DITPA) and other compounds for the treatment of heart failure and the treatment of elevated cholesterol. These dates do not include possible term extensions.

We have rights to 10 U.S. patents expiring in 2009 and 2010 and several foreign patents expiring in 2011 covering pharmaceutical compositions and methods of use for gallium complexes. These dates do not include possible term extensions. We are also the exclusive licensee of certain issued U.S. and foreign patents related to the use of gallium compounds to treat rheumatoid arthritis. The U.S. patent term expires in 2010. In addition, we are licensees of certain issued U.S. and foreign patents and patent applications relating to methods of use to inhibit the growth of P. aeruginosa, and to treat infections caused by intracellular pathogens and pathogens causing chronic pulmonary infections, and human immunodeficiency virus infections. The two issued U.S. patents have terms expiring in 2016. We have filed additional patent applications covering the use of gallium complexes in treating infection by intracellular prokaryotes, DNA viruses, and retroviruses, treating inflammatory arthritis, treatment and prevention of adverse liver conditions, and treatment of biofilm-associated infections. One issued Australian patent and one issued European patent, unbundled as seven national patents, relating to treating infection by intracellular prokaryotes, DNA viruses, and retroviruses, have terms expiring in 2020. These dates do not include possible term extensions.

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 financial and other resources, larger research and development staffs 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.

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, might 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.

Iloperidone

Several products categorized as atypical antipsychotics 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 iloperidone 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.

Spheramine

Several new treatments for Parkinson s disease are in pre-clinical and clinical development. In addition, several public and private companies, including StemCells, Inc., are actively pursuing alternative cell transplant technologies. Deep brain stimulation, also known as subthalamic stimulation is also a competing therapy for patients with advanced Parkinson s disease. The FDA has approved a stimulator device (Activa) manufactured by Medtronic, Inc., which is marketed in the U.S. We believe Spheramine may have potential competitive advantages to this therapy.

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.

Human clinical trials on drugs are typically conducted in three sequential phases, although the phases may overlap. Phase I trials typically consist of testing the product in a small number of healthy volunteers or patients, primarily for safety in one or more doses. During Phase II, in addition to safety, dose selection and efficacy of the product is evaluated in up to several hundred patients and sometimes more. Phase III trials typically involve additional testing for safety and confirmation of efficacy in an expanded patient population at multiple test sites. The FDA may order the temporary or permanent discontinuation of a clinical trial at any time.

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, or 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.

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, 2007 we had 44 full-time employees. None of our employees are represented by a labor union. We have not experienced any work stoppages and consider our relations with our employees to be good. See Risk Factors We may not be able to retain our key management and scientific personnel.

Available Information

We electronically file our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K with the Securities and Exchange Commission (SEC) pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934. Any materials we file with the SEC are accessible to the public at the SEC s Public Reference Room at 450 Fifth Street, NW, Washington, DC 20549. You may obtain information on the operation of the SEC s Public Reference Room by calling the SEC at (800) SEC-0330. The public may also utilize the SEC s Internet website, which contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. The address of the SEC website is http://www.sec.gov.

You may obtain free copies of our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K and amendments to those reports on our website at http://www.titanpharm.com, or by contacting our corporate office by calling (650) 244-4990, or by sending an e-mail message to info@titanpharm.com.

Item 1A. Risk Factors

Our business is subject to numerous risks.

We have a history of operating losses and may never be profitable.

From our inception through December 31, 2007, we had an accumulated deficit of approximately $241.6 million. We will continue to incur losses for the foreseeable future as a result of the various costs associated with our research, development, financial, administrative, regulatory and management activities. We may never achieve or sustain profitability.

Our products are at various stages of development and may not be successfully developed or commercialized.

We do not currently have any products being sold on the commercial market. Our proposed products are at various stages of development, but all will require significant further capital expenditures, development, testing, and regulatory clearances prior to commercialization. Of the large number of drugs in development, only a small percentage successfully complete the U.S. Food and Drug Administration (FDA) regulatory approval process and are commercialized. We are subject to the risk that some or all of our proposed products:

- will be found to be ineffective or unsafe;
- will not receive necessary regulatory clearances;
- will be unable to get to market in a timely manner;
- will not be capable of being produced in commercial quantities at reasonable costs;
- will not be successfully marketed; or
- will not be widely accepted by the physician community.

To date, we have experienced setbacks in some of our product development efforts. For example, the results of a study evaluating the EKG profile of patients taking iloperidone lead 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.

In addition, our Spheramine product is based upon new technology which may be risky and fail to show efficacy. We are not aware of any other cell therapy products for CNS disorders that have been approved by the FDA or any similar foreign government entity and cannot assure you that we will be able to obtain the required regulatory approvals for any products based upon such technology.

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 any products.

We must comply with extensive government regulations.

Our research, development, preclinical and clinical trial activities and the manufacture and marketing of any products that we may successfully develop 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 regulatory submissions may be delayed or we may cancel plans to make submissions for proposed products for a number of reasons, including:

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.

If we and our corporate partners are unable to obtain regulatory approval for our products, our business will be seriously harmed.

In addition, we and our collaborative partners may be subject to regulation under state and federal laws, including requirements regarding occupational safety, laboratory practices, environmental protection and hazardous substance control, and may be subject to other local, state, federal and foreign regulation. We cannot predict the impact of such regulation on us, although it could seriously harm our business.

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 many uncertainties relating to our human clinical trial strategy and results.

In order to obtain the regulatory approvals that we need to commercialize any of our product candidates, we must demonstrate that each product candidate is safe and effective for use in humans for each target indication. The results of preclinical and Phase I and Phase II clinical studies are not necessarily indicative of whether a

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product will demonstrate safety and efficacy in large patient populations. Although two of our product candidates have reached Phase III human clinical trials, results from the studies have not supported a regulatory filing. Several other product candidates are currently advancing into Phase II human clinical trials. We may not be able to demonstrate that any of our product candidates will be safe or effective in advanced trials that involve larger numbers of patients. Clinical trials are subject to oversight by institutional review boards and the FDA and:

- must be conducted in conformance with the FDA s good laboratory practice regulations;
- must meet requirements for institutional review board oversight;
- must meet requirements for informed consent;
- must meet requirements for good clinical practices;
- are subject to continuing FDA oversight; and
- may require large numbers of test subjects.

As described above in Our products are at various stages of development and may not be successfully developed or commercialized, our product development programs have in the past been and may in the future be curtailed, redirected or eliminated at any time for some or all of the following reasons:

- unanticipated, negative or ambiguous results;
- undesirable side effects which delay or extend the trials;
- our inability to locate, recruit and qualify a sufficient number of patients for our trials;
- regulatory delays or other regulatory actions;
- difficulties in manufacturing sufficient quantities of the particular product candidate or any other components needed for our preclinical testing or clinical trials;
- change in the focus of our development efforts; and
- reevaluation of our clinical development strategy.

Accordingly, our clinical trials may not proceed as anticipated or otherwise adequately support our applications for regulatory approval.

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. 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.

As is commonplace in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. To the extent our employees are involved in research areas which are similar to those areas in which they were involved at their former employers, we may be subject to claims that such employees and/or we have inadvertently or otherwise used or disclosed the alleged trade secrets or other proprietary information of the former employers. Litigation may be necessary to defend against such claims, which could result in substantial costs and be a distraction to management even if we are successful in defending such claims.

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. Most of our consultants are employed by, or have consulting agreements with, third parties and any inventions discovered by such individuals generally will not become our property. There is a risk that other parties may breach confidentiality agreements or that our trade secrets may become known or independently discovered by competitors.

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.

We are dependent upon our key collaborative relationships and license and sponsored research agreements.

As a company with limited resources, we rely significantly on the resources of third parties to conduct research and development and complete the regulatory approval process on our behalf. For example, our ability to ultimately derive revenues from iloperidone is almost entirely dependent upon Novartis and Vanda Pharmaceuticals completing the regulatory approval process and implementing the marketing program necessary to commercialize iloperidone if the product is approved by the FDA. We are similarly dependent upon Bayer Schering, our collaborator for the development and commercialization of Spheramine. Beyond our contractual rights, we cannot control the amount or timing of resources that any existing or future corporate partner devotes to product development and commercialization efforts for our product candidates. We depend on our ability to maintain existing collaborative relationships, to develop new collaborative relationships with third parties and to acquire or in-license additional products and technologies for the development of new product candidates. We cannot assure you that we will be able to maintain or develop new collaborative relationships, or that any such third-party products or technology will be available on acceptable terms, if at all.

Conflicts with our collaborators and strategic partners could result in strained relationships with them and impair our ability to enter into future collaborations, either of which could seriously harm our business. Our collaborators have, and may, to the extent permitted by our agreements, develop competing products, preclude us from entering into collaborations with their competitors or terminate their agreements with us prematurely. Moreover, disagreements could arise with our collaborators or strategic partners over rights to our intellectual property and our rights to share in any of the future revenues from products or technologies resulting from use of our technologies, or our activities in separate fields may conflict with other business plans of our collaborators.

We must meet payment and other obligations under our license and sponsored research agreements.

Our license agreements relating to the in-licensing of technology generally require the payment of up-front license fees and royalties based on sales with minimum annual royalties, the use of due diligence in developing and bringing products to market, the achievement of funding milestones and, in some cases, the grant of stock to the licensor. Our sponsored research agreements generally require periodic payments on an annual or quarterly basis. Our failure to meet financial or other obligations under license or sponsored research agreements in a timely manner could result in the loss of our rights to proprietary technology or our right to have the applicable university or institution conduct research and development efforts.

We may be dependent upon third parties to manufacture and market any products we successfully develop.

We currently do not have the resources or capacity to commercially manufacture or directly market any of our proposed products. Collaborative arrangements may be pursued regarding the manufacture and marketing of any products that may be successfully developed. We may be unable to enter into additional collaborative arrangements to manufacture or market any proposed products or, in lieu thereof, establish our own manufacturing operations or sales force.

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. 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 have to pay higher salaries to attract and retain personnel.

We will need additional financing.

At December 31, 2007, we had approximately $30.0 million of cash, cash equivalents, and marketable securities. Our financing agreement with Azimuth Opportunity Ltd. can provide us with up to an additional $24.0 million, subject to shareholder approval for certain amounts under this agreement, as well as an increase in our authorized capital stock. We will need to seek additional financing to continue our product development activities, and will be required to obtain substantial funding to commercialize any products other than iloperidone or Spheramine that we may successfully develop. Other than the Common Stock Purchase Agreement with Azimuth Opportunity Ltd., we do not have any funding commitments or arrangements. If we are unable to generate adequate revenues, enter into a corporate collaboration, complete a debt or equity offering, or otherwise obtain sufficient financing when and if needed, we may be required to reduce, defer or discontinue one or more of our product development programs.

We will need to seek and obtain stockholder approval of an increase in our authorized capital stock in order to raise additional equity financing or undertake certain potential business transactions.

As of December 31, 2007, only 894,767 shares of our authorized common stock remained available for issuance (excluding shares that have been reserved for issuance upon exercise of outstanding options and warrants). While we intend to seek approval of an increase in our authorized capital stock at or prior to the next annual meeting of stockholders, we may not be successful in obtaining the necessary approval. Unless and until we obtain approval of an increase in our authorized capital stock, our ability to raise additional equity financing or pursue certain business opportunities that would entail the issuance of our shares, will be restricted.

Future sales of our common stock in the public market could adversely impact our stock price.

Future sales of our common stock by existing stockholders pursuant to Rule 144 under the Securities Act, pursuant to an effective registration statement or otherwise, could decrease the price of our common stock.

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.

The market price of our common stock may fluctuate in a way that is disproportionate to our operating performance.

The stock markets in general, and the American Stock Exchange and the market for pharmaceutical and biotechnological companies in particular, have experienced extreme price and volume fluctuations recently. These fluctuations often have been unrelated or disproportionate to the operating performance of these companies. These broad market and industry factors could reduce the market price of our common stock, regardless of our actual operating performance.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

We have a five-year operating lease, expiring in June 2010, for approximately 15,782 square feet of office space in South San Francisco, California. We also have a lease, expiring in March 2008, for approximately 2,100 square feet of office and laboratory space in Somerville, New Jersey. In February 2008, we entered into a lease, expiring in March 2011, for approximately 3,135 square feet of office space in Fort Lee, New Jersey.

Item 3. Legal Proceedings

In March 2005, Dr. Bernard Sabel initiated an appraisal proceeding in the Court of Chancery of the State of Delaware relating to the merger of Titan s subsidiary ProNeura, Inc. into Titan. The complaint indicates that Mr. Sabel wants the court to appraise the value of the 108,800 shares of the common stock of ProNeura owned by him. The complaint does not specify an amount that Mr. Sabel considers the fair value of the shares. Discovery is proceeding in connection with this appraisal proceeding.

In July 2007, a complaint was filed in the United States District Court in and for the Middle District of Florida against, among others, Berlex, Inc., Schering AG, the Regents of the University of California and us alleging that a patient in the Spheramine Phase IIb clinical trial suffered certain physical effects and that she and her husband suffered emotional distress as a result of her participation in the trial. The complaint alleged breach of contract, product liability and fraud and deceit claims. The plaintiffs were seeking $5.2 million in damages, as well as punitive damages, costs and attorney s fees. In September 2007, the plaintiff voluntarily dismissed the complaint and filed a substantially similar action in the Superior Court of the State of California, Alameda County. The parties are in the final stages of settling this dispute and it is not expected that we will be required to make any payments in connection with such settlement.

Item 4. Submission of Matters to a Vote of Security Holders

None.

PART II

Item 5. Market for Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

(a) Price Range of Securities

Our common stock trades on the American Stock Exchange under the symbol TTP. The table below sets forth the high and low sales prices of our common stock as reported by the American Stock Exchange for the periods indicated.

	High	Low
Fiscal Year Ended December 31, 2007:		
First Quarter	$ 3.36	$ 2.10
Second Quarter	$ 2.74	$ 1.93
Third Quarter	$ 2.50	$ 1.83
Fourth Quarter	$ 2.60	$ 1.47
Fiscal Year Ended December 31, 2006:		
First Quarter	$ 4.99	$ 1.35
Second Quarter	$ 3.39	$ 1.69
Third Quarter	$ 2.52	$ 1.65
Fourth Quarter	$ 4.10	$ 1.92

(b) Approximate Number of Equity Security Holders

The number of record holders of our common stock as of February 29, 2008 was approximately 150. Based on the last Broadridge search, we believe there are approximately 10,000 beneficial holders of our common stock.

(c) Dividends

We have never paid a cash dividend on our common stock and anticipate that for the foreseeable future any earnings will be retained for use in our business and, accordingly, do not anticipate the payment of cash dividends.

Performance Graph

The information contained in the Performance Graph shall not be deemed to be soliciting material or filed with the SEC or subject to the liabilities of Section 18 of the Securities Exchange Act of 1934, as amended (the Exchange Act), except to the extent that we specifically incorporate it by reference into a document filed under the Securities Act of 1933, as amended (the Securities Act), or the Exchange Act.

The following graph compares the cumulative total stoc