TITAN PHARMACEUTICALS INC
Form 10-K
March 15, 2005

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

FOR ANNUAL AND TRANSITION REPORTS PURSUANT TO SECTIONS 13 OR 15(d) OF THE SECURITIES ECHANGE ACT OF 1934

(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, 2004
Or

.. **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15() OF THE SECURITIES EXCHANGE ACT OF 1934**

Commission file number 0-27436

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 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 an accelerated filer (as defined in Rule 12b-2 of the Act). Yes x No ¨

The aggregate market value of the 32,119,236 shares of voting and non-voting common equity held by non-affiliates of the registrant based on the closing price on June 30, 2004 was $86.4 million.

As of March 1, 2005, 32,343,921 shares of common stock, $.001 par value, of the registrant were issued and outstanding.

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 results of financing efforts, the effect of our accounting policies, and other risks detailed in our Securities and Exchange Commission filings.

Probuphine®, Spheramine® 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.

Item 1. Business

(a) General Development of Business

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

- Iloperidone: for the treatment of schizophrenia and related psychotic disorders (partnered with Vanda Pharmaceuticals, Inc.)
- Probuphine: for the treatment of opiate addiction
- Spheramine: for the treatment of advanced Parkinson s disease (partnered with Schering AG)
- DITPA: for the treatment of congestive heart failure
- Gallium maltolate: for the treatment of bone related diseases and certain cancers.

We are directly developing our product candidates and also utilizing strategic partnerships. These collaborations help fund product development and enable us to retain significant economic interest in our products. In June 2004, we announced that Vanda Pharmaceuticals, Inc. (Vanda) had acquired from Novartis Pharma AG (Novartis) the worldwide rights to develop and commercialize iloperidone, our proprietary antipsychotic agent in Phase III clinical development for the treatment of schizophrenia and related psychotic disorders. Vanda will now pursue advancement of 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 development is primarily funded by our corporate partner for Spheramine, Schering AG, Germany (Schering). We are no longer directly pursuing development of the monoclonal antibodies CeaVac, TriAb, and TriGem for the treatment of various cancers, and further development of Pivanex for treatment of lung cancer was also discontinued.

We were incorporated in Delaware in February 1992 and have been funded through various sources, including an initial public offering in January 1996 and private placements of securities, as well as proceeds from warrant and option exercises, corporate licensing and collaborative agreements, and government-sponsored research grants.

(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
Iloperidone	Schizophrenia, psychosis	Phase III	Vanda Pharmaceuticals, Inc.
Probuphine	Opiate addiction	Phase I/II	Titan
Spheramine	Parkinson s disease	Phase IIb	Schering AG
DITPA	Congestive heart failure	Phase II	Titan
Gallium maltolate	Bone related disease and certain cancers	Phase I/II	Titan

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. For a full discussion of risks and uncertainties of our product development, see Risk Factors Our products are at various stages of development and may not be successfully developed or commercialized.

Iloperidone

Iloperidone is our novel, proprietary product in development for the treatment of schizophrenia and related psychotic disorders. Iloperidone has been evaluated in an extensive Phase III program comprising over 3,500 patients at more than 200 sites in 24 countries, administered and funded by Novartis Pharma AG. In three completed efficacy studies, 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. Additionally, Novartis has completed a study in elderly patients with good results. Although iloperidone was considered safe in the above efficacy studies, it has shown a dose dependent increase in the QTc interval.

The results of a study evaluating the potential effect of iloperidone on the EKG profile (QTc interval prolongation) of patients receiving the drug were announced in July 2002. The study indicated that there was a dose dependent increase in QTc interval and results for iloperidone were roughly comparable to that for ziprasidone, one of the currently marketed agents in the study. The FDA has concurred with this assessment and has indicated that one additional successful pivotal Phase III study is necessary to complete the efficacy data package prior to NDA submission. The QTc profile may potentially limit the opportunity of iloperidone as first line therapy for schizophrenia.

In June 2004, we announced that Vanda Pharmaceuticals, Inc. acquired from Novartis Pharma AG 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. Under its agreement with Novartis, Vanda will now pursue advancement of 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.

Probuphine

We are developing Probuphine for the treatment of opiate 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 therapeutic levels of buprenorphine, an approved agent for the treatment of opiate addiction.

In June 2002, we presented data at the International Conference on Pain and Chemical Dependency in New York demonstrating that Probuphine continuously delivered buprenorphine for one year in preclinical studies. In June 2004, we announced final results from a pilot clinical study that evaluated the safety, pharmacokinetics and preliminary efficacy of Probuphine in opiate-dependent 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 also safe and well tolerated in this pilot study, with no significant adverse events.

We are currently in the process of discussing clinical development strategy with regulatory authorities in various countries that may lead to marketing authorization for Probuphine. We are also currently scaling up manufacturing process development for Probuphine in support of planned Phase III clinical development activities and commercial supply. We expect to initiate pivotal clinical testing of Probuphine in the treatment of opiate addiction in the third quarter of 2005. We also plan to initiate pilot clinical testing of Probuphine in chronic pain in 2005.

Spheramine

Spheramine is a cell-based therapeutic being developed for potential 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 directly 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 in six patients 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. At the AAN annual meeting in 2003, two-year results from this study were presented that demonstrated an average 41% improvement in those patients motor function two years post treatment with no significant adverse events.

In December 2002, we announced the initiation of a multicenter, randomized, blinded, controlled study of Spheramine in Parkinson s disease. This Phase IIb clinical study will enroll 68 patients with advanced Parkinson s disease (Hoehn and Yahr Stages III and IV) to further evaluate the efficacy, safety, and tolerability of Spheramine. Following the second safety review by the Independent Data Monitoring Committee (IDMC) in the third quarter 2004, and after treatment of 36 patients in the Phase IIb clinical study of Spheramine, the IDMC recommended continuation of enrollment in the third and final cohort of 32 patients in this study. We are now enrolling the third and final cohort of 32 patients in this Phase IIb clinical study. We estimate that this Phase IIb clinical study will be completed by the second half of 2006. The Company was advised by the U.S. Food and Drug Administration (FDA) that additional information regarding study inclusion/exclusion criteria, criteria for patient selection, and related monitoring procedures should be updated and submitted to FDA prior to further patient treatment in this study. Patient enrollment continues and the Company anticipates that further patient treatment should occur on

schedule, subsequent to submission to, and approval by FDA of the additional requested documentation. Schering, our corporate partner for worldwide development and commercialization of Spheramine, is funding the clinical development program for Spheramine. Under this agreement, Schering received exclusive, worldwide development, manufacturing and commercialization rights, and, in addition to the clinical and manufacturing development funding and milestone payments, Schering will pay us a royalty on future product sales.

In July 2004, we announced that the FDA had granted us 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.

DITPA

Our novel, proprietary product in development for the treatment of congestive heart failure (CHF) is 3,5-diiodothyropropionic acid, or DITPA, an orally active analogue of thyroid hormone. DITPA represents a potential new class of agents for CHF, based upon the central role of thyroid hormone in regulating cardiovascular function. DITPA has demonstrated in preclinical and clinical studies to date the ability to significantly improve cardiac function without significantly increasing heart rate. Specifically, in preclinical studies, when DITPA was administered alone or in combination with captopril in animal models of heart failure, cardiac output was improved and left ventricular end diastolic pressure was decreased, without significantly increasing heart rate. In addition, DITPA improved the time for ventricular relaxation, indicating a potential beneficial effect on diastolic function. In clinical studies DITPA has demonstrated similar potentially beneficial effects in preliminary human testing. A double blind, placebo controlled Phase II study in 19 patients with moderately severe (NYHA Class II-III) heart failure demonstrated a significant improvement in cardiac index, a significant decrease in systemic vascular resistance, and no significant increase in heart rate. These study results also supported a beneficial effect of DITPA on diastolic function. In addition, results from this study as well as previous preclinical testing suggest that DITPA is potentially compatible with other current treatments such as Angiotensin-Converting Enzyme (ACE) inhibitors.

We plan to initially develop DITPA as a potential treatment for congestive heart failure (CHF) associated with low serum thyroid hormone (T_3). Congestive heart failure is a syndrome of progressive decrease in cardiac function and inability of the heart to pump sufficient blood for proper function of the lungs, kidneys, and other vital organs and tissues. Symptoms include decreasing activity capacity, shortness of breath, and peripheral and pulmonary edema. There are a total of approximately nine million people in the U.S. and Europe with CHF. In the U.S., approximately 25% of patients have moderate or severe symptoms (New York Hospital Association Class III or IV), and CHF is the most common hospital discharge diagnosis in the U.S. for patients over 65. Currently, only approximately 50% of patients diagnosed with CHF survive for five years, and only 50% of patients with class IV CHF survive one year. New treatments for CHF are greatly needed to improve symptoms, enhance cardiac function, and avoid dangerous and progressive complications of congestive heart failure.

Researchers have demonstrated that approximately 30% of patients with advanced (NYHA Class III and IV) congestive heart failure have abnormally low levels of T_3, the active form of thyroid hormone needed by heart cells, and that low levels of T_3 are a strong independent predictor of increased mortality in CHF patients.

The important role of thyroid hormone in maintaining heart and blood vessel function, and the association of low T_3 and increased mortality in CHF suggest a potential role for DITPA as a thyroid hormone replacement therapy in CHF. Currently available thyroid hormone medications are generally not

suitable for chronic use in CHF, because they are primarily T4 preparations, or have too short a half-life, and have the potential to increase heart rate, which is an unwanted side effect in CHF patients.

In December 2004, we initiated a placebo controlled Phase IIb clinical study with DITPA in Class III and Class IV CHF patients with low T3 levels. This study will evaluate 150 patients with NYHA Class III-IV CHF and low serum T3 levels. Patients will receive either of two doses of DITPA or placebo for six months. The study will be performed at 35 centers in the U.S. The study will evaluate clinical and laboratory parameters related to severity of CHF, including change in global clinical status, echocardiographic parameters, BNP levels, exercise testing and quality of life measurements in addition to safety.

In addition to evaluation of DITPA in CHF patients with low T3 levels, we believe that scientific evidence concerning thyroid hormone and cardiovascular function suggest potential utility of DITPA in the setting of diastolic dysfunction, left ventricular dysfunction post myocardial infarction, cardiopulmonary bypass surgery and hyperlipidemia.

DITPA is also currently being evaluated in a second randomized, double blind, placebo controlled Phase II study in 150 patients with NYHA Class II-IV CHF, sponsored by the Department of Veterans Affairs Cooperative Studies Program and funded by a $3.8 million grant.

Gallium Maltolate

Gallium maltolate is our novel oral agent for the potential treatment of bone disease and cancer. Gallium is a semi-metallic element with two distinct potential mechanisms of action, one with potential for the treatment of bone disease and the other for the potential treatment of certain cancers. Gallium acts upon bone by enhancing the formation of osteoblasts and inhibiting osteoclasts, thereby increasing bone deposition and reducing bone turnover. Additionally, gallium also inhibits ribonucleotide reductase, a key enzyme essential for DNA replication in cancer cells.

In preclinical studies in animal models of rheumatoid arthritis conducted by the Company, oral dosing of gallium maltolate reduced the severity of disease related end points in a dose-dependent manner. Based on these results, we believe gallium maltolate may have potential in the treatment of rheumatoid arthritis.

Prior independent studies using intravenously administered gallium nitrate have demonstrated preliminary evidence of clinical activity in several cancers, including multiple myeloma, lymphoma, bladder cancer and prostate cancer. An intravenous formulation of gallium nitrate, received FDA approval in 1991 for the treatment of hypercalcemia of malignancy. Evidence suggests that gallium may concentrate at sites of malignancy and then act at these sites to inhibit abnormal cell proliferation.

In the first quarter of 2005, a dose ranging clinical study of gallium maltolate in patients with multiple myeloma, metastatic prostate cancer, metastatic bladder cancer and refractory lymphoma was completed. Significant blood levels of gallium were achieved, and a maximum tolerated dose level was not reached in this study. We are currently completing development of a new formulation of gallium maltolate with increased bioavailability, and subsequent clinical trials will use this new formulation of gallium maltolate.

Pivanex

Pivanex is a novel small molecule that acts by inhibiting key enzymes called histone deacetylases, which are responsible for changing the expression of cancer-related genes. By altering gene expression, Pivanex slows cancer cell growth and helps in the destruction of cancer cells.

Based on data generated from an open label Phase II study of Pivanex in refractory non-small cell lung cancer we initiated in January 2003 a dose escalation study to assess the safety of Pivanex combined with docetaxel as a second line treatment of NSCLC. The objective of this pilot study was to establish a

safe and effective dose to be used in a subsequent Phase IIb clinical trial. In August 2003, we announced positive results from this pilot study demonstrating that Pivanex and docetaxel can be administered safely to non-small cell lung cancer patients. The regimen tested utilized the previously tested single-agent dose of Pivanex and the currently approved dose of docetaxel. The results were presented in August 2003 at the 10th World Conference on Lung Cancer in Vancouver.

In June 2003, we initiated a multicenter, randomized, controlled Phase IIb clinical trial with Pivanex in the treatment of advanced non-small cell lung cancer. The study was designed to evaluate the safety and efficacy of Pivanex plus docetaxel, versus docetaxel alone. In June 2004, we announced that an interim safety analysis by an independent data monitoring committee (IDMC) had identified significant safety issues in the combination treatment of Pivanex with docetaxel. This randomized study evaluating treatment with Pivanex and docetaxel versus docetaxel alone had already completed its enrollment target of 225 patients by that time. As a result of the IDMC finding and upon their recommendation, we discontinued treatment with Pivanex for the remaining patients on the study. Data collection for this study is now complete, and preliminary analysis indicates no significant difference in survival in the two treatment arms. Final study analysis is expected to be complete in the second quarter of 2005. Following these results, we have refocused priorities and Pivanex studies in chronic lymphocytic leukemia and melanoma are being discontinued.

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 15-minute 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.

We are developing our ProNeura sustained drug delivery technology for potential applications in the treatment of a number of disorders, including opiate addiction, chronic pain, Parkinson s disease, alcoholism, schizophrenia, and others, 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 up to 6 - 12 months.

In November 2003, we announced positive preclinical results demonstrating that continuous drug delivery using our ProNeura sustained drug delivery technology reduced the risk of motor symptoms in a validated primate model of Parkinson s disease. In this study, researchers at Titan and the National Institutes of Health (NIH) compared constant administration of a dopaminergic agent using our technology, to once daily administration, for a period of six months. The drug chosen was apomorphine, a dopamine agonist that has shown efficacy in Parkinson s disease. The study results were first presented at the 2003 American Academy of Neurology Meeting in Honolulu.

In addition to Probuphine, which is our first product in clinical testing to utilize our proprietary ProNeura long term drug delivery technology, we have also demonstrated preliminary proof of principle of ProNeura technology with a number of other drugs in preclinical testing, including drugs for the treatment of Parkinson s disease, psychiatric disorders and alcohol addiction.

The status of additional development programs is as follows:

Immunotherapeutics

There are two clinical trials in progress that utilize combinations of our cancer immunotherapy products, CeaVac and TriAb, and are funded by the National Cancer Institute, specifically:

- A Phase II study conducted by the Radiation Therapy Oncology Group utilizing a combination of CeaVac and TriAb in patients with limited stage non-small cell lung cancer,

- A Phase II study conducted by the Cancer and Leukemia Group B utilizing a combination of CeaVac and TriAb in patients with resected Dukes D colorectal cancer.

At this time, we are not devoting any additional internal resources to the monoclonal antibodies CeaVac, TriAb, and TriGem. Treatment in these studies has been completed and follow-up of patients continues.

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.

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 Aventis SA (formerly Hoechst Marion Roussel, Inc.). The 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 payments to Aventis during the life of the Novartis agreement, and will also pay to Aventis and Titan a royalty on future net sales of the product. The results of a QTc study evaluating the EKG profile of patients taking iloperidone announced in July 2002 found that iloperidone has a similar profile to ziprasidone (Geodon), an approved product. These results have significantly delayed the regulatory filings for this product.

In June 2004, we announced that Vanda Pharmaceuticals, Inc. acquired from Novartis Pharma AG the worldwide rights to develop and commercialize iloperidone, our proprietary antipsychotic agent in Phase III clinical development for the treatment of schizophrenia and related psychotic disorders. Under its agreement with Novartis, Vanda will pursue advancement of 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.

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 sale of products and processes incorporating the licensed technology, as well as a percentage of income derived from sublicenses of the licensed technology.

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 Schering granting Schering exclusive worldwide commercialization rights to Spheramine. Under the agreement, we will collaborate with 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. Schering will fully fund, and manage in collaboration with us, all future pilot and pivotal clinical studies, and manufacturing and development activities. Schering will pay us a royalty on net sales of Spheramine. Schering may terminate this sublicense for any reason by providing us 90 days notice in advance.

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 $50,000, 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.

Pivanex

We have acquired, from Bar-Ilan Research and Development Co. Ltd., in Israel, an exclusive, worldwide license to an issued United States patent and certain foreign patents, and patent applications covering novel analogues of butyric acid owned by Bar-Ilan University and Kupat Hulim Health Insurance Institution. The Bar-Ilan agreement provides for the payment by us to Bar-Ilan of royalties based on net sales of products and processes incorporating the licensed technology, subject to minimum annual amounts commencing in 1995, as well as a percentage of any income derived from any sublicense of the licensed technology. We must also pay all costs and expenses incurred in patent prosecution and maintenance and use reasonable best efforts to bring any products developed under the Bar-Ilan agreement to market. Our minimum annual royalty payment to Bar-Ilan is $60,000.

Immunotherapeutics

In May 1996, we acquired an exclusive, worldwide license under certain United States and foreign patent and patent applications pursuant to a license agreement with the University of Kentucky Research Foundation. These patent and patent applications relate to the anti-idiotypic antibodies known as 3H1, 1A7 and 11D10 and their fragments, derivatives or analogues. The Kentucky agreement required us to fund research at the University of Kentucky at amounts agreed to on an annual basis for the five-year period ending November 14, 2001. The Kentucky agreement provides for the payment of certain license fees as well as royalties based on future net sales of licensed products by Titan or any sublicensees. We must also pay all costs and expenses incurred in obtaining and maintaining patents, and diligently pursue a vigorous development program for the products in order to maintain our license rights under the Kentucky agreement.

In November 1998, we entered into an agreement with the Wistar Institute of Anatomy and Biology, a not-for-profit organization in Philadelphia, Pennsylvania, for a non-exclusive license under certain patents for the use of anti-idiotypic antibodies for the treatment of tumors. The Wistar agreement provides for the payment of certain license fees as well as royalties based on future net sales of licensed products. Our minimum annual royalty payment to Wistar is $30,000.

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 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. Unless its term is extended, the U.S. patent that covers certain aspects of our iloperidone product and its use will expire in 2011. Prosecution of various divisional and continuation applications and their foreign counterparts continues satisfactorily, although it is uncertain whether additional patents will be granted.

ProNeura Long-term Drug Delivery System

We are the exclusive licensee under the MIT license to three U.S. patents, expiring in 2007, 2009 and 2014, and certain European patents relating to a long-term drug delivery system, expiring in 2008 and 2010.

Additional patent applications have been filed which incorporate the use of specific compounds with the ProNeura technology.

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 that will expire in 2010, 2014, 2015, and 2017, one European patent, which has been unbundled as 15 European national patents, all of which will expire in 2011, and one Australian and one Canadian patent, both of which will expire in 2011. Patents have issued relating to aspects of our gene transfer technology, including two U.S. patents that will expire in 2016, two Australian patents that will expire in 2017, one South African patent that will expire in 2017, one Taiwanese patent that will expire in 2017, and one Philippine patent that will expire 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 continues satisfactorily, as does prosecution of their foreign counterparts, although it is uncertain whether additional patents will be granted. Three 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 will expire in 2018, one New Zealand patent that will expire in 2020, and one South African patent that will expire in 2020. These dates do not include possible term extensions.

DITPA

Through our wholly-owned subsidiary, Developmental Therapeutics, Inc., we hold an exclusive license from the University of Arizona to two U.S. patents, both expiring in 2021, one pending U.S. patent, and related foreign patent applications relating to the use of 3,5-diiodothyroproprionic acid (DITPA) for the treatment of heart failure and elevated cholesterol.

Gallium Complexes

We are the exclusive licensee under the license agreement with Dr. Lawrence Bernstein of certain U.S. and foreign patents and patent applications relating to the gallium complexes. 10 U.S. patents and several foreign patents have issued that cover pharmaceutical compositions and methods of use for gallium complexes. Prosecution of other U.S. and foreign patent applications relating to this technology continues satisfactorily, although it is uncertain whether additional patents will be granted. Patents in this family will begin to expire in 2009. However, this date does not include any possible patent term extensions, typically 3 to 5 years, or restorations available under 35 U.S.C.§ 154 et seq. We have also filed additional patent applications covering the use of gallium complexes in treating infection by intracellular prokaryotes and DNA viruses, treating inflammatory arthritis, and treating and preventing adverse liver conditions.

Pivanex

We are the exclusive licensee under the Bar-Ilan agreement of an issued U.S. patent, expiring in 2010 unless extended, patents in major European countries and Japan expiring in 2008 unless extended, a Canadian patent expiring in 2011, a Hong Kong patent expiring in 2008, and an Israeli patent expiring in 2007, all relating to Pivanex and/or formulations and uses of Pivanex. We also have a Patent Cooperation

Treaty (PCT) patent application designating multiple countries abroad, including a designation in the U.S., for certain aspects of Pivanex.

Immunotherapeutics

We are the exclusive licensee under a license agreement with the University of Kentucky Research Foundation of certain U.S. and foreign patents and patent applications related to the anti-idiotype antibodies known as 3H1, 1A7 and 11D10 and their fragments, derivatives or analogues. U.S. and foreign patents have been issued that relate to aspects of these technologies. Prosecution of patent applications relating to these technologies continues satisfactorily, although it is uncertain whether additional patents will be granted. Patents that cover certain aspects of CeaVac (antibody 3H1) include two U.S. patents that will expire in 2014 and 2017, two European patents, one of which has been unbundled as 16 European national patents and the other of which has been unbundled as 17 European national patents, all of which will expire in 2015, and three Australian patents, two of which will expire in 2015 and one of which will expire in 2017. Patents that cover certain aspects of TriGem (antibody 1A7) include five U.S. patents, four of which will expire in 2015 and one of which will expire in 2018, and two Australian patents which will expire in 2016 and 2018, respectively. Patents that cover certain aspects of TriAb (antibody 11D10) include one U.S. patent which will expire in 2018 and two Australian patents which will expire in 2016 and 2018, respectively. 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.

Iloperidone

With respect to 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.

Probuphine

With regard to Probuphine, we are aware that Reckitt & Benckaiser, Inc. received FDA approval in 2002 for a sublingual buprenorphine product (combined with naloxone) for the treatment of opiate dependence. This product, to be administered daily, might compete with our six-month implantable product for drug abuse. 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 for drug abuse.

Spheramine

With regard to Spheramine, we are aware of several new treatments for Parkinson s disease that 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.

DITPA

We are aware of several other companies which are currently marketing drugs such as beta blockers, ace inhibitors and inotropes, which may be used for the treatment of heart failure. These companies include Abbott, AstraZeneca, Aventis, Johnson & Johnson, Pfizer and Sanofi-Synthelabo. In addition, companies such as Bristol-Myers Squibb, Merck and OSI Pharmaceuticals are developing new drugs which may be used to treat heart failure. Although DITPA represents a potential new class of agents for the treatment of CHF, these products may compete with DITPA.

Gallium Complexes

We are aware that intravenously administered gallium nitrate is approved to treat hypercalcemia related to malignancy and may have potential for treatment of certain cancers. Other intravenous products, including the bisphosphonates, are available or are in development in the U.S. or Europe to treat osteoporosis, Paget s disease, primary hyperparathyroidism, hypercalcemia of malignancy and metastatic bone disease. Our product, gallium maltolate, is an orally administered drug and may have potential advantages in the treatment of cancer as well as bone-related diseases. Genta has previously stated that it is developing oral gallium compounds to treat bone-losing conditions.

See Risk Factors We face intense competition.

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 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, 2004 we had 71 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.

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, 2004, we had an accumulated deficit of approximately $185.7 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 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. The results of a study evaluating the EKG profile of patients taking iloperidone, for example, found that iloperidone appeared to prolong the cardiac QTc interval, potentially a cause for concern. While iloperidone was shown to have a similar QTc profile to ziprasidone (Geodon), a product already approved by the FDA, these results significantly delayed the regulatory filings for that product and we cannot predict when, if ever, the development program for iloperidone will advance. Furthermore, we previously announced study results with CeaVac that did not meet their primary endpoint, and, as a result, we have determined to discontinue our internal activities in the development of the monoclonal antibodies CeaVac, TriAb, and TriGem.

In June 2004, we announced that an interim safety analysis by an independent data monitoring committee (IDMC) had identified significant safety issues in the combination treatment of Pivanex with docetaxel. The randomized study evaluating treatment with Pivanex and docetaxel versus docetaxel alone had already completed its enrollment target of 225 patients at the time of such interim safety analysis. As a result of the IDMC findings and upon its recommendation, we discontinued the combination treatment of Pivanex and Docetaxel for the remaining patients on the study. Further development of Pivanex for treatment of lung cancer was also discontinued.

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;
- changes in regulations or the adoption of new regulations;
- unanticipated enforcement of existing regulations;
- unexpected technological developments; and
- developments by our competitors.

Consequently, we cannot assure you that we will make our submissions promptly, or at all, or that our submissions will receive approval from the FDA. If our corporate partners and we 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. Our business could be materially adversely affected should third party laboratories and medical institutions conducting studies of our products fail to maintain both good laboratory and clinical practices. Similarly, we could be materially adversely affected if the manufacturers of any products we develop in the future fail to comply with Good Manufacturing Practices of the FDA.

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 product will demonstrate safety and efficacy in large patient populations. Two of our product candidates have reached Phase III human clinical trials, however 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, adverse 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 adversely impact 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 and which may have a material adverse effect on us, 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, which could adversely affect us.

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 conducting the Phase III trials and 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 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. In addition, we also receive substantial government funding for our cancer immunotherapeutic programs. We cannot assure you that we will continue to receive such governmental funding. If such funds are no longer available, some of our current and future development efforts may be delayed or terminated. 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 have an adverse impact on our 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 encounter difficulties managing our growth, which could adversely affect our results of operations.

Our success will depend on our ability to expand and manage our growth. We may not be able to manage our growth, to meet the staffing requirements of additional collaborative relationships or successfully assimilate and train new employees. If we continue to grow, our existing management skills and systems may not be adequate and we may not be able to manage any additional growth effectively. If we fail to achieve any of these goals, there could be a material adverse effect on our business, financial condition or results of operations.

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 Dr. Louis R. Bucalo, our Chairman, President and Chief Executive Officer, as well as the other principal members of our 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, 2004, we had approximately $36.3 million of cash, cash equivalents, and marketable securities that we believe will enable us to fund our operations through 2005. 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. 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.

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 have an adverse effect on 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.

Many of these factors are beyond our control.

In addition, 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 may adversely affect the market price of our common stock, regardless of our actual operating performance.

Item 2. Properties

We have a five-year operating lease, expiring in June 2010, for approximately 22,595 square feet of office space in South San Francisco, California. We also have a five-year lease, expiring in January 2007, for approximately 4,200 square feet of office and laboratory space in Somerville, New Jersey.

Item 3. Legal Proceedings

Not applicable

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

Not applicable

PART II

Item 5. Market for Registrant s Common Equity and Related Stockholder Matters.

(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, 2004:		
First Quarter	$ 5.89	$ 2.80
Second Quarter	$ 5.15	$ 2.43
Third Quarter	$ 2.84	$ 1.80
Fourth Quarter	$ 3.39	$ 1.94
Fiscal Year Ended December 31, 2003:		
First Quarter	$ 1.81	$ 1.36
Second Quarter	$ 3.09	$ 1.44
Third Quarter	$ 2.80	$ 1.91
Fourth Quarter	$ 4.00	$ 2.42

(b) Approximate Number of Equity Security Holders

The number of record holders of our common stock as of March 1, 2005 was approximately 155. Based on the last ADP search, we believe there are in excess of 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.

Item 6. Selected Financial Data

The selected financial data presented below summarizes certain financial data which has been derived from and should be read in conjunction with our consolidated financial statements and footnotes thereto included in the section beginning on page F-1. See also Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations.

	Year Ended December 31,				
	2004	2003	2002	2001	2000
	(in thousands, except per share data)				
Statement of Operations Data:					
Total revenue(1)	$ 31	$ 89	$ 2,892	$ 4,572	$ 1,880
Operating expenses:					
Research and development	20,415	22,258	29,819	23,339	16,744
Acquired/in-process research and development(2)	759	3,896			4,969
General and administrative	5,237	5,109	5,076	5,383	4,070
Other income, net	376	1,285	3,821	6,686	5,115
Net loss	$ (26,004)	$ (29,889)	$ (28,182)	$ (17,464)	$ (18,788)
Basic and diluted net loss per share	$ (0.83)	$ (1.07)	$ (1.02)	$ (0.63)	$ (0.73)
Shares used in computing:					
Basic and diluted net loss per share	31,381	27,907	27,642	27,595	25,591

(1) Revenues for 2001 include $2.5 million license fee payment from Novartis for the development and commercialization of iloperidone in Japan. Revenues for 2002 include a $2.0 million milestone payment from Schering.

(2) Acquired research and development reflects the acquisition of the minority shares of Proneura in 2004, the acquisition of DTI in 2003 and in-process research and development reflects the acquisition of GeoMed in 2000.

	As of December 31,				
	2004	2003	2002	2001	2000
	(in thousands)				
Balance Sheet Data:					
Cash, cash equivalents, and marketable securities	$ 36,322	$ 46,555	$ 73,450	$ 105,051	$ 117,523
Working capital	33,760	44,578	70,702	100,193	115,386
Total assets	38,626	49,008	75,926	107,132	118,442
Total stockholders equity	33,713	44,426	70,740	100,127	114,738

Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion should be read in conjunction with the Consolidated Financial Statements and Notes thereto beginning on page F-1 in this report.

The following discussion contains certain forward-looking statements, within the meaning of the safe harbor provisions of the Private Securities Reform Act of 1995, the attainment of which involves various risks and uncertainties. Forward-looking statements may be identified by the use of forward-looking terminology such as may, will, expect, believe, estimate, plan, anticipate, continue, or similar terms, variations or the negative of those terms. Our actual results may differ materially from those described in these forward-looking statements due to, among other factors, the results of ongoing research and development activities and pre-clinical testing, the results of clinical trials and the availability of additional financing through corporate partnering arrangements or otherwise.

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

Overview

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

- Iloperidone: for the treatment of schizophrenia and related psychotic disorders (partnered with Vanda Pharmaceuticals, Inc.)
- Probuphine: for the treatment of opiate addiction
- Spheramine: for the treatment of advanced Parkinson s disease (partnered with Schering AG)
- DITPA: for the treatment of congestive heart failure
- Gallium maltolate: for the treatment of bone related diseases and certain cancers.

We are directly developing our product candidates and also utilizing strategic partnerships. These collaborations help fund product development and enable us to retain significant economic interest in our products. In June 2004, we announced that Vanda Pharmaceuticals, Inc. had acquired from Novartis Pharma AG the worldwide rights to develop and commercialize iloperidone, our proprietary antipsychotic agent in Phase III clinical development for the treatment of schizophrenia and related psychotic disorders. Vanda will now pursue advancement of 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 development is primarily funded by our corporate partner for Spheramine, Schering AG, Germany (Schering). We are no longer directly pursuing development of the monoclonal antibodies CeaVac, TriAb, and TriGem for the treatment of various cancers, and further development of Pivanex for treatment of lung cancer was also discontinued.

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

Product	Potential Indication(s)	Phase of Development	Marketing Rights
Iloperidone	Schizophrenia, psychosis	Phase III	Vanda Pharmaceuticals, Inc.
Probuphine	Opiate addiction	Phase I/II	Titan
Spheramine	Parkinson s disease	Phase IIb	Schering AG
DITPA	Congestive heart failure	Phase II	Titan
Gallium maltolate	Bone related disease and certain cancers	Phase I/II	Titan

For additional information on our product development programs, see Item 1(c) Narrative Description of Business section.

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 and we do not expect to generate any revenue from product sales or royalties in the foreseeable future. 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. An estimation of product completion dates and completion costs can vary significantly for each product and are difficult to predict. Various statutes and regulations also influence our product development progress and the success of obtaining approval is highly uncertain. We will also continue to identify new technologies and/or product candidates for possible in-licensing or acquisition. Accordingly, we expect to incur operating losses for the foreseeable future. We cannot assure you that we will ever achieve profitable operations. For a full discussion of risks and uncertainties in our product development, see Risk Factors Our products are at various stages of development and may not be successfully developed or commercialized.

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 financial statements and accompanying notes. Actual results could differ materially from those estimates. We believe the following accounting policies and estimates for the year ended December 31, 2004, to be critical:

- We have elected to continue to follow Accounting Principles Board Opinion No. 25 (or APB 25), *Accounting for Stock Issued to Employees,* to account for employee stock options because the alternative fair value method of accounting prescribed by Statement of Financial Accounting Standards No. 123 (or SFAS 123), *Accounting for Stock-Based Compensation,* requires the use of option valuation models that were not developed for use in valuing employee stock options. Under APB 25, no compensation expense is recognized when the exercise price of our employee stock options equals the market price of the underlying stock on the date of grant. Had we elected to follow SFAS 123 and to apply the fair value method to stock-based employee compensation, we would have recorded an additional $1.1 million in net loss, or an additional $0.03 of net loss per share for the year ended December 31, 2004.

Results of Operations

Comparison of Years Ended December 31, 2004 and 2003

Revenues in 2004 were $31,000 compared to $89,000 for 2003, a decrease of $58,000. Our revenues during 2004 and 2003 were derived from fees received under various licensing agreements.

Research and development expenses for 2004 were $20.4 million compared to $22.3 million for 2003, a decrease of $1.9 million. The decrease in research and development was primarily associated with the pending completion of a Phase II clinical study and the reduction of internal resources to our immunotherapy products in 2004. Of our 2004 research and development expenses, approximately 44%, or $9.0 million, were attributable to external R&D expenses. External R&D 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. In 2004, approximately $3.9 million of external R&D expenses were related to Pivanex, $1.4 million to Probuphine, $1.3 million to gallium maltolate, $1.2 million to DITPA, $0.2 million to Spheramine, and the remainder to other projects.

Remaining R&D expenses were attributable to internal operating costs, which include clinical research and development personnel salaries and employment related expenses, clinical trials related travel expenses, and allocation of facility and corporate costs. In 2004, we recorded a $759,000 acquired research and development expense in connection with the acquisition of minority shares of ProNeura, Inc. The entire purchase price of the shares was charged to acquired research and development on the acquisition date in accordance with generally accepted accounting principles. 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 product candidates.

General and administrative expenses for 2004 were $5.2 million compared to $5.1 million for 2003.

Other income, net, for 2004 was $376,000 compared to $1.3 million for 2003, a decrease of $900,000. The decrease, primarily in interest income, was a result of declining interest rates and our smaller average cash and marketable securities position.

As a result of the foregoing, we had a net loss of $26.0 million in 2004 compared to a net loss of $29.9 million in 2003.

Comparison of Years Ended December 31, 2003 and 2002

Revenues in 2003 were $0.1 million compared to $2.9 million for 2002, a decrease of $2.8 million. Our 2002 revenue included a one-time $2 million milestone payment from Schering AG following successful completion of our Phase I/II clinical study of Spheramine in the treatment of Parkinson s disease and Schering s decision to initiate randomized clinical testing of Spheramine for the treatment of patients with advanced Parkinson s disease (see Note 7 to the Consolidated Financial Statements beginning on page F-1 in this report). In addition, our 2002 revenue also included SBIR grant revenues from the National Institutes of Health in support of the development of Spheramine. We had no comparable milestone or grant revenue in 2003.

Research and development expenses for 2003 were $22.3 million compared to $29.8 million for 2002, a decrease of $7.5 million. The decrease in research and development was primarily associated with the completion of a randomized, placebo-controlled Phase III clinical study in 2002. Of our 2003 research and development expenses, approximately 52%, or $11.7 million, were attributable to external R&D expenses. External R&D 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. In 2003, approximately $5.2 million of external R&D expenses were related to Pivanex, $1.2 million to Probuphine, $1.3 million to gallium maltolate, $0.6 million to Spheramine, and the remainder to other projects. Remaining R&D expenses were attributable to internal operating costs, which include clinical research and development personnel salaries and employment related expenses, clinical trials related travel expenses, and allocation of facility and corporate costs. In 2003, we recorded a $3.9 million acquired research and development expense in connection with the acquisition of DITPA, a novel product for the potential treatment of congestive heart failure. The entire purchase price was charged to acquired research and development on the acquisition date in accordance with generally accepted accounting principles. See Note 8 to the Consolidated Financial Statements beginning on page F-1 in this report.

General and administrative expenses for 2003 were $5.1 million compared to $5.1 million for 2002.

Other income, net, for 2003 was $1.3 million compared to $3.8 million for 2002, a decrease of $2.5 million. The decrease, primarily in interest income, was a result of declining interest rates and our smaller average cash and marketable securities position.

As a result of the foregoing, we had a net loss of $29.9 million in 2003 compared to a net loss of $28.2 million in 2002.

Liquidity and Capital Resources

	2004	2003	2002
	(in thousands)		
As of December 31:			
Cash, cash equivalents and marketable securities	$ 36,322	$ 46,555	$ 73,450
Working capital	$ 33,760	$ 44,578	$ 70,702
Current ratio	10:1	14:1	19:1
Year Ended December 31:			
Cash (used in) provided by operating activities	$ (23,912)	$ (26,438)	$ (29,291)
Cash (used in) provided by investing activities	$ 7,977	$ 26,002	$ 30,678
Cash (used in) provided by financing activities	$ 14,566	$ 113	$ (4)

We have funded our operations since inception primarily through sales of our securities, as well as proceeds from warrant and option exercises, corporate licensing and collaborative agreements, and government sponsored research grants.

In October 2003, we acquired DITPA through the acquisition of Developmental Therapeutics, Inc. in a stock transaction for 1,187,500 shares of our common stock valued at approximately $3.6 million using the average market price of our common stock over the five-day trading period, including and prior to the date of the merger. In addition, up to a total of 750,000 shares of our common stock will be issued only upon the achievement of positive pivotal study results or certain other substantial milestones within five years.

Uses of cash in operating activities were primarily to fund product development programs and administrative expenses. We have entered into various agreements with research institutions, universities, and other entities for the performance of research and development activities and for the acquisition of licenses related to those activities. Certain of the licenses 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, and meeting project-funding milestones.

The following table sets forth the aggregate contractual cash obligations as of December 31, 2004 (in thousands):

	Payments Due by Period				
Contractual obligations	**Total**	**< 1 year**	**1-3 years**	**3-5 years**	**5 years+**
Operating leases	$ 3,676	$ 893	$ 1,331	$ 1,157	295
Sponsored research & license agreements	$ 2,408	$ 753	$ 653	$ 668	$ 334
Total contractual cash obligations	$ 6,086	$ 1,646	$ 1,985	$ 1,826	$ 629

We expect to continue to incur substantial additional operating losses from costs related to continuation and expansion of product and technology development, clinical trials, and administrative activities. We believe that we currently have sufficient working capital to sustain our planned operations through 2005. In February 2004 we filed a shelf registration statement with the Securities and Exchange Commission to sell up to $50 million of common or preferred stock. Under this registration statement, shares may be sold periodically to provide additional funds for our operations. In March 2004, we completed a sale of 3,075,000 shares of our common stock offered under the registration statement at a price of $5.00 per share, for gross proceeds of approximately $15.4 million. Net proceeds were

approximately $14.4 million. For a full discussion of risks and uncertainties regarding our need for additional financing, see Risk Factors We will need additional financing.

Off-Balance Sheet Arrangements

We have never entered into any off-balance sheet financing arrangements and we have never established any special purpose entities. We have not guaranteed any debt or commitments of other entities or entered into any options on non-financial assets.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Our portfolio of marketable securities exposes us to interest rate risk. We adhere to an investment policy that requires us to limit amounts invested in securities based on maturity, type of instrument, investment grade and issuer. We satisfy liquidity requirements by investing excess cash in securities with different maturities to match projected cash needs and limit concentration of credit risk by diversifying our investments among a variety of high credit-quality issuers. A hypothetical 100 basis point decrease in interest rates would result in an approximate $200,000 decrease in cash flow over the subsequent year. We do not use derivative financial instruments in our investment portfolio.

The following table summarizes principal amounts and related weighted-average interest rates by year of maturity on our interest-bearing investment portfolio at December 31, 2004 (in thousands, except interest rate):

	Face Value						
Cash equivalents and marketable securities:	**2005**		**2006**		**Total**		**Estimated Fair value**
Variable rate securities	$ 5,005				$ 5,005		$ 5,005
Average interest rate	1.38	%			1.38	%	
Fixed rate securities	$ 26,885		$ 3,990		$ 30,875		$ 30,859
Average interest rate	1.40	%	2.85	%	1.59	%	

Item 8. Consolidated Financial Statements and Supplementary Data.

The response to this item is included in a separate section of this Report. See Index to Consolidated Financial Statements on Page F-1.

Item 9. Changes and Disagreements with Accountants on Accounting and Financial Disclosure.

None

Item 9A. Controls and Procedures.

(a) *Evaluation of Disclosure Controls and Procedures*: Our principal executive and financial officers reviewed and evaluated our disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e)) as of the end of the period covered by this Form 10-K. Based on that evaluation, our principal executive and financial officers concluded that our disclosure controls and procedures are effective in timely providing them with material information relating to the company, as required to be disclosed in the reports we file under the Exchange Act.

(b) *Management s Annual Report on Internal Control Over Financial Reporting*: Our management is responsible for establishing and maintaining adequate internal control over our financial reporting. Management assessed the effectiveness of our internal control over financial reporting as of December 31, 2004. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in *Internal Control Integrated Framework*. Based on the

assessment using those criteria, management concluded that, as of December 31, 2004, our internal control over financial reporting was effective.

Our independent registered public accountants, Odenberg Ullakko Muranishi & Co., LLP, audited the consolidated financial statements included in this Annual Report on Form 10-K and have issued an audit report on management s assessment of our internal control over financial reporting as well as on the effectiveness of our internal control over financial reporting. Each of the report on the audit of internal control over financial reporting and the report on the audit of the consolidated financial statements appear elsewhere in this Annual Report on Form 10-K.

(c) *Changes in Internal Control Over Financial Reporting*: There were no significant changes in our internal control over financial reporting during our most recently completed fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None

PART III

Item 10. Directors and Executive Officers of Registrant.

The following table sets forth the names, ages and positions of our executive officers and directors.

Name	Age	Position
Louis R. Bucalo, M.D.(1)	46	Chairman, President and Chief Executive Officer
Sunil Bhonsle	55	Executive Vice President, Chief Operating Officer, and Director
Richard C. Allen, Ph.D.	62	Executive Vice President, Cell Therapy
Robert E. Farrell	55	Executive Vice President and Chief Financial Officer
Ernst-Günter Afting, M.D., Ph.D.	62	Director
Victor Bauer, Ph.D.	69	Director
Eurelio M. Cavalier(1)(3)(4)	72	Director
Hubert Huckel, M.D.(1)(2)(3)	73	Director
M. David MacFarlane, Ph.D.(2)(4)	64	Director
Ley S. Smith(1)(2)(4)	70	Director
Konrad M. Weis, Ph.D.(1)(3)	76	Director

(1) Member of Executive Committee

(2) Member of Audit Committee

(3) Member of Compensation Committee

(4) Member of Nominating Committee

Louis R. Bucalo, M.D. is the founder of Titan and has served as our President and Chief Executive Officer since January 1993. Dr. Bucalo has served as a director of Titan since March 1993 and was elected Chairman of the Board of Directors in January 2000. From July 1990 to April 1992, Dr. Bucalo was Associate Director of Clinical Research at Genentech, Inc., a biotechnology company. Dr. Bucalo holds an M.D. from Stanford University and a B.A. in biochemistry from Harvard University.

Sunil Bhonsle has served as our Executive Vice President and Chief Operating Officer since September 1995, and has served as a director of Titan since February 2004. Mr. Bhonsle served in various positions, including Vice President and General Manager-Plasma Supply and Manager-Inventory and Technical Planning, at Bayer Corporation from July 1975 until April 1995. Mr. Bhonsle holds an M.B.A. from the University of California at Berkeley and a B.Tech. in chemical engineering from the Indian Institute of Technology.

Richard C. Allen, Ph.D., has served as our Executive Vice President, Cell Therapy, since August 1995. From January 1995 until it was merged into Titan in March 1999, he also served as President and Chief Executive Officer of Theracell, Inc. From June 1991 until December 1994, Dr. Allen was Vice President and General Manager of the Neuroscience Strategic Business Unit of Hoechst-Roussel Pharmaceuticals, Inc. Dr. Allen holds a Ph.D. in medicinal chemistry and a B.S. in pharmacy from the Medical College of Virginia.

Robert E. Farrell has served as our Executive Vice President and Chief Financial Officer since September 1996. Mr. Farrell was employed by Fresenius USA, Inc. from 1991 until August 1996 where he served in various capacities, including Vice President Administration, Chief Financial Officer and General Counsel. His last position was Corporate Group Vice President. Mr. Farrell holds a B.A. from the University of Notre Dame and a J.D. from Hastings College of Law, University of California.

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Ernst-Günter Afting, M.D., Ph.D., has served on our Board of Directors since May 1996. He has served as the President of the GSF-National Center for Environment and Health, a government research center in Germany, since 1995. From 1984 until 1995, Dr. Afting was employed in various capacities by the Hoechst Group, serving as Divisional Head of the Pharmaceuticals Division of the Hoechst Group from 1991 to 1993 and as President and Chief Executive Officer of Roussel Uclaf (a majority stockholder of Hoechst AG) in Paris from 1993 until 1995. He currently serves on the Board of Directors of Sequenom, Inc.

Victor J. Bauer, Ph.D., has served on our Board of Directors since November 1997. He joined Titan in February 1997 and currently serves as our Executive Director of Corporate Development. From April 1996 until its merger into Titan, Dr. Bauer also served as a director and Chairman of Theracell. From December 1992 until February 1997, Dr. Bauer was a self-employed consultant to companies in the pharmaceutical and biotechnology industries. Prior to that time, Dr. Bauer was with Hoechst-Roussel Pharmaceuticals Inc., where he served as President from 1988 through 1992.

Eurelio M. Cavalier has served on our Board of Directors since September 1998. He was employed in various capacities by Eli Lilly & Co. from 1958 until his retirement in 1994, serving as Vice President Sales from 1976 to 1982 and Group Vice President U.S. Pharmaceutical Business Unit from 1982 to 1993. Mr. Cavalier currently serves on the Board of Directors of ProSolv, Inc.

Hubert Huckel, M.D. has served on our Board of Directors since October 1995. He served in various positions with The Hoechst Group from 1964 until his retirement in December 1992. At the time of his retirement, Dr. Huckel was Chairman of the Board of Hoechst-Roussel Pharmaceuticals, Inc., Chairman and President of Hoechst-Roussel Agri-Vet Company and a member of the Executive Committee of Hoechst Celanese Corporation. He currently serves on the Board of Directors of Thermogenesis, Corp. and Amarin Pharmaceuticals, plc and is a member of their compensation committees.

M. David MacFarlane, Ph.D., has served on the Board of Directors since May 2002. From 1989 until his retirement in August 1999, Dr. MacFarlane served as Vice President and Responsible Head of Regulatory Affairs of Genentech, Inc. Prior to joining Genentech, Inc., he served in various positions with Glaxo Inc., last as Vice President of Regulatory Affairs.

Ley S. Smith has served on our Board of Directors since July 2000. He served in various positions with The Upjohn Company and Pharmacia & Upjohn from 1958 until his retirement in November 1997. From 1991 to 1993 he served as Vice Chairman of the Board of The Upjohn Company, and from 1993 to 1995 he was President and Chief Operating Officer of The Upjohn Company. At the time of his retirement, Mr. Smith was Executive Vice President of Pharmacia & Upjohn, and President of Pharmacia & Upjohn s U.S. Pharma Product Center. He currently serves on the Board of Directors of Protana, Inc.

Konrad M. Weis, Ph.D., has served on our Board of Directors since March 1993. He is the former President, Chief Executive Officer and Honorary Chairman of Bayer Corporation. Dr. Weis serves as a director of PNC Equity Management Company, Michael Baker Corporation, Visible Genetics, Inc. and Demegen, Inc.

Directors serve until the next annual meeting or until their successors are elected and qualified. Officers serve at the discretion of the Board of Directors, subject to rights, if any, under contracts of employment. See Item 11. Executive Compensation Employment Agreements.

Code of Ethics

We have adopted a Code of Business Conduct and Ethics (the Code) that applies to our directors, officers and employees, including our Chief Executive Officer and Chief Financial Officer (our principal executive officer and principal financial and accounting officer, respectively). The Code was filed as Exhibit 14 to our annual report on Form 10-K for the year ended December 31, 2003 and has been

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incorporated by reference into this annual report. A written copy of the Code will be provided upon request at no charge by writing to our Chief Financial Officer, Titan Pharmaceuticals, Inc., 400 Oyster Point Boulevard, Suite 505, South San Francisco, California 94080.

Board Committees and Designated Directors

The Board of Directors has an Executive Committee, a Compensation Committee, an Audit Committee, and a Nominating Committee.

Executive Committee. The Executive Committee exercises all the power and authority of the Board of Directors in the management of Titan between Board meetings, to the extent permitted by law.

Compensation Committee. The Compensation Committee makes recommendations to the Board of Directors concerning salaries and incentive compensation for our officers, including our Chief Executive Officer, and employees and administers our stock option plans. The Compensation Committee consists of three directors, each of whom meets the independence requirements and standards currently established by the American Stock Exchange.

Nominating Committee. The Nominating Committee operates under a written charter. The Nominating Committee consists of three directors, each of whom meets the independence requirements and standards currently established by the American Stock Exchange. The purpose of the Nominating Committee is to assist the Board of Directors in identifying qualified individuals to become board members, in determining the composition of the Board of Directors and in monitoring a process to assess Board effectiveness.

Audit Committee. The Audit Committee operates under a written charter. The Audit Committee consists of three directors, each of whom meets the independence requirements and standards currently established by the American Stock Exchange and the SEC. In addition, the Board of Directors has determined that Mr. Ley Smith is an audit committee financial expert and independent as defined under the relevant rules of the SEC and the American Stock Exchange. The Audit Committee assists the Board of Directors in fulfilling its oversight of the quality and integrity of Titan s financial statements and Titan s compliance with legal and regulatory requirements. The Audit Committee is responsible for retaining (subject to stockholder ratification) and, as necessary, terminating, the independent auditors, annually reviews the qualifications, performance and independence of the independent auditors and the audit plan, fees and audit results, and pre-approves audit and non-audit services to be performed by the auditors and related fees. The Audit Committee also oversees the performance of Titan s internal audit and compliance functions.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934, as amended (the Exchange Act), requires our executive officers, directors and persons who beneficially own more than 10% of a registered class of our equity securities to file with the Securities and Exchange Commission initial reports of ownership and reports of changes in ownership of our common stock and other equity securities. Such executive officers, directors, and greater than 10% beneficial owners are required by SEC regulation to furnish us with copies of all Section 16(a) forms filed by such reporting persons.

There was a failure to timely file Form 4s to report the February 9, 2004 grants of stock options to officers of the Company. Based solely on our review of such forms furnished to us and written representations from certain reporting persons, we believe that all other filing requirements applicable to our executive officers, directors and greater than 10% beneficial owners were complied with during 2004.

Item 11. Executive Compensation.

The following summary compensation table sets forth, for each of the last three fiscal years, the aggregate compensation awarded to, earned by, or paid to the Chief Executive Officer and to the three other executive officers at December 31, 2004 whose annual compensation exceeded $100,000 for the fiscal year ended December 31, 2004 (collectively, the named executive officers):

Summary Compensation Table

Name and Principal Position	Year	Annual Compensation Salary	Bonus	Other Compensation
Louis R. Bucalo, M.D.	2004	$ 357,042		
President and Chief Executive Officer	2003	$348,038		
	2002	$339,896		
Sunil Bhonsle	2004	$ 272,125		
Executive Vice President and Chief Operating Officer	2003	$265,276		
	2002	$259,167		
Richard C. Allen, Ph.D.	2004	$ 238,200		
Executive Vice President, Cell Therapy	2003	$232,230		
	2002	$226,821		
Robert E. Farrell, J.D.	2004	$ 227,217		
Executive Vice President and Chief Financial Officer	2003	$221,447		
	2002	$216,254		$59,766 (1)

(1) The amount disclosed for Mr. Farrell represents an accrued vacation payment made in 2002.

Option Grants in Last Fiscal Year

The following table contains information concerning the stock option grants made to the named executive officers during the fiscal year ended December 31, 2004. No stock appreciation rights were granted to these individuals during such year.

Name	Number of Securities Underlying Options Granted	% of Total Options Granted to Employees In Fiscal Year	Exercise or Base Price ($/Sh)(1) Individual Grant	Expiration Date	Potential Realizable Value at Assumed Annual Rate of Stock Price Appreciation For Option Terms 5%	10%
Louis R. Bucalo	75,000	6.73 %	$ 3.69	02/09/2014	$ 174,047	$ 441,068
Louis R. Bucalo	20,000	1.79 %	$ 2.37	09/01/2014	$ 32,416	$ 79,693
Sunil Bhonsle	60,000	5.38 %	$ 3.69	02/09/2014	$ 139,237	$ 352,855
Richard C. Allen	30,000	2.69 %	$ 3.69	02/09/2014	$ 69,619	$ 176,427
Robert E. Farrell	35,000	3.14 %	$ 3.69	02/09/2014	$ 81,222	$ 205,832

(1) The exercise price may be paid in cash, in shares of common stock valued at the fair market value on the exercise date or through a cashless exercise procedure involving a same-day sale of the purchase shares.

Aggregate Option Exercises in Last Fiscal Year and Fiscal Year-End Option Values

The following table sets forth information concerning option exercises and option holdings for the fiscal year ended December 31, 2004 with respect to the named executive officers. No stock appreciation rights were exercised during such year or were outstanding at the end of that year.

Name	Shares Acquired on Exercise	Value Realized	Number of Securities Underlying Unexercised Options at FY-End		Value of Unexercised in-the-Money Options at FY-End(1)	
			Exercisable	Unexercisable	Exercisable	Unexercisable
Louis R. Bucalo	81,755	$ 253,441	1,552,356	109,063	$ 230,149	$ 41,779
Sunil Bhonsle			681,655	66,250	$ 75,250	$ 10,750
Richard C. Allen			565,309	34,375	$ 241,396	$ 7,525
Robert E. Farrell			277,677	39,375	$ 155,799	$ 7,525

(1) Based on the fair market value of our common stock at year-end, $3.22 per share, less the exercise price payable for such shares.

Director Compensation

Non-employee directors are entitled to receive a fee for each meeting attended and all directors are entitled to receive stock options pursuant to our stockholder-approved stock option plans, including an initial grant of 10,000 options upon becoming a director, a biennial grant of 15,000 options thereafter, and an annual grant of 5,000 options for each committee on which they serve. During 2004, each director was granted an annual option to purchase 5,000 shares of our common stock at an exercise price of $2.37, which was equal to the fair market value of our common stock at date of grant, with respect to each committee of the Board on which each director served. In addition to having their out-of-pocket expenses reimbursed, non-employee directors received $2,500 for each Board of Directors meeting attended in 2004. Directors are not precluded from serving us in any other capacity and receiving compensation therefore. Commencing in 2005, non-employee directors are entitled to receive an annual retainer fee of $5,000 in addition to the fee received for each meeting attended. The biennial grant of options to directors pursuant to our stockholder-approved stock option plans will be increased from 15,000 options to 20,000 options.

We are a party to a consulting agreement with Dr. Ernst-Günter Afting pursuant to which he receives fees of $7,000 annually.

Compensation Committee Interlocks and Insider Participation

Members of our Compensation Committee of the Board of Directors were Dr. Eurelio M. Cavalier, Dr. Hubert E. Huckel and Dr. Konrad M. Weis. No member of our Compensation Committee was, or has been, an officer or employee of Titan or any of our subsidiaries.

No member of the Compensation Committee has a relationship that would constitute an interlocking relationship with Executive Officers or Directors of the Company or another entity.

Employment Agreements

We are a party to an employment agreement with Dr. Bucalo which, as amended in February 2005, expires in February 2008 and provides for a base annual salary of $210,000, subject to annual increases of 5% and bonuses of up to 25% at the discretion of the Board of Directors. In the event of the termination of the agreement by us without just cause or by Dr. Bucalo for just cause, we are obligated to make severance payments equal to his base annual salary for the greater of the balance of the term of the agreement or two years, subject to offset for earnings after the first 18 months.

Employment agreements with each of Dr. Allen, Mr. Bhonsle and Mr. Farrell provide for a base annual salary of $185,000 subject to automatic annual increases based on increases in the consumer price index, and bonuses of up to 20% at the discretion of the Board of Directors. In the event the employee s employment is terminated other than for good cause (as defined in each employment agreement), we are obligated to make severance payments equal to the base annual salary for six months. All of the agreements contain confidentiality provisions.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The following table sets forth, as of March 1, 2005, certain information concerning the beneficial ownership of our common stock by (i) each stockholder known by us to own beneficially five percent or more of our outstanding common stock; (ii) each director; (iii) each executive officer; and (iv) all of our executive officers and directors as a group, and their percentage ownership and voting power.

Name and Address of Beneficial Owner(1)	Shares Beneficially Owned(2)		Percent of Shares Beneficially Owned	
Louis R. Bucalo, M.D.	2,076,008	(3)	6.4	%
Ernst-Günter Afting, M.D., Ph.D.	66,437	(4)	*	
Richard C. Allen, Ph.D.	604,449	(5)	1.9	%
Victor J. Bauer, Ph.D.	256,581	(6)	*	
Sunil Bhonsle	928,299	(7)	2.9	%
Eurelio M. Cavalier	130,935	(8)	*	
Robert E. Farrell	364,832	(9)	1.1	%
Hubert Huckel, M.D.	163,435	(10)	*	
M. David MacFarlane, Ph.D.	38,019	(11)	*	
Ley S. Smith	108,435	(12)	*	
Konrad M. Weis, Ph.D.	159,343	(13)	*	
Kevin Douglas and The Douglas Family Trust 1101 Fifth Avenue, Suite 360 San Rafael, CA 94901	1,674,100	(14)	5.2	%
All executive officers and directors as a group (11) persons	4,896,773		15.1	%

* Less than one percent.

(1) Unless otherwise indicated, the address of such individual is c/o Titan Pharmaceuticals, Inc., 400 Oyster Point Boulevard, Suite 505, South San Francisco, California 94080.

(2) In computing the number of shares beneficially owned by a person and the percentage ownership of a person, shares of our common stock subject to options held by that person that are currently exercisable or exercisable within 60 days of March 1, 2005 are deemed outstanding. Such shares, however, are not deemed outstanding for purposes of computing the percentage ownership of each other person. Except as indicated in the footnotes to this table and pursuant to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all shares of common stock.

(3) Includes 1,641,522 shares issuable upon exercise of outstanding options.

(4) Includes 66,437 shares issuable upon exercise of outstanding options.

(5) Includes 574,067 shares issuable upon exercise of outstanding options.

(6) Includes 247,937 shares issuable upon exercise of outstanding options.

(7) Includes 747,905 shares issuable upon exercise of outstanding options.

(8) Includes 100,935 shares issuable upon exercise of outstanding options.

(9) Includes 317,052 shares issuable upon exercise of outstanding options.

(10) Includes (i) 123,935 shares issuable upon exercise of outstanding options, and (ii) 3,000 shares held by Dr. Huckel s wife.

(11) Includes 28,019 shares issuable upon exercise of outstanding options.

(12) Includes 98,435 shares issuable upon exercise of outstanding options.

(13) Includes 123,769 shares issuable upon exercise of outstanding options.

(14) Derived from a Schedule 13G/A filed by Kevin Douglas and The Douglas Family Trust on February 14, 2005.

Equity Compensation Plan Information

The following table sets forth aggregate information regarding our equity compensation plans in effect as of December 31, 2004:

Plan category	Number of securities to be issued upon exercise of outstanding options (a)	Weighted-average exercise price of outstanding options (b)	Number of securities remaining available for future issuance under equity compensation plans (c)
Equity compensation plans approved by security holders	4,090,831	$ 9.18	1,399,146
Equity compensation plans not approved by security holders(1)(2)	2,354,555	$ 7.01	65,091
Total	6,445,386	$ 8.39	1,464,237

(1) In August 2002, we amended our 2001 Employee Non-Qualified Stock Option Plan. Pursuant to this amendment, a total of 1,750,000 shares of common stock were reserved and authorized for issuance for option grants to employees and consultants who are not officers or directors of Titan.

(2) In November 1999 and in connection with the redemption of warrants, we granted 813,000 non-qualified stock options outside of our stock option plans to our executive officers, at an exercise price of $12.69, vesting equally over 36 months from the date of grant.

Item 13. Certain Relationships and Related Transactions.

Not applicable

Item 14. Principal Accountant Fees and Services.

Aggregate fees billed by Ernst & Young LLP and Odenberg, Ullakko, Muranishi & Co LLP during the fiscal year ended December 31, 2004 and aggregate fees billed by Ernst & Young LLP during the fiscal year ended December 31, 2003 were as follows:

	2004	2003
Audit Fees	$ 213,200	$ 175,500
Audit-Related Fees	33,000	9,900
Tax Fees	30,000	63,900
All Other Fees		
Total	**$ 276,200**	**$ 249,300**

Ernst & Young LLP served as our principal accountant for the fiscal year ended December 31, 2003 and until November 8, 2004, the effective date of their resignation. The amounts related to fiscal year 2004 include audit fees of $43,200 and audit related fees of $33,000 billed by Ernst & Young LLP for services provided as our principle accountants up to November 8, 2004. Odenberg, Ullakko, Muranishi & Co LLP were engaged as our principal accountant effective November 9, 2004, the filing date of our Form 10-Q for the quarter ended September 30, 2004.

Audit Fees This category includes aggregate fees billed by our independent auditors for the audit of Titan s annual financial statements, audit of management s assessment and effectiveness of internal controls over financial reporting, review of financial statements included in our quarterly reports on Form 10-Q and services that are normally provided by the auditor in connection with statutory and regulatory filings for those fiscal years.

Audit-Related Fees This category consists of services by our independent auditors that, including accounting consultations on transaction related matters, are reasonably related to the performance of the audit or review of Titan s financial statements and are not reported above under Audit Fees.

Tax Fees This category consists of professional services rendered for tax compliance and preparation of Titan s corporate tax returns and other tax advice.

All Other Fees During the years ended December 31, 2004 and 2003, Ernst & Young LLP and Odenberg, Ullakko, Muranishi & Co LLP did not incur any fees for other professional services.

The Audit Committee reviewed and approved all audit and non-audit services provided by Ernst & Young LLP and Odenberg, Ullakko, Muranishi & Co LLP and concluded that these services were compatible with maintaining its independence. The Audit Committee approved the provision of all non-audit services by Ernst & Young LLP and Odenberg, Ullakko, Muranishi & Co LLP.

Pre-Approval Policies and Procedures

In accordance with the SEC s new auditor independence rules, which became effective on May 6, 2003, the Audit Committee has established the following policies and procedures by which it approves in advance any audit or permissible non-audit services to be provided to Titan by its independent auditor.

Prior to the engagement of the independent auditor for any fiscal year s audit, management submits to the Audit Committee for approval lists of recurring audit, audit-related, tax and other services expected to be provided by the auditor during that fiscal year. The Audit Committee adopts pre-approval schedules describing the recurring services that it has pre-approved, and is informed on a timely basis, and in any event by the next scheduled meeting, of any such services rendered by the independent auditor and the related fees.

The fees for any services listed in a pre-approval schedule are budgeted, and the Audit Committee requires the independent auditor and management to report actual fees versus the budget periodically throughout the year. The Audit Committee will require additional pre-approval if circumstances arise where it becomes necessary to engage the independent auditor for additional services above the amount of fees originally pre-approved. Any audit or non-audit service not listed in a pre-approval schedule must be separately pre-approved by the Audit Committee on a case-by-case basis.

Every request to adopt or amend a pre-approval schedule or to provide services that are not listed in a pre-approval schedule must include a statement by the independent auditors as to whether, in their view, the request is consistent with the SEC s rules on auditor independence.

The Audit Committee will not grant approval for:

- any services prohibited by applicable law or by any rule or regulation of the SEC or other regulatory body applicable to Titan;

- provision by the independent auditor to Titan of strategic consulting services of the type typically provided by management consulting firms; or

- the retention of the independent auditor in connection with a transaction initially recommended by the independent auditor, the tax treatment of which may not be clear under the Internal Revenue Code and related regulations and which it is reasonable to conclude will be subject to audit procedures during an audit of Titan s financial statements.

Tax services proposed to be provided by the auditor to any director, officer or employee of Titan who is in an accounting role or financial reporting oversight role must be approved by the Audit Committee on a case-by-case basis where such services are to be paid for by Titan, and the Audit Committee will be informed of any services to be provided to such individuals that are not to be paid for by Titan.

In determining whether to grant pre-approval of any non-audit services in the all other category, the Audit Committee will consider all relevant facts and circumstances, including the following four basic guidelines**:**

- whether the service creates a mutual or conflicting interest between the auditor and the Company;

- whether the service places the auditor in the position of auditing his or her own work;

- whether the service results in the auditor acting as management or an employee of the Company; and

- whether the service places the auditor in a position of being an advocate for the Company.

PART IV

Item 15. Exhibits, Financial Statements Schedules and Reports on Form 8-K

(a) 1. Financial Statements

An index to Consolidated Financial Statements appears on page F-1.

2. Schedules

All financial statement schedules are omitted because they are not applicable, not required under the instructions or all the information required is set forth in the financial statements or notes thereto.

(b) Exhibits

3.1	Restated Certificate of Incorporation of the Registrant(1)
3.2	Form of Amendment to Restated Certificate of Incorporation of the Registrant(1)
3.3	By-laws of the Registrant(1)
4.7	Certificate of Designation of Series C Preferred Stock(6)
10.1*	1993 Stock Option Plan(1)
10.2*	1995 Stock Option Plan, as amended(2)
10.3*	Employment Agreement between the Registrant and Louis Bucalo dated February 1, 1993, amended as of February 3, 1994(1).
10.4*	Employment Agreement between Registrant and Richard Allen dated July 28, 1995(1)
10.5*	Employment Agreement between Registrant and Sunil Bhonsle, dated August 6, 1995(1)
10.6	Form of Indemnification Agreement(1)
10.9	MDR Exclusive License Agreement between Ingenex, Inc. (formerly Pharm-Gen Systems Ltd.) and the Board of Trustees of the University of Illinois dated May 6, 1992(1)
10.11	License Agreement between Theracell, Inc. and New York University dated November 20, 1992, as amended as of February 23, 1993 and as of February 25, 1995(1)
10.12	License Agreement between the Registrant and the Massachusetts Institute of Technology dated September 28, 1995(1)
10.14	Exclusive License Agreement between Ingenex, Inc. and the Board of Trustees of the University of Illinois, dated July 1, 1994(1)
10.15	Exclusive License Agreement between Ingenex, Inc. and the Board of Trustees of the University of Illinois, dated July 1, 1994(1)
10.16	License Agreement between Ingenex, Inc. and the Massachusetts Institute of Technology, dated September 11,1992(1)
10.17	License Agreement between Ingenex, Inc. and Baylor College of Medicine, dated October 21, 1992(1)
10.18	Lease for Registrant s facilities, amended as of October 1, 2004.
10.20	License Agreement between Trilex Pharmaceuticals, Inc. (formerly Ascalon Pharmaceuticals, Inc.) and the University of Kentucky Research Foundation dated May 30, 1996(3)

10.22	License Agreement between the Registrant and Aventis SA (formerly Hoechst Marion Roussel, Inc.) effective as of December 31, 1996(4)
10.23*	Employment Agreement between Registrant and Robert E. Farrell dated August 9, 1996(4)
10.27	License Agreement between the Registrant and Bar-Ilan Research and Development Company Limited effective November 25, 1997(5)
10.28	License Agreement between the Registrant and Ansan Pharmaceuticals, Inc. dated November 24, 1997(5)
10.30	Sublicense Agreement between the Registrant and Novartis Pharma AG dated November 20, 1997(5)
10.31*	1998 Stock Option Plan, as amended.(7)
10.32	License Agreement between the Registrant and Schering AG dated January 25, 2000. (8)
10.34	Agreement and Plan of Merger by and among the Registrant, GeoMed Merger Sub Corp., GeoMed, Inc. and Dr. Lawrence Bernstein, Dr. Neil Gesundheit, Leland Wilson and Dr. Virgil Place dated July 11, 2000.(9)
10.35*	2001 Non-Qualified Employee Stock Option Plan.(10)
10.37*	2002 Stock Option Plan.(11)
10.38	Merger Agreement between the Registrant and Developmental Therapeutics, Inc. dated October 15, 2003.
10.39	Addendums to License Agreement between the Registrant and Schering AG dated January 25, 2000.
10.40*	Amendment to Employment Agreement between the Registrant and Louis Bucalo dated February 7, 2005.
14	Code of Business Conduct and Ethics. (12)
23.1	Consent of Odenberg Ullakko Muranishi & Co. LLP, Independent Registered Public Accounting Firm.
23.2	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm.
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act, as amended.
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act, as amended.
32	Certification of Chief Executive Office and Chief Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 .

Confidential treatment has been granted with respect to portions of this exhibit.

* Represents a management contract or compensatory plan.

(1) Incorporated by reference from the Registrant s Registration Statement on Form SB-2 (File No. 33-99386).

(2) Incorporated by reference from the Registrant s Definitive Proxy Statement filed on September 3, 1996.

(3) Incorporated by reference from the Registrant s Registration Statement on Form SB-2 (File No. 333-13469) filed on October 4, 1996, amended on November 25, 1996.

(4) Incorporated by reference from the Registrant s Annual Report on Form 10-KSB for the year ended December 31, 1996.

(5) Incorporated by reference from the Registrant s Registration Statement on Form S-3 (File No. 333-42367) filed on December 16, 1997.

(6) Incorporated by reference from the Registrant s Annual Report on Form 10-K for the year ended December 31, 1997.

(7) Incorporated by reference from the Registrant s Definitive Proxy Statement filed on July 28, 2000.

(8) Incorporated by reference from the Registrant s Annual Report on Form 10-K for the year ended December 31, 1999.

(9) Incorporated by reference from the Registrant s Quarterly Report on Form 10-Q for the period ended September 30, 2000.

(10) Incorporated by reference from the Registrant s Annual Report on Form 10-K for the year ended December 31, 2001.

(11) Incorporated by reference from the Registrant s Annual Report on Form 10-K for the year ended December 31, 2002.

(12) Incorporated by reference from the Registrant s Annual Report on Form 10-K for the year ended December 31, 2003.

TITAN PHARMACEUTICALS, INC.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Titan Pharmaceuticals, Inc.

We have audited management s assessment, included in the accompanying Management Report on Internal Controls Over Financial Reporting included in Item 9A that Titan Pharmaceuticals, Inc. and its subsidiaries (the Company) maintained effective internal control over financial reporting as of December 31, 2004, based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). The Company s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management s assessment and an opinion on the effectiveness of the Company s internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management s assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company s assets that could have a material effect on the financial statements.

Because of the inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of the effectiveness to future periods are subject to the risk that the controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management s assessment that the Company maintained effective internal control over financial reporting as of December 31, 2004, is fairly stated, in all material respects, based on the COSO criteria. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2004, based on the COSO criteria.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheet of Titan Pharmaceuticals, Inc. and its subsidiaries as of December 31, 2004, and the related consolidated statements of operations, stockholders equity, and cash flows for the year then ended and our report dated February 15, 2005 expressed an unqualified opinion thereon.

/s/ Odenberg Ullakko Muranishi & Co. LLP

San Francisco, California
February 15, 2005

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Titan Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheet of Titan Pharmaceuticals, Inc. and its subsidiaries as of December 31, 2004, and the related consolidated statements of operations, stockholders equity, and cash flows for the year then ended. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements audited by us present fairly, in all material respects, the financial position of Titan Pharmaceuticals, Inc. and its subsidiaries at December 31, 2004, and the results of their operations and their cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Titan Pharmaceuticals, Inc. s internal control over financial reporting as of December 31, 2004, based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 15, 2005 expressed an unqualified opinion thereon.

/s/ Odenberg Ullakko Muranishi & Co. LLP

San Francisco, California

February 15, 2005

REPORT OF ERNST & YOUNG LLP, INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders
Titan Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheet of Titan Pharmaceuticals, Inc. as of December 31, 2003, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2003. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company s internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company s internal control over financial reporting. Accordingly we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Titan Pharmaceuticals, Inc. at December 31, 2003, and the consolidated results of its operations and its cash flows for each of the two years in the period ended December 31, 2003, in conformity with U.S. generally accepted accounting principles.

Palo Alto, California
February 20, 2004

TITAN PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS

	December 31, 2004 (in thousands of dollars)	2003
Assets		
Current assets:		
Cash and cash equivalents	$ 5,463	$ 6,832
Marketable securities	30,859	39,723
Related party receivables	18	123
Prepaid expenses, other receivables and current assets	1,092	1,241
Total current assets	37,432	47,919
Property and equipment, net	1,044	789
Investment in other companies	150	300
	$ 38,626	$ 49,008
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 689	$ 1,505
Accrued clinical trials expenses	1,445	634
Other accrued liabilities	1,538	1,202
Total current liabilities	3,672	3,341
Commitments		
Minority interest Series B preferred stock of Ingenex, Inc.	1,241	1,241
Stockholders Equity		
Preferred stock, $0.001 par value per share; 5,000,000 shares authorized, issuable in series:		
Convertible Series C, 222,400 shares designated, 222,400 shares issued and outstanding, with an aggregate liquidation value of $2,000 at December 31, 2004 and 2003		
Common stock, at amounts paid in, $0.001 par value per share; 50,000,000 shares authorized, 32,307,638 and 28,903,043 shares issued and outstanding at December 31, 2004 and 2003, respectively	210,264	195,331
Additional paid-in capital	9,327	9,047
Deferred compensation	(82)	(211)
Accumulated deficit	(185,745)	(159,741)
Accumulated other comprehensive income	(51)	
Total stockholders equity	33,713	44,426
	$ 38,626	$ 49,008

See accompanying notes.

TITAN PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENT OF OPERATIONS

	Year ended December 31, 2004	2003	2002
	(in thousands, except per share amount)		
Revenue:			
Contract revenue	$	$ 28	$ 2,696
License revenue	31	61	
Grant revenue			196
Total revenue	31	89	2,892
Operating expenses:			
Research and development	20,415	22,258	29,819
Acquired research and development	759	3,896	
General and administrative	5,237	5,109	5,076
Total operating expenses	26,411	31,263	34,895
Loss from operations	(26,380)	(31,174)	(32,003)
Other income (expense):			
Interest income	673	1,278	4,221
Other income (expense)	(297)	7	(400)
Other income, net	376	1,285	3,821
Net loss	$ (26,004)	$ (29,889)	$ (28,182)
Basic and diluted net loss per share	$ (0.83)	$ (1.07)	$ (1.02)
Weighted average shares used in computing basic and diluted net loss per share	31,381	27,907	27,642

See accompanying notes.

TITAN PHARMACEUTICALS, INC

CONSOLIDATED STATEMENT OF STOCKHOLDERS EQUITY

(in thousands)

	Preferred Stock Shares	Amount	Common Stock Shares	Amount	Additional Paid-In Capital	Deferred Compensation	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders Equity
Balances at December 31, 2001	**222**	**$**	**27,642**	**$ 191,684**	**$ 9,017**	**$ (795)**	**$ (101,670)**	**$ 1,891**	**$ 100,127**
Comprehensive loss:									
Net loss							(28,182)		(28,182)
Unrealized loss on marketable securities								(1,519)	(1,519)
Comprehensive loss									(29,701)
Issuance of common stock upon exercise of options, net of issuance costs of $6				(4)					(4)
Compensation related to stock options					144	(141)			3
Amortization of deferred compensation						315			315
Balances at December 31, 2002	**222**	**$**	**27,642**	**$ 191,680**	**$ 9,161**	**$ (621)**	**$ (129,852)**	**$ 372**	**$ 70,740**
Comprehensive loss:									
Net loss							(29,889)		(29,889)
Unrealized loss on marketable securities								(372)	(372)
Comprehensive loss									(30,261)
Issuance of common stock to acquire technologies, net of issuance costs of $22			1,188	3,538					3,538
Issuance of common stock upon exercise of options			73	113					113
Compensation related to stock options					(114)	114			
Amortization of deferred compensation						296			296
Balances at December 31, 2003	**222**	**$**	**28,903**	**$ 195,331**	**$ 9,047**	**$ (211)**	**$ (159,741)**	**$**	**$ 44,426**
Comprehensive loss:									
Net loss							(26,004)		(26,004)
Unrealized loss on marketable securities								(51)	(51)
Comprehensive loss									(26,055)
Issuance of common stock, net of issuance costs of $1,020			3,075	14,355					14,355
Issuance of common stock upon exercise of options			180	211					211
Issuance of common stock upon tender of Proneura, Inc. shares			150	367					367
Compensation related to stock options					280	(154)			126
Amortization of deferred compensation						283			283
Balances at December 31, 2004	**222**	**$**	**32,308**	**$ 210,264**	**$ 9,327**	**$ (82)**	**$ (185,745)**	**$ (51)**	**$ 33,713**

See accompanying notes.

TITAN PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENT OF CASH FLOWS

	Years ended December 31,		
	2004	**2003**	**2002**
	(in thousands of dollars)		
Cash flows from operating activities:			
Net loss	$ (26,004)	$ (29,889)	$ (28,182)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Depreciation and amortization	466	439	374
(Gain) loss on investment activities	261	(51)	309
Gain on disposition of property and equipment	4		
Acquired research and development	759	3,873	
Non-cash compensation related to stock options	409	296	318
Changes in operating assets and liabilities:			
Prepaid expenses, receivables and other current assets	254	(166)	(291)
Accounts payable	(816)	(675)	1,007
Accrued clinical trials and other liabilities	755	(265)	(826)
Deferred contract revenue			(2,000)
Net cash used in operating activities	(23,912)	(26,438)	(29,291)
Cash flows from investing activities:			
Purchases of property and equipment, net	(725)	(248)	(778)
Investment in other companies		91	
Purchases of marketable securities	(12,098)	(47,660)	(25,114)
Proceeds from maturities of marketable securities	20,800	64,819	43,718
Proceeds from sales of marketable securities		9,000	12,852
Net cash provided by investing activities	7,977	26,002	30,678
Cash flows from financing activities:			
Issuance of common stock, net	14,566	113	(4)
Net cash (used in) provided by financing activities	14,566	113	(4)
Net increase (decrease) in cash and cash equivalents	(1,369)	(323)	1,383
Cash and cash equivalents at beginning of year	6,832	7,155	5,772
Cash and cash equivalents at end of year	5,463	6,832	7,155
Marketable securities at end of year	30,859	39,723	66,295
Cash, cash equivalents and marketable securities at end of year	$ 36,322	$ 46,555	$ 73,450
Schedule of non-cash transaction:			
Issuance of common stock to acquire technologies, net	$ 367	$ 3,538	$

See accompanying notes.

TITAN PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Summary of Significant Accounting Policies

The Company and its Subsidiaries

We are a biopharmaceutical company developing proprietary therapeutics for the treatment of central nervous system (CNS) disorders, cardiovascular disease and cancer. Our product development programs focus on large pharmaceutical markets with significant unmet medical needs and commercial potential. We are directly developing our product candidates and also utilizing strategic partnerships, including a collaboration with Schering AG, Germany (Schering). These collaborations help fund product development and enable us to retain significant economic interest in our products. Some of our preclinical product development work is conducted through our two consolidated subsidiaries: Ingenex, Inc., and ProNeura, Inc. At December 31, 2004, we owned 81% of Ingenex, assuming the conversion of all preferred stock to common stock, and 89% of ProNeura. In the fourth quarter of 2003, we acquired 3,5-diiodothyropropionic acid (DITPA), a novel product in clinical testing, for the treatment of congestive heart failure (CHF) through the acquisition of Developmental Therapeutics, Inc. (DTI), a private company established to develop DITPA. We operate in one business segment, the development of pharmaceutical products.

Basis of Presentation and Consolidation

The accompanying consolidated financial statements include the accounts of Titan and our wholly and majority owned subsidiaries. All significant intercompany balances and transactions are eliminated.

Reclassifications

Certain prior year balances have been reclassified to conform to the current year presentation. These reclassifications have no impact on the results of operations.

Use of Estimates

The preparation of 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 the financial statements and accompanying notes. Actual results could differ from those estimates.

Stock Option Plans

We have elected to continue to follow Accounting Principles Board Opinion No. 25 (or APB 25), *Accounting for Stock Issued to Employees,* rather than the alternative method of accounting prescribed by Statement of Financial Accounting Standards No. 123 (or SFAS 123), *Accounting for Stock-Based Compensation.* Under APB 25, no compensation expense is recognized when the exercise price of our

employee stock options equals the market price of the underlying stock on the date of grant. The following table illustrates the effect on our net loss and net loss per share if we had applied the provisions of SFAS 123 to estimate and recognize compensation expense for our stock-based employee compensation.

	Year Ended December 31,		
	2004	2003	2002
Net loss, as reported	$ (26,004)	$ (29,889)	$ (28,182)
Add: Stock-based employee compensation expense included in reported net loss	268	296	318
Deduct: Stock-based employee compensation expense determined under fair value method for all stock option grants	(1,390)	(2,319)	(8,489)
Pro forma net loss	$ (27,126)	$ (31,912)	$ (36,353)
Basic and diluted net loss per share, as reported	$ (0.83)	$ (1.07)	$ (1.02)
Pro forma basic and diluted net loss per share	$ (0.86)	$ (1.14)	$ (1.32)

Cash, Cash Equivalents and Marketable Securities

Our cash and investment policy emphasizes liquidity and preservation of principal over other portfolio considerations. We select investments that maximize interest income to the extent possible given these two constraints. We satisfy liquidity requirements by investing excess cash in securities with different maturities to match projected cash needs and limit concentration of credit risk by diversifying our investments among a variety of high credit-quality issuers and limit the amount of credit exposure to any one issuer. The estimated fair values have been determined using available market information. We do not use derivative financial instruments in our investment portfolio.

All investments with original maturities of three months or less are considered to be cash equivalents. Our marketable securities, consisting primarily of high-grade debt securities including money market funds, U.S. government and corporate notes and bonds, and commercial paper, are classified as available-for-sale at time of purchase and carried at fair value. If the fair value of a security is below its amortized cost for six consecutive months or if its decline is due to a significant adverse event, the impairment is considered to be other-than-temporary. Other-than-temporary declines in fair value of our marketable securities are charged against interest income. We recognized expenses of approximately $102,000 in 2004, $40,000 in 2003, and $9,000 in 2002 as a result of charges related to other-than-temporary declines in the fair values of certain of our marketable securities. Amortization of premiums and discounts, and realized gains and losses are included in interest income. Unrealized gains and losses are included as accumulated other comprehensive income, a separate component of stockholders equity. The cost of securities sold is based on use of the specific identification method.

Property and Equipment

Property and equipment are recorded at cost and depreciated using the straight-line method over the estimated useful lives of the assets ranging from three to five years. Leasehold improvements are amortized over the shorter of the lease term or the estimated useful life of the assets.

Investment in Other Companies

We have invested in equity instruments of privately held companies for business and strategic purposes. These investments are classified as long-term assets and are accounted for under the cost method as we do not have the ability to exercise significant influence over their operations. We monitor our investments for impairment and record reductions in carrying value when events or changes in circumstances indicate that the carrying value may not be recoverable. Determination of impairment is based on a number of factors, including an assessment of the strength of investee s management, the length

of time and extent to which the fair value has been less than our cost basis, the financial condition and near-term prospects of the investee, fundamental changes to the business prospects of the investee, share prices of subsequent offerings, and our intent and ability to hold the investment for a period of time sufficient to allow for any anticipated recovery in our carrying value.

In July 2001, we made a $300,000 equity investment in Altagen Biosciences Inc. (formerly CSS Acquisition Corporation) for 300 shares of Series D Preferred stock, representing 2.5% of total equity in the company. In December 2001, we made a $300,000 equity investment in Molecular Medicine BioServices, Inc. for 714,286 shares of Series A Preferred stock, and at December 31, 2004, these shares represent 4.6% of total equity in the company. In June 2002, we recorded a $300,000 reduction in the carrying value of our investment in Altagen, and in July 2003, we returned the 300 shares of Series D Preferred stock to Altagen in settlement of outstanding liabilities and recorded a gain on investment of approximately $90,000. In September 2004, we recorded a $150,000 reduction in the carrying value of our investment in Molecular Medicine BioServices, Inc., and included the loss in other income (expense).

Revenue Recognition

We generate revenue principally from collaborative research and development arrangements, technology licenses, and government grants. Revenue arrangements with multiple components are divided into separate units of accounting if certain criteria are met, including whether the delivered component has stand-alone value to the customer, and whether there is objective and reliable evidence of the fair value of the undelivered items. Consideration received is allocated among the separate units of accounting based on their respective fair values, and the applicable revenue recognition criteria are then applied to each of the units.

Revenue is recognized when the four basic criteria of revenue recognition are met: (1) a contractual agreement exists; (2) transfer of technology has been completed or services have been rendered; (3) the fee is fixed or determinable; and (4) collectibility is reasonably assured. For each source of revenue, we comply with the above revenue recognition criteria in the following manner:

- Collaborative arrangements typically consist of non-refundable and/or exclusive technology access fees, cost reimbursements for specific research and development spending, and various milestone and future product royalty payments. If the delivered technology does not have stand-alone value or if we do not have objective or reliable evidence of the fair value of the undelivered component, the amount of revenue allocable to the delivered technology is deferred. Non-refundable upfront fees with stand-alone value that are not dependent on future performance under these agreements are recognized as revenue when received, and are deferred if we have continuing performance obligations and have no evidence of fair value of those obligations. Cost reimbursements for research and development spending are recognized when the related costs are incurred and when reimbursements are received. Payments received related to substantive, performance-based at-risk milestones are recognized as revenue upon achievement of the clinical success or regulatory event specified in the underlying contracts, which represent the culmination of the earnings process. Amounts received in advance are recorded as deferred revenue until the technology is transferred, costs are incurred, or milestone is reached.

- Technology license agreements typically consist of non-refundable upfront license fees, annual minimum access fees or royalty payments. Non-refundable upfront license fees and annual minimum payments received with separable stand-alone values are recognized when the technology is transferred or accessed, provided that the technology transferred or accessed is not dependent on the outcome of our continuing research and development efforts.

- Government grants, which support our research efforts in specific projects, generally provide for reimbursement of approved costs as defined in the notices of grants. Grant revenue is recognized when associated project costs are incurred.

Research and Development Costs

Research and development expenses include internal and external costs. Internal costs include salaries and employment related expenses, facility costs, administrative expenses and allocations of corporate costs. External expenses consist of costs associated with outsourced clinical research organization activities, sponsored research studies, product registration, patent application and prosecution, and investigator sponsored trials. In accordance with SFAS No. 2, *Accounting for Research and Development Costs*, all such costs are charged to expense as incurred.

Net Loss Per Share

We calculate basic net loss per share using the weighted average common shares outstanding for the period. Diluted net income per share would include the impact of other dilutive equity instruments, primarily our preferred stock, options and warrants. For the years ended December 31, 2004, 2003, and 2002, outstanding preferred stock, options and warrants totaled 6.7 million, 6.1 million, and 6.4 million shares, respectively. We reported net losses for all years presented and, therefore, preferred stock, options and warrants were excluded from the calculation of diluted net loss per share as they were anti-dilutive.

Comprehensive Income

Comprehensive income is comprised of net loss and other comprehensive income. The only component of other comprehensive income is unrealized gains and losses on our marketable securities. Comprehensive loss for the years ended December 31, 2004, 2003, and 2002 was $26.1 million, $30.3 million, and $29.7 million, respectively. Comprehensive loss has been disclosed in the Statement of Stockholders Equity for all periods presented.

Recent Accounting Pronouncements

In December 2004, the Financial Accounting Standards Board (FASB) issued their final standard on accounting for share-based payments in FASB Standard No. 123R (revised 2004), *Share-Based Payment* (FAS 123R). This statement replaces FASB Statement 123, *Accounting for Stock-Based Compensation*, and supersedes Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees*. The statement is effective for all interim and annual periods beginning after June 15, 2005 and requires companies to measure and recognize compensation expense for all stock-based payments at fair value. Stock-based payments include stock option grants under Company stock plans. The adoption of FAS 123R could materially impact our results of operations.

2. Cash, Cash Equivalents and Marketable Securities

The following is a summary of our cash, cash equivalents and marketable securities at December 31, 2004 and 2003 (in thousands):

	2004				2003			
Classified as:	**Amortized Cost**	**Gross Unrealized Gain**	**Gross Unrealized (Loss)**	**Fair Value**	**Amortized Cost**	**Gross Unrealized Gain**	**Gross Unrealized (Loss)**	**Fair Value**
Cash	$ 458	$	$	$ 458	$ 253	$	$	$ 253
Cash equivalents:								
Money market funds	5,005			5,005	5,082			5,082
Commercial paper					1,497			1,497
Total cash equivalents	5,005			5,005	6,579			6,579
Marketable securities:								
Securities of the U.S. government and its agencies	29,910	3	(54)	29,859	33,178	47	(17)	33,208
Corporate notes and bonds					4,246	9	(38)	4,217
Commercial paper	1,000			1,000	2,299		(1)	2,298
Total marketable securities	30,910			30,859	39,723	56	(56)	39,723
Total cash, cash equivalents and marketable securities	$ 36,373	$ 3	$ (54)	$ 36,322	$ 46,555	$ 56	$ (56)	$ 46,555
Securities available-for-sale:								
Maturing within 1 year	$ 31,909			$ 31,869	$ 30,353			$ 30,353
Maturing between 1 to 2 years	$ 4,000			$ 3,995	$ 15,949			$ 15,949

There were no material gross realized gains or losses on sales of marketable securities for the year ended December 31, 2004. For the year ended December 31, 2003, there were no gross realized gains and $17,000 of gross realized losses. For the year ended December 31, 2002, there were $119,000 of gross realized gains and $3,000 of gross realized losses.

The aggregate amount of unrealized losses and the related fair value of investments with unrealized losses at December 31, 2004 were approximately $54,000 and $23.1 million, respectively. The unrealized losses were caused by fluctuation in market interest rates and are not considered other-than-temporary until a continuous decline has occurred.

We recorded charges totaling $51,000 related to other than temporary impairments of debt and equity securities for the year ended December 31, 2004.

3. Property and Equipment

Property and equipment consisted of the following at December 31 (in thousands):

	2004	2003
Furniture and office equipment	$ 540	$ 530
Leasehold improvements	413	368
Laboratory equipment	935	428
Computer equipment	871	810
	2,759	2,136
Less accumulated depreciation and amortization	(1,715)	(1,347)
Property and equipment, net	$ 1,044	$ 789

Depreciation and amortization expense was $466,000, $436,000, and $374,000 for the years ended December 31, 2004, 2003, and 2002, respectively.

4. Research and License Agreements

We have entered into various agreements with research institutions, universities, clinical research organizations and other entities for the performance of research and development activities and for the acquisition of licenses related to those activities. Expenses under these agreements totaled $3.5 million, $2.6 million, and $1.3 million in the years ended December 31, 2004, 2003, and 2002, respectively.

At December 31, 2004, the annual aggregate commitments we have under these agreements, including minimum license payments, are as follows (in thousands):

2005	$ 753
2006	324
2007	329
2008	334
2009	334
	$ 2,074

After 2009, we must make annual payments aggregating $334,000 per year to maintain certain licenses. Certain licenses provide for the payment of royalties by us on future product sales, if any. In addition, in order to maintain these licenses and other rights during product development, we must comply with various conditions including the payment of patent related costs and obtaining additional equity investments.

5. Agreement with Aventis SA

In 1997, we entered into an exclusive license agreement with Aventis SA (formerly Hoechst Marion Roussel, Inc.). The agreement gave us a worldwide license to the patent rights and know-how related to the antipsychotic agent iloperidone, including the ability to develop, use, sublicense, manufacture and sell products and processes claimed in the patent rights. We are required to make additional benchmark payments as specific milestones are met. Upon commercialization of the product, the license agreement provides that we will pay royalties based on net sales.

6. Iloperidone Sublicense to Novartis Pharma AG

We entered into an agreement with Novartis Pharma AG (Novartis) in 1997 pursuant to which we granted Novartis a sublicense for the worldwide (with the exception of Japan) development, manufacturing and marketing of iloperidone. In April 2001, we entered into an amendment to the agreement for the development and commercialization of iloperidone in Japan. Under the amendment, in exchange for rights to iloperidone in Japan, we received a $2.5 million license fee in May 2001. Novartis will make our milestone payments to Aventis during the life of the Novartis agreement, and will also pay to Aventis and us a royalty on future net sales of the product, providing us with a net royalty of 8% on the first $200 million of sales annually and 10% on all sales above $200 million on an annual basis. Novartis has assumed the responsibility for all clinical development, registration, manufacturing and marketing of iloperidone, and we have no remaining obligations under the terms of this agreement, except for maintaining certain usual and customary requirements, such as confidentiality covenants.

In June 2004, we announced that Vanda Pharmaceuticals, Inc. (Vanda) had acquired from Novartis the worldwide rights to develop and commercialize iloperidone, our proprietary antipsychotic agent in Phase III clinical development for the treatment of schizophrenia and related psychotic disorders. Under its agreement with Novartis, Vanda will pursue advancement of 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.

7. Licensing and Collaborative Agreement with Schering AG

In January 2000, we entered into a licensing and collaborative agreement with Schering, under which we will collaborate with Schering on manufacturing and clinical development of our cell therapy product, Spheramine®, for the treatment of Parkinson s disease. Under the agreement, we will perform clinical development activities for which we will receive funding. As of December 31, 2004, we have recognized $2.8 million under this agreement. In February 2002, we announced that we received a $2.0 million milestone payment from Schering. The milestone payment followed Schering s decision in the first quarter 2002 to initiate larger, randomized clinical testing of Spheramine for the treatment of patients with advanced Parkinson s disease following the successful completion of our Phase I/II clinical study of Spheramine. As a result, we recognized $2.0 million in contract revenue in the first quarter of 2002. Schering will fully fund, and manage in collaboration with us, all future pilot and pivotal clinical studies, and manufacturing and development activities. We are entitled to receive up to an aggregate of $8 million over the life of the Schering agreement upon the achievement of specific milestones.

8. DITPA Acquisition

On October 16, 2003, we announced the acquisition of a novel product in clinical testing for the treatment of congestive heart failure (CHF). The product in development, 3,5-diiodothyropropionic acid (DITPA), is an orally active analogue of thyroid hormone that has demonstrated in preclinical and clinical studies to date the ability to improve cardiac function, with no significant adverse effects. We acquired DITPA through the acquisition of Developmental Therapeutics, Inc. (DTI), a private company established to develop DITPA, and the exclusive licensee of recently issued U.S. patent and pending U.S. and international patent applications covering DITPA. We acquired DTI in a stock transaction for 1,187,500 shares of our common stock valued at approximately $3.6 million using the average market price of our common stock over the five-day trading period, including and prior to the date of the merger in accordance with generally accepted accounting principles. We also made a cash payment of $171,250 to the licensor of the technology. In the fourth quarter of 2003, the total acquisition cost of $3.9 million was reported as acquired research and development in the statement of operations. An additional payment of 712,500 shares of our common stock will be made only upon the achievement of positive pivotal study results or certain other substantial milestones within five years. In addition, a cash payment of $102,750 or, alternatively, an additional payment of 37,500 shares of our common stock, will be made to the licensor of the technology upon achievement of such study results or such other substantial milestones within five years.

9. Commitments and Contingencies

Lease Commitments

We lease facilities under operating leases that expire at various dates through June 2010. We also lease certain office equipment under operating and capital leases that expire at various dates through July 2008. Rental expense was $832,000, $825,000, and $765,000 for years ended December 31, 2004, 2003, and 2002, respectively.

The following is a schedule of future minimum lease payments at December 31, 2004 (in thousands):

2005	$ 893
2006	764
2007	567
2008	573
2009	584
Thereafter	295
	$ 3,676

Legal Proceedings

On November 4, 2003, a purported class action suit entitled *Patrick Magee v. Titan Pharmaceuticals, Inc., et al* was filed in the United States District Court for the Northern District of California on behalf of purchasers of Titan s common stock during the period between December 1, 1999 and July 22, 2002. Subsequently, several similar actions were filed in the same court. The complaints alleged that Titan and certain of its executive officers violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 by issuing false and misleading statements that failed to disclose certain key information regarding iloperidone. The complaints sought unspecified damages.

On November 6, 2003, a stockholder purporting to act on our behalf filed a derivative action in the California Superior Court for the County of San Mateo against Titan s executive officers and directors and certain former directors seeking unspecified damages, injunctive relief and restitution. Titan was also named as a nominal defendant. The derivative action is based on the same factual allegations as the purported class actions and alleges state law claims for breach of fiduciary duty, abuse of control, gross mismanagement, waste of corporate assets and unjust enrichment.

On February 2, 2004, we announced that all of the class action and derivative lawsuits filed against the Company had been dismissed without prejudice. In every case, the plaintiffs agreed to voluntarily dismiss the lawsuits after discussion of the facts with Titan s counsel, without any further legal action necessary by Titan. Titan, its affiliates, and insurers made no payment in connection with dismissal of the lawsuits, and have no obligation to make any payments whatsoever to any plaintiffs or their counsel in connection with the dismissals. Furthermore, Titan has no other obligations in connection with the dismissals.

10. Guarantees and Indemnifications

As permitted under Delaware law and in accordance with our Bylaws, we indemnify our officers and directors for certain events or occurrences while the officer or director is or was serving at the Company s request in such capacity. The term of the indemnification period is for the officer s or director s lifetime. The maximum amount of potential future indemnification is unlimited; however, we have a director and officer insurance policy that limits our exposure and may enable us to recover a portion of any future amounts paid. We believe the fair value of these indemnification agreements is minimal. Accordingly, we have not recorded any liabilities for these agreements as of December 31, 2004.

In the normal course of business, we have commitments to make certain milestone payments to various clinical research organizations in connection with our clinical trial activities. Payments are contingent upon the achievement of specific milestones or events as defined in the agreements, and we have made appropriate accruals in our consolidated financial statements for those milestones that were achieved as of December 31, 2004. We also provide indemnifications of varying scope to our clinical research organizations and investigators against claims made by third parties arising from the use of our products and processes in clinical trials. Historically, costs related to these indemnification provisions were immaterial. We also maintain various liability insurance policies that limit our exposure. We are unable to estimate the maximum potential impact of these indemnification provisions on our future results of operations.

11. Stockholders Equity

Preferred Stock

In connection with the merger of our Trilex Pharmaceuticals, Inc. subsidiary (Trilex) in 1997, we issued 222,400 shares of Series C convertible preferred stock (the Series C Preferred) to certain members of the Trilex management team and to certain consultants of Trilex. The Series C Preferred automatically converts to our common stock, on a one-to-one basis, only if certain development milestones are achieved within a certain timeframe. Upon achievement of the milestones, we would be required to value the

technology using the then fair market value of our common stock issuable upon conversion. Certain milestones were not achieved by October 6, 2004. Therefore, we have the right to redeem all, but not less than all, of the outstanding shares of Series C Preferred Stock at a redemption price equal to the aggregate par value of the shares plus accrued and unpaid dividends, if any. Holders of Series C Preferred are not entitled to vote but are entitled to receive dividends, when, as and if declared by the Board of Directors ratably with any declaration or payment of any dividend on our common stock or other junior securities. The Series C Preferred has a liquidation preference equal to $0.01 per share. No value was assigned to the Series C Preferred in the accompanying financial statements. There were no accrued and unpaid dividends outstanding as of December 31, 2004.

Common Stock

In October 2004, we issued 149,599 shares of our common stock in exchange for 101,700 shares of ProNeura, Inc. (ProNeura) common stock under a share exchange agreement with two of the three minority shareholders of ProNeura. Our common stock was valued at $367,000 using the average market price of our common stock over a five day trading period, including two days prior to and subsequent to the date of issuance.

In February 2004, we filed a shelf registration statement with the Securities and Exchange Commission to sell up to $50 million of common or preferred stock. Under this registration statement, shares may be sold periodically to provide additional funds for our operations. In March 2004, we completed a sale of 3,075,000 shares of our common stock offered under the registration statement at a price of $5.00 per share, for gross proceeds of approximately $15.4 million. Net proceeds were approximately $14.4 million.

In October 2003, we acquired DITPA through the acquisition of Developmental Therapeutics, Inc. (DTI) in a stock transaction for 1,187,500 shares of our common stock valued at approximately $3.6 million using the average market price of our common stock over the five-day trading period, including and prior to the date of the merger. In addition, up to a total of 750,000 shares of common stock will be issued only upon the achievement of positive pivotal study results or certain other substantial milestones within five years.

Shares Reserved for Future Issuance

As of December 31, 2004, shares of common stock reserved by us for future issuance consisted of the following (shares in thousands):

Stock options	7,910
Preferred stock	222
DTI merger contingent shares	750
	8,882

12. Stock Option Plans

In July 2002, we adopted the 2002 Stock Option Plan (2002 Plan). The 2002 Plan assumed the options which remain available for grant under our option plans previously approved by stockholders. Under the 2002 Plan and predecessor plans, a total of 6.4 million shares of our common stock were authorized for issuance to employees, officers, directors, consultants, and advisers. Options granted under the 2002 Plan and predecessor plans may either be incentive stock options within the meaning of Section 422 of the Internal Revenue Code and/or options that do not qualify as incentive stock options; however, only employees are eligible to receive incentive stock options. Options granted under the option plans generally expire no later than ten years from the date of grant, except when the grantee is a 10% shareholder, in

which case the maximum term is five years from the date of grant. Options generally vest at the rate of one fourth after one year from the date of grant and the remainder ratably over the subsequent three years, although options with different vesting terms are granted from time-to-time. Generally, the exercise price of any options granted under the 2002 Plan must be at least 100% of the fair market value of our common stock on the date of grant, except when the grantee is a 10% shareholder, in which case the exercise price shall be at least 110% of the fair market value of our common stock on the date of grant.

In July 2002, our Board of Directors elected to continue the option grant practice under our amended 1998 Option Plan, which provided for the automatic grant of non-qualified stock options (Directors Options) to our directors who are not 10% stockholders (Eligible Directors). Each Eligible Director will be granted an option to purchase 10,000 shares of common stock on the date that such person is first elected or appointed a director. Commencing on the day immediately following the later of (i) the 2000 annual stockholders meeting, or (ii) the first annual meeting of stockholders after their election to the Board, each Eligible Director will receive an automatic biennial (i.e. every two years) grant of an option to purchase 15,000 shares of common stock as long as such director is a member of the Board of Directors. In addition, each Eligible Director will receive an automatic annual grant of an option to purchase 5,000 shares of common stock for each committee of the Board on which they serve. The exercise price of the Director s Options shall be equal to the fair market value of our common stock on the date of grant.

In August 2001, we adopted the 2001 Employee Non-Qualified Stock Option Plan (2001 NQ Plan) pursuant to which 1,750,000 shares of common stock were authorized for issuance for option grants to employees and consultants who are not officers or directors of Titan. Options granted under the option plans generally expire no later than ten years from the date of grant. Option vesting schedule and exercise price are determined at time of grant by the Board of Directors. Historically, the exercise prices of options granted under the 2001 NQ Plan were 100% of the fair market value of our common stock on the date of grant.

Activity under our stock option plans, as well as non-plan activity are summarized below (shares in thousands):

	Shares Available For Grant	Number of Options Outstanding	Weighted Average Exercise Price
Balance at December 31, 2001	1,291	4,128	$ 13.20
Increase in shares reserved	2,750		
Options granted	(2,200)	2,200	$ 4.44
Options exercised			
Options cancelled	132	(138)	$ 15.31
Balance at December 31, 2002	1,973	6,190	$ 10.05
Options granted	(699)	699	$ 1.83
Options exercised		(73)	$ 1.57
Options cancelled	864	(864)	$ 8.67
Balance at December 31, 2003	2,138	5,952	$ 9.39
Options granted	(1,407)	1,407	$ 2.90
Options exercised		(180)	$ 1.17
Options cancelled	734	(734)	$ 7.81
Balance at December 31, 2004	1,465	6,445	$ 8.39

Our option plans allow for stock options issued as the result of a merger or consolidation of another entity, including the acquisition of minority interest of our subsidiaries, to be added to the maximum number of shares provided for in the plan (Substitute Options). Consequently, Substitute Options are not

returned to the shares reserved under the plan when cancelled. During 2004, 2003 and 2002, the number of Substitute Options cancelled was immaterial.

Options for 5.0 million and 3.9 million shares were exercisable at December 31, 2004 and 2003, respectively. The options outstanding at December 31, 2004 have been segregated into three ranges for additional disclosure as follows (option shares in thousands):

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Life (Years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$0.08 - $3.38	2,157	7.92	$ 2.13	1,085	$ 1.83
$3.43 - $8.77	2,344	5.35	$ 6.32	2,010	$ 6.66
$9.06 - $46.50	1,944	5.61	$ 17.82	1,944	$ 17.82
$0.08 - $46.50	6,445	6.29	$ 8.39	5,039	$ 9.92

In addition, Ingenex has a stock option plan under which options to purchase common stock of Ingenex have been and may be granted. No options have been granted under such plan since 1997.

We have elected to continue to follow APB 25 in accounting for our stock options. Under APB 25, no compensation expense is recognized when the exercise price of our stock options equals the market price of the underlying stock on the date of grant.

Pro forma net loss and net loss per share information required by SFAS 123 as amended by SFAS 148 has been determined as if we had accounted for our employee stock options under the fair value method of SFAS 123. The fair value for these options was estimated at the date of grant using a Black-Scholes option pricing model with the following assumptions for 2004, 2003, and 2002: weighted-average volatility factor of 0.70, 0.70, and 0.79, respectively; no expected dividend payments; weighted-average risk-free interest rates in effect of 3.0%, 2.2%, and 2.4%, respectively; and a weighted-average expected life of 3.97, 3.01, and 3.54 years, respectively. For purposes of disclosure, the estimated fair value of options is amortized to expense over the options vesting period.

The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options that have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions including the expected stock price volatility. Because our employee stock options have characteristics significantly different from those of traded options, and because changes in the subjective input assumptions can materially affect the fair value estimate, in management s opinion, the existing models do not necessarily provide a reliable single measure of the fair value of our employee stock options.

Based upon the above methodology, the weighted-average fair value of options granted during the years ended December 31, 2004, 2003, and 2002 was $1.65, $0.89, and $2.32, respectively. A tabular presentation of pro forma net loss and net loss per share information for all reporting periods is presented in Note 1.

13. Minority Interest

The $1.2 million received by Ingenex upon the issuance of its Series B convertible preferred stock has been classified as minority interest in the consolidated balance sheet. As a result of the Series B preferred stockholders liquidation preference, the balance has not been reduced by any portion of the losses of Ingenex.

Amounts invested by outside investors in the common stock of the consolidated subsidiaries have been apportioned between minority interest and additional paid-in capital in the consolidated balance

sheets. Losses applicable to the minority interest holdings of the subsidiaries common stock have been reduced to zero.

14. Related Party Transactions

We make loans to our employees from time to time in order to attract and retain the best available talent and to encourage the highest level of performance. At December 31, 2004 and 2003, such receivables were $18,000 and $123,000, respectively.

15. Income Taxes

As of December 31, 2004, we had net operating loss carryforwards for federal income tax purposes of approximately $184.2 million that expire at various dates through 2024, and federal research and development tax credits of approximately $5.3 million that expire at various dates through 2024. We also had net operating loss carryforwards for state income tax purposes of approximately $58.9 million that expire at various dates through 2014, and state research and development tax credits of approximately $4.0 million which do not expire.

Utilization of our net operating loss may be subject to substantial annual limitation due to ownership change limitations provided by the Internal Revenue Code and similar state provisions. Such an annual limitation could result in the expiration of the net operating loss carryforwards before utilization.

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of our deferred tax assets are as follows (in thousands):

	December 31,	
	2004	2003
Deferred tax assets:		
Net operating loss carryforwards	$ 66,070	$ 59,000
Research credit carryforwards	9,344	6,400
Other, net	1,732	4,200
Total deferred tax assets	77,146	69,600
Deferred tax liabilities:		
Unrealized gain on investments		(50)
Valuation allowance	(77,146)	(69,550)
Net deferred tax assets	$	$

Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by $7.6 million, $17.6 million, and $11.1 million during 2004, 2003, and 2002, respectively. The valuation allowance at December 31, 2004 includes $4.0 million related to deferred tax assets arising from tax benefits associated with stock option plans. This benefit, when realized, will be recorded as an increase to stockholders equity.

16. Quarterly Financial Data (Unaudited)

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
	(in thousands, except per share amount)			
2004				
Total revenue	$ 1			$ 30
Net loss	$ (6,381)	$ (5,555)	$ (6,270)	$ (7,798)
Basic and diluted net loss per share	$ (0.22)	$ (0.17)	$ (0.20)	$ (0.24)
2003				
Total revenue	$ 26	$ 2		$ 61
Net loss	$ (6,530)	$ (6,681)	$ (6,169)	$ (10,509)
Basic and diluted net loss per share	$ (0.24)	$ (0.24)	$ (0.22)	$ (0.37)

SIGNATURES

Pursuant to the requirements of Section 13 of the Securities and Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

TITAN PHARMACEUTICALS, INC.

Date: March 15, 2005 By: /s/ LOUIS R. BUCALO
Louis R. Bucalo, M.D.,
Chairman, President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons in the capacities and on the dates stated.

Signature	Title	Date
/s/ LOUIS R. BUCALO Louis R. Bucalo, M.D.	Chairman, President and Chief Executive Officer (principal executive officer)	March 15, 2005
/s/ ERNST-GüNTER AFTING Ernst-Günter Afting, M.D., Ph.D.	Director	March 15, 2005
/s/ VICTOR J. BAUER Victor J. Bauer, Ph.D.	Director	March 15, 2005
/s/ SUNIL BHONSLE Sunil Bhonsle	Executive Vice President, Chief Operating Officer and Director	March 15, 2005
/s/ EURELIO M. CAVALIER Eurelio M. Cavalier	Director	March 15, 2005
/s/ HUBERT E. HUCKEL Hubert E. Huckel, M.D.	Director	March 15, 2005
/s/ M. DAVID MACFARLNE M. David MacFarlane, Ph.D.	Director	March 15, 2005
/s/ LEY S. SMITH Ley S. Smith	Director	March 15, 2005
/s/ KONRAD M. WEIS Konrad M. Weis, Ph.D.	Director	March 15, 2005
/s/ ROBERT E. FARRELL Robert E. Farrell, J.D.	Executive Vice President and Chief Financial Officer (principal financial and accounting officer)	March 15, 2005