# 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

■ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2003

or

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) 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

(State or other jurisdiction of incorporation or organization)

94-3171940

(I.R.S. Employer identification number)

400 Oyster Point Blvd., Suite 505, South San Francisco, California 94080

(Zip code)

(Address of principal executive offices)

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

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

Common Stock, \$.001 par value

Title of each class

Name of each exchange on which registered

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  $\blacksquare$  No  $\square$ 

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.  $\square$ 

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Act). Yes 

■ No □

The aggregate market value of the 26,821,434 shares of voting and non-voting common equity held by non-affiliates of the registrant

based on the closing price on June 30, 2003 was \$63.6 million.

As of March 5, 2004, 29,012,264 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.

Spheramine®, Pivanex®, Probuphine®, CeaVac®, TriAb®, TriGem<sup>TM</sup> and CCM<sup>TM</sup> are trademarks of Titan Pharmaceuticals, Inc. This Form 10-K also includes 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, cancer, and cardiovascular disease. Our product development programs focus on large pharmaceutical markets with significant unmet medical needs and commercial potential. Our internal resources are focused primarily on clinical development of the following five products:

- Spheramine: for the treatment of late stage Parkinson's disease
- Pivanex: for the treatment of non-small cell lung cancer
- Gallium maltolate: for the treatment of several cancers and bone related disease associated with cancer
- Probuphine: for the treatment of opiate addiction
- DITPA: for the treatment of congestive heart failure

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. Spheramine development is primarily funded by our corporate partner for Spheramine, Schering. Following the announcement of clinical study results in mid 2002, Novartis is considering alternatives for the iloperidone program for the treatment of schizophrenia, including sub-licensing the product to another company for further development, or returning product rights to Titan. Titan is no longer directly pursuing development of the monoclonal antibodies—CeaVac, TriAb, and TriGem—for the treatment of various cancers, and remaining clinical studies are externally funded collaborations with co-operative groups.

Titan was incorporated in Delaware in February 1992 and has 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.

Some of our preclinical product development work is conducted through our two consolidated subsidiaries: Ingenex, Inc., and ProNeura, Inc. References to us and our products throughout this document include the products under development by the two subsidiaries.

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### (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

Spheramine	Parkinson's disease	Phase IIb	Schering AG
Pivanex	Non-small cell lung cancer	Phase IIb	Titan
Gallium maltolate	Several cancers and bone disease associated with cancer	Phase I/II	Titan
Probuphine	Opiate addiction	Phase I/II	Titan
DITPA	Congestive heart failure	Phase II	Titan
Iloperidone	Schizophrenia, psychosis	Phase III*	Novartis
_			Pharma AG

<sup>\*</sup> Further development under review.

#### **Spheramine**

Spheramine is a cell-based therapeutic being developed for potential treatment of 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 L-dopa-producing 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 late-stage 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 later-stage Parkinson's disease (Hoehn and Yahr Stages III and IV) to further evaluate the efficacy, safety, and tolerability of Spheramine. Enrollment is proceeding on schedule, and we estimate that this Phase IIb study will be completed in the second half of 2005. Schering, Titan's corporate partner for worldwide development and commercialization of Spheramine, is fully 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 February 2002, Titan announced the receipt of a \$2 million milestone payment from Schering following the successful completion of Titan's Phase I/II clinical study of Spheramine, and the decision by

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Schering to initiate larger, randomized clinical testing of Spheramine for the treatment of late-stage Parkinson's disease.

### 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. In May 2002, we presented data from a Phase II clinical study at the American Society of Clinical Oncology Annual Meeting showing that Pivanex demonstrated clinical benefit and showed promise for treatment of refractory non-small cell lung cancer (NSCLC). In that multicenter, open-label study, 47 patients with advanced NSCLC who had failed prior chemotherapy were treated with Pivanex. Results showed disease stabilization of 12 weeks or more in 30% of patients and responses in 3 patients. In 29 patients whose cancer had progressed after one or two prior chemotherapy regimens, one-year survival was 47% and median survival was 7.9 months. This compares well to historical data with the approved agent in this setting, docetaxel, in similar patient groups, where one-year survival was 37% and median survival was approximately 7.5 months. In addition, patients treated with Pivanex in this preliminary Phase II study showed decreased pleural effusions, weight gain, decreased cough and resolution of hemoptysis. Pivanex was well tolerated, without severe side effects such as nausea, vomiting and decreased blood cells seen with many current cancer treatments.

In January 2003, we initiated 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 10<sup>th</sup> World Conference on Lung Cancer in Vancouver.

In June 2003, we announced the initiation of a multicenter, randomized, controlled Phase IIb clinical trial with Pivanex in the treatment of advanced non-small cell lung cancer. The study will evaluate the safety and efficacy of Pivanex plus docetaxel, versus docetaxel alone. This 225 patient study is expected to be completed by the end of 2004.

In July 2003, we announced new preclinical study results further demonstrating that Pivanex, combined with docetaxel, significantly increased anti-tumor activity in non-small cell lung cancer cells. The new data, presented at the 94<sup>th</sup> annual meeting of the American Association for Cancer Research, confirmed results of previous studies that have shown Pivanex demonstrates significant anti-cancer activity, and is synergistic in combination with several current chemotherapy agents.

In November 2003, we announced additional new preclinical study results demonstrating that Pivanex inhibits key enzymes and related

cancer promoting genes in lung cancer cells. The data were presented in Boston at the AACR-NCI-EORTC Conference on Molecular Targets and Cancer Therapeutics.

#### Gallium Maltolate

Gallium maltolate is an orally administered form of gallium, a semi-metallic element. 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 IV 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. Gallium maltolate has two distinct potential mechanisms of action: directly targeting and killing cancer cells, and protecting bone

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from the effects of tumor metastasis. A key enzyme essential for DNA replication in cancer cells is ribonucleotide reductase, which is active when bound to ferric iron. Gallium concentrates in tumor tissues and by substituting for ferric iron inhibits the activity of ribonucleotide reductase. This action inhibits DNA synthesis and cancer cell growth.

Gallium maltolate has preliminarily been shown to safely provide sustained blood levels of gallium for the potential treatment of cancer and other diseases. Titan is completing a dose ranging clinical study of gallium maltolate in patients with multiple myeloma, metastatic prostate cancer, metastatic bladder cancer and refractory lymphoma. The maximum tolerated dose level has not yet been reached. Accordingly, additional patient cohorts are being enrolled at higher doses. This Phase I clinical study may be completed in the first half of 2004, establishing a potential dose for the Phase II studies.

In September 2003, we presented favorable results from a pilot study at the 25<sup>th</sup> Annual Meeting of the American Society For Bone and Mineral Research in Minneapolis, Minnesota, demonstrating that oral gallium maltolate can achieve targeted, potentially therapeutic serum levels of gallium in patients with advanced Paget's disease. The clinical trial evaluated the safety of gallium maltolate, and gallium serum levels, after oral administration of one of three doses, 200, 400, or 600 mg, in twelve patients with advanced Paget's disease of bone or primary hyperparathyroidism. Results demonstrated that serum gallium concentrations increased in a linear fashion with increasing doses. A three-fold increase in the oral gallium maltolate dose resulted in approximately a three-fold increase in mean serum gallium levels. Gallium maltolate was well-tolerated and clinically observed adverse events were generally mild in this preliminary study.

### Probuphine / ProNeura Continuous Drug Delivery Technology

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, alcoholism, schizophrenia, depression, and others, in which conventional treatment is limited by variability in blood drug levels and poor patient compliance. The technology consists of a polymeric drug delivery system that potentially can provide controlled drug release on an outpatient basis over extended periods (i.e., from three to six months).

Our first product based upon this delivery system is Probuphine, which is intended to provide therapeutic levels of buprenorphine for the treatment of opiate addiction. Buprenorphine has demonstrated effectiveness in clinical studies as an oral therapy in the treatment of opiate addiction and was recently approved for marketing in the U.S. Our product is implanted subcutaneously and provides systemic delivery of medication as body fluids wash over the implant and the drug is released. This results in a constant rate of release similar to intravenous administration. We believe that such long-term, linear release characteristics are desirable by avoiding peak and trough level dosing that poses problems for many CNS and other therapeutic agents.

In 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 2003, we announced the initiation of a pilot clinical study that will evaluate the safety, pharmacokinetics and preliminary efficacy of Probuphine in up to 18 opiate-dependent patients. In September 2003, we announced positive interim results for the first cohort of six patients in this pilot clinical study. Preliminary data, presented at the International Society of Addiction Medicine in Amsterdam, demonstrated that all six patients treated with Probuphine at the first dose level have been safely switched from daily sublingual buprenorphine therapy to Probuphine, with maintenance of therapeutic benefit and no significant adverse events for up to three and a half months after a single treatment. These six patients, who were taking 8 mg of buprenorphine daily, have been switched to Probuphine, and have not displayed any significant signs of withdrawal or craving. Additional patients

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are now under treatment at the second dose level. This pilot study may be completed in the second half of 2004.

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.

#### DITPA

In October 2003, Titan acquired a novel product in clinical testing for the treatment of congestive heart failure. The product in development, 3,5-diiodothyropropionic acid, or 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. Potential beneficial effects demonstrated in these studies include improved cardiac output, as well as improvement in measures of diastolic function. DITPA has also demonstrated cholesterol and triglyceride lowering capability in pilot clinical testing.

Titan plans to develop DITPA as a potential treatment for congestive heart failure (CHF). We expect to initiate two pilot studies with DITPA in Class IV CHF patients in the second half of 2004. In addition, a small randomized, double blind Phase II safety study in patients with Class II-IV CHF will be initiated in 2004. This multicenter safety study is funded by a \$3.8 million government grant from the federal Veterans Administration (VA) system.

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 9 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.

DITPA represents a potential new class of agents for CHF, based upon the central role of thyroid hormone in regulating cardiovascular function. DITPA is a thyroid hormone analogue that was selected based upon its ability to significantly improve cardiac function in experimental models of heart failure without significantly increasing heart rate. Specifically, 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.

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 ACE inhibitors.

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The status of additional programs is as follows:

# Iloperidone

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. 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 QT 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. Novartis is currently evaluating the next steps for the iloperidone program, which may include sublicensing the compound to another company or returning the rights to Titan.

### **Immunotherapeutics**

We have two clinical trials in progress that utilize combinations of Titan's cancer immunotherapy products, CeaVac and TriAb, and are funded by the National Cancer Institute (NCI), 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 the present time, clinical testing of these products will be pursued solely through these studies supported by the NCI.

RB94 is a truncated variant of the Retinoblastoma (RB) gene, which encodes a tumor suppressor protein that has a critical role in regulating cell proliferation. The RB pathway is inactivated in the vast majority of cancers, and we believe that the RB94 gene product is more effective at suppressing tumor cell growth and promoting tumor cell death than the full-length RB gene product.

In December 2002, we presented data on the down-regulation of telomerase activity and the shortening of telomeres by combined RB94 and cisplatin therapy in human head and neck squamous cell carcinoma at the American Association of Cancer Research special meeting on The Role of Telomeres and Telomerase in Cancer.

In July 2003, we presented results on FGF2-targeted RB94 therapy at the Annual Meeting of the American Association of Cancer Research. We demonstrated that FGF receptors are overexpressed on most human head and neck squamous cell carcinoma (HNSCC) cells and that FGF2-targeted RB94 significantly enhanced the therapeutic outcome of combined RB94 and cisplatin therapy resulting in greater tumor regression. Furthermore, the combined therapy significantly increased telomere degradation in human HNSCC cells.

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Similar results were seen in human pancreatic tumor cells *in vitro* and *in vivo*. FGF2- targeted RB94 augmented tumor cell apoptosis, resulting in an increased inhibition of *in vivo* tumor growth. In November 2003, at the European Society of Gene Therapy Annual Meeting, we presented results from *in vivo* studies using human pancreatic Panc-1 xenografts in nude mice showing that intratumoral injections with FGF2-targeted RB94 therapy significantly enhanced the induction of tumor cell apoptosis, which correlated with a higher inhibition of tumor growth in treated animals.

In February 2004, we published a study on the treatment of pancreatic cancer with RB94 therapy in the journal *Clinical Cancer Research*. We demonstrated that RB94 has stronger antiproliferative effects than the RB wild type gene, and that RB94 treatment led to accumulation at the S-G2 cell cycle phase and can cause tumor cell apoptosis.

We are currently evaluating product development paths for this product, including important delivery and regulatory issues with respect to gene therapy, and we expect that any further development will be funded through external collaborations and grants.

# **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.

### 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, Schering and Titan will collaborate 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.

# 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.

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# 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.

### 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 Titan 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 Titan 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 Titan 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.

### 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.

### 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

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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. Under the provisions of this sublicense agreement, Novartis has the obligation to determine, within a reasonable period of time, the next steps for the iloperidone program, which may include sublicensing the compound to another company or returning the rights to Titan.

# 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.

### Gene Therapy Product—RB94

In October 1992, we acquired an exclusive, worldwide license under United States and foreign patent applications assigned to Baylor College of Medicine relating to the RB gene and its truncated variant, RB94, including the use of the gene in conferring senescence to tumors. The Baylor license provides for royalties based on net sales of products and processes incorporating the licensed technology, subject to a minimum annual license payment of \$36,000 and a percentage of sublicensing income arising from the license of such products and processes. Some of the additional conditions under the Baylor license require us to use reasonable best efforts to bring any products developed under the Baylor license to market, make timely payment of royalty fees, and pay all costs and expenses incurred in patent filing, prosecution and maintenance.

### **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."

# 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

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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 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, and one South African patent that will expire in 2020. These dates do not include possible term extensions.

#### 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.

### 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. Nine 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. This date does 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 one U.S. patent, expiring in 2020, one pending U.S. patent, and related foreign patent applications relating to the use of 2,4-diiodothyroproprionic acid (DITPA) for the treatment of heart failure and elevated cholesterol.

# 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.

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# 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.

### **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 2018, respectively. These dates do not include possible term extensions.

### Gene Therapy Product—RB94

We are the exclusive licensee under the Baylor license of U.S. and foreign patents and patent applications, two of which are U.S. patents expiring in 2013 and 2016 relating to p94Rb. In particular, the issued claims relate to nucleotide sequences encoding p94Rb, to vectors comprising such nucleotide sequences, to cells comprising such vectors, and to the use of such nucleotide sequences and vectors in suppressing the proliferation of tumor cells. We are aware of the existence of a certain European patent publication made available to the public prior to the filing date of the applications from which the two U.S. patents matured. One seeking to challenge the validity of certain claims of the above-mentioned patents could argue that this publication discloses a nucleotide sequence comprising a nucleotide sequence encoding p94Rb. Although the U.S. patents are entitled to a presumption of validity, it cannot be certain that the challenged claims will not be found to be invalid in view of the disclosure of this publication.

### 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.

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### **Spheramine**

With regard to Spheramine, we are aware of several new treatments for Parkinson's disease that are in pre-clinical and clinical development. Amgen Inc. is pursuing clinical trials in Parkinson's patients with glial derived neurotrophic factor (GDNF) and is collaborating with Medtronic, Inc. in its delivery to the central nervous system. 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.

# Pivanex

We are aware of several other companies developing anticancer drugs that destroy cancer cells by the same mechanism as Pivanex. Companies that are known to have histone deacetylase inhibitors in preclinical or clinical development include Pfizer, Schering AG, Novartis, Fujisawa, Aton Pharma and MethylGene. There is considerable scientific interest in histone deacetylase inhibitors as a category of cancer drugs and it is expected that competition in this segment will increase.

### 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. Genta is marketing this product under the brand name Ganite<sup>TM</sup>. 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 is also developing oral gallium compounds to treat bone-losing conditions.

In addition to the foregoing, colleges, universities, governmental agencies and other public and private research organizations are likely to continue to conduct research and are becoming more active in seeking patent protection and licensing arrangements to collect royalties for use of technology that they have developed, some of which may directly compete with the technologies being developed by us.

# 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

### Long-term Drug Delivery System

With regard to our long-term drug delivery system, we are aware of an implantable therapeutic system being developed by ALZA Corporation. Companies such as Medtronic, Inc. are developing implantable pumps that could be used to infuse drugs into the central nervous system. Additionally, Reckitt & Benckaiser, Inc. received FDA approval in 2002 for 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.

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# *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.

#### **Immunotherapeutics**

With regard to our immunotherapeutic products, we are aware of several companies involved in the development of cancer therapeutics that target the same cancers as our products. Such companies include Progenics Pharmaceutical Inc., Biomira Inc., AltaRex Corp., Genentech Inc., ImClone Systems Incorporated and GlaxoSmithKline plc.

#### Gene or Protein Delivery Therapeutics

With regard to our RB94 product, we are aware of several development stage and established enterprises that are exploring the field of human gene and/or protein delivery or are actively engaged in research and development in this area, including Introgen Therapeutics, Inc., Targeted Genetics Corp. and Cell Genesys, Inc. We are aware of other commercial entities that have produced gene and/or protein products used in human trials. It is expected that competition in this field will intensify.

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 the products for commercial marketing. 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 preclinical 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

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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.

In addition, our gene therapy product candidate is subject to guidelines established by the National Institutes of Health (NIH), covering deliberate transfers of recombinant DNA into human subjects conducted within NIH laboratories or with NIH funds, which provides that such products must be approved by the NIH Director. The NIH has established the Recombinant DNA Advisory Committee which sets forth guidelines concerning approval of NIH-supported research involving the use of recombinant DNA. Although the jurisdiction of the NIH applies only when NIH-funded research or facilities are involved in any aspect of the protocol, the Advisory Committee encourages all gene transfer protocols to be submitted for its review. We intend to comply with the Advisory Committee and NIH guidelines.

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**

We currently have 61 full-time employees. None of our employees is 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."

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### **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.

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# 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, 2003, we had an accumulated deficit of approximately \$159.7 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.

We may 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. Of our product candidates, iloperidone is furthest in development. The results of a study evaluating the EKG profile of patients taking iloperidone 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. Novartis is currently evaluating the next steps for the iloperidone program, which may include sublicensing the compound to another company or returning the rights to us. 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 its primary endpoint, and, as a result, have determined to discontinue our internal activities in development of the monoclonal antibodies CeaVac, TriAb, and TriGem.

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 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

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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

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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.

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

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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

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 or a new corporate partner 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

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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 may need additional financing.

At December 31, 2003, we had approximately \$46.6 million of cash, cash equivalents, and marketable securities that we believe will enable us to fund our operations through the first half of 2005. We may 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 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.

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### 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 2007, 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

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# **PART II**

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

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.

	I	ligh		Low
			_	
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
Fiscal Year Ended December 31, 2002:				
First Quarter	\$	9.81	\$	5.60
Second Quarter	\$	7.00	\$	3.10
Third Quarter	\$	4.17	\$	1.35
Fourth Quarter	\$	2.86	\$	1.20

# (b) Approximate Number of Equity Security Holders

The number of record holders of our common stock as of March 5, 2004 was approximately 154. Based on the last ADP search, we believe there are in excess of 11,000 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.

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### 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,										
	2003		2003		2002			2000		1999	
				(in thous	sands, except per sha			are data)			
Statement of Operations Data:											
Total revenue(1)	\$	89	\$	2,892	\$	4,572	\$	1,880	\$	337	
Operating expenses:											
Research and development		22,258		29,819		23,339		16,744		9,429	
Acquired/in-process research and development(2)		3,896		_		_		4,969		136	
General and administrative		5,109		5,076		5,383		4,070		2,794	
Other income, net		1,285		3,821		6,686		5,115		726	
Net loss	\$	(29,889)	\$	(28,182)	\$	(17,464)	\$	(18,788)	\$	(11,296)	
					_						
Basic and diluted net loss per share	\$	(1.07)	\$	(1.02)	\$	(0.63)	\$	(0.73)	\$	(0.70)	
Shares used in computing:											
Basic and diluted net loss per share		27,907		27,642		27,595		25,591		16,112	

- (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 DTI in 2003 and in-process research and development reflects the acquisition of GeoMed in 2000, and the acquisition of a minority interest in Theracell in 1999.

		As of December 31	,	
2003	2002	2001	2000	1999

Balance Sheet Data:					
Cash, cash equivalents, and marketable securities	\$ 46,555	\$ 73,450	\$ 105,051	\$ 117,523 \$	46,454
Working capital	44,578	70,702	100,193	115,386	45,128
Total assets	49,008	75,926	107,132	118,442	47,362
Total stockholders' equity	44,426	70,740	100,127	114,738	44,302

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### 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 of those terms 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.

Spheramine®, Pivanex®, Probuphine®, CeaVac®, TriAb®, TriGem™ and CCM™ are trademarks of Titan Pharmaceuticals, Inc.

### Overview

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

- Spheramine: for the treatment of late stage Parkinson's disease
- Pivanex: for the treatment of non-small cell lung cancer
- Gallium maltolate: for the treatment of several cancers and bone related disease associated with cancer
- Probuphine: for the treatment of opiate addiction
- DITPA: for the treatment of congestive heart failure

We are directly developing our product candidates and also utilizing strategic partnerships, including a collaboration with Schering. These collaborations help fund product development and enable us to retain significant economic interest in our products. Spheramine development is primarily funded by our corporate partner for Spheramine, Schering. Following the announcement of clinical study results in mid 2002, Novartis is considering alternatives for the iloperidone program for the treatment of schizophrenia, including sub-licensing the product to another company for further development, or returning product rights to Titan. Titan is no longer directly pursuing development of the monoclonal antibodies—CeaVac, TriAb, and TriGem—for the treatment of various cancers, and remaining clinical studies are externally funded collaborations with co-operative groups.

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

Product	Potential Indication(s)	Phase of Development	Marketing Rights
Spheramine	Parkinson's disease	Phase IIb	Schering AG
Pivanex	Non-small cell lung cancer	Phase IIb	Titan
Gallium maltolate	Myeloma, prostate and bladder cancer, lymphoma, bone disease associated with cancer	Phase I/II	Titan
Probuphine	Opiate addiction	Phase I/II	Titan
DITPA	Congestive heart failure	Phase II	Titan
Iloperidone	Schizophrenia, psychosis	Phase III*	Novartis Pharma AG

<sup>\*</sup> Further development under review.

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. 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. 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, 2003, 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 \$2.0 million in net loss, or an additional \$0.07 of net loss per share for the year ended December 31, 2003.

### **Results of Operations**

# 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

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disease and Schering's decision to initiate randomized clinical testing of Spheramine for the treatment of patients with late-stage 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. 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 2003 were \$5.1 million compared to \$5.1 million for 2002. We expect G&A costs to remain approximately the same in 2004.

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.

None of our products has been commercialized, and we do not expect to generate any revenue from product sales or royalties in the foreseeable future. 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.

Revenues in 2002 were \$2.9 million compared to \$4.6 million for 2001, a decrease of \$1.7 million. Our 2001 revenue included a one-time license fee payment of \$2.5 million received from Novartis for the development and commercialization of iloperidone in Japan, and an SBIR grant received from the National Institutes of Health in support of the development of Spheramine.

Research and development expenses for 2002 were \$29.8 million compared to \$23.3 million for 2001, an increase of \$6.5 million. The increase in research and development was primarily associated with the completion of the randomized, placebo-controlled Phase III clinical study of CeaVac in Dukes' D colorectal cancer and our other expanded clinical programs in cancer, specifically the Phase II studies with Pivanex and the Phase I/II study with gallium maltolate.

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General and administrative expenses for 2002 were \$5.1 million compared to \$5.4 million for 2001, a decrease of \$300,000. The decrease was primarily due to lower stock option related non-cash compensation expenses.

Other income, net, for 2002 was \$3.8 million compared to \$6.7 million for 2001, a decrease of \$2.9 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 \$28.2 million in 2002 compared to a net loss of \$17.5 million in 2001.

### **Liquidity and Capital Resources**

	2003		2002	2001		
As of December 31:						
Cash, cash equivalents and marketable securities	\$	46,555	\$ 73,450	\$	105,051	
Working capital	\$	44,578	\$ 70,702	\$	100,193	
Current ratio		14:1	19:1		18:1	
Year Ended December 31:						
Cash used in operating activities	\$	(26,438)	\$ (29,291)	\$	(13,739)	
Cash provided by (used in) investing activities	\$	26,002	\$ 30,678	\$	(1,710)	
Cash provided by (used in) financing activities	\$	113	\$ (4)	\$	921	

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 Titan 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.

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.

Payments Due by Period

The following table sets forth the aggregate contractual cash obligations as of December 31, 2003 (in thousands):

	Tayments Due by Terrou									
Contractual obligations		Total	<	1 year	1.	·3 years	3	-5 years	5	years+
Operating leases	•	3,121	Φ	924	Φ	1.852	Φ	345		
Sponsored research & license agreements	\$	1,974	\$	319	\$	653	\$	668	\$	334
Total contractual cash obligations	\$	5,095	\$	1,243	\$	2,505	\$	1,013	\$	334

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

provide additional funds for our operations. For a full discussion of risks and uncertainties regarding our need for additional financing, see "Risk Factors—We may need additional financing."

### **Off-Balance Sheet Arrangements**

Titan has never entered into any off-balance sheet financing arrangements and has 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 \$330,000 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, 2003 (in thousands, except interest rate):

Cash equivalents and marketable securities:	2004	2005	Total		Estimated Fair Value
Variable rate securities	\$ 5,082	_	\$ 5,082	\$	5,082
Average interest rate	0.88%	_	0.889	6	
Fixed rate securities	\$ 24,810 \$	15,885	\$ 40,695	\$	41,220
Average interest rate	3.15%	1.42%	2.489	6	

### 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.

Not applicable.

### Item 9A. Controls and Procedures.

We maintain "disclosure controls and procedures," as such term is defined under Exchange Act Rule 13a-15(e), that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures. In designing and evaluating the disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives and in reaching a reasonable level of assurance our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. We

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have carried out an evaluation under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of December 31, 2003. Based upon their evaluation and subject to the foregoing, the Chief Executive Officer and Chief Financial Officer concluded that as of December 31, 2003, our disclosure controls and procedures were effective in ensuring that material information relating to Titan, is made known to the Chief Executive Officer and Chief Financial Officer by others within Titan during the period in which this report was being prepared.

There were no changes in our internal controls or in other factors during the most recent quarter that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

### 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)	45	Chairman, President and Chief Executive Officer
Sunil Bhonsle	54	Executive Vice President, Chief Operating
		Officer, and Director
Richard C. Allen, Ph.D.	61	Executive Vice President, Cell Therapy
Robert E. Farrell	54	Executive Vice President and Chief Financial
		Officer
Ernst-Günter Afting, M.D., Ph.D.	61	Director
Victor Bauer, Ph.D.	68	Director
Eurelio M. Cavalier(1)(3)(4)	71	Director
Michael K. Hsu(2)	55	Director
Hubert Huckel, M.D.(1)(2)(3)	72	Director
M. David MacFarlane, Ph.D.(4)	63	Director
Ley S. Smith(1)(2)(4)	69	Director
Konrad M. Weis, Ph.D.(1)(3)	75	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.

Group, a merchant bank specializing in making investments into the healthcare and life science industries. Mr. Hsu has served as Director-Corporate Finance of National Securities Corp. from November 1995 through April 1998, and from November 1994 through October 1995 served with Coleman & Company Securities in the same capacity. Mr. Hsu previously held various executive positions with Steinberg and Lyman Health Care Company, Ventana Venture Growth Fund and Asian Pacific Venture Group (Thailand).

**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 M.D.S. Proteomics 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.

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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 is filed as Exhibit 14 to this Form 10-K. 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, 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 each of Mr. Michael K. Hsu and 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

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 October 31, 2003 automatic grants of stock options to members of each of the committees of the Board. 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 2003.

### Item 11. Executive Compensation.

The following summary compensation table sets forth the aggregate compensation awarded to, earned by, or paid to the Chief Executive Officer at December 31, 2003 and to the four other executive officers at December 31, 2003 whose annual compensation exceeded \$100,000 for the fiscal year ended December 31, 2003 (collectively, the "named executive officers"):

### **Summary Compensation Table**

			Annual Com	pensa				
Name and Principal Position			Salary		Bonus	Other Compensation		
Louis R. Bucalo, M.D. President and Chief Executive Officer	2003 2002 2001	\$ \$ \$	348,038 339,896 320,252	\$	67,005		_	
Sunil Bhonsle Executive Vice President and Chief Operating Officer	2003 2002 2001	\$ \$ \$	265,276 259,167 246,366	\$	41,280		_ _ _	
Richard C. Allen, Ph.D. Executive Vice President, Cell Therapy	2003 2002 2001	\$ \$ \$	232,230 226,821 217,766	\$	 		_	
Robert E. Farrell, J.D. Executive Vice President and Chief Financial Officer	2003 2002 2001	\$ \$ \$	221,447 216,254 207,773	\$	  19,865	\$	59,766(1) —	
Frank H. Valone(3) Executive Vice President Clinical Development and Regulatory Affairs	2003 2002	\$ \$	237,442(2 216,827(2	1	_		_	

- (1) The amount disclosed for Mr. Farrell represents accrued vacation payment made in 2002.
- (2) Dr. Valone left the company and ceased to be an officer in October 2003.
- (3) Dr. Valone joined Titan in March 2002.

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# **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, 2003. No stock appreciation rights were granted to these individuals during such year.

	Number of Securities	% of Total Options Granted	Exercise or Base Price		Potential Realiza Assumed A Rate of Sto Appreciation Term	Annual ck Price For Option
Name	Underlying Options Granted	to Employees In Fiscal Year	(\$/Sh)(1) Individual Grant	Expiration Date	5%	10%
Louis R. Bucalo	80,000	12.34% \$	1.50	03/1/2013	. ,	\$ 201,624
Louis R. Bucalo	5,000	0.77% \$	3.29	10/31/2013	\$ 10,345	\$ 26,217

Sunil Bhonsle	50,000	7.71% \$	1.50	03/1/2013 \$	51,239 \$ 126,015
Richard C. Allen	35,000	5.40% \$	1.50	03/1/2013 \$	35,868 \$ 88,211
Robert E. Farrell	35,000	5.40% \$	1.50	03/1/2013 \$	35,868 \$ 88,211
Frank H. Valone	40,000	6.17% \$	1.50	03/1/2013 \$	40,991 \$ 100,812

(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, 2003 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.

	Shares		Number of Securities Underlying Unexercised Options at FY-End			Value of Unexercised in-the-Money Options at FY-End(1)			
Name	Acquired on Exercise	Value Realized	Exercisable	Unexercisable		Exercisable		Unexercisable	
Louis R. Bucalo	_	_	1,559,923	88,251	\$	323,457	\$	83,100	
Sunil Bhonsle	_	_	645,905	42,000	\$	26,625	\$	44,375	
Richard C. Allen	_	_	538,267	31,417	\$	182,302	\$	31,063	
Robert E. Farrell	_	_	255,177	26,875	\$	101,273	\$	31,063	
Frank H. Valone	11,666	\$ 15,166	51,621	0	\$	0	\$	0	

(1) Based on the fair market value of our common stock at year-end, \$2.92 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 2003, each director was granted an annual option to purchase 5,000 shares of our common stock at an exercise price of \$3.29, 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 2003. Directors are not precluded from serving us in any other capacity and receiving compensation therefore.

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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 expiring in February 2007 that 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 with Dr. Bucalo, other than for reasons specified therein, 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 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.

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.

	Shares	D 4 401
Name and Address of Beneficial Owner(1)	Beneficially Owned(2)	Percent of Shares Beneficially Owned
Louis R. Bucalo, M.D.	1,944,904(3)	6.7%
Ernst-Günter Afting, M.D., Ph.D.	57,166(4)	*
Richard C. Allen, Ph.D.	556,865(5)	1.9%
Victor J. Bauer, Ph.D.	240,227(6)	*
Sunil Bhonsle	841,464(7)	2.9%
Eurelio M. Cavalier	108,333(8)	*
Robert E. Farrell	312,748(9)	1.1%
Michael K. Hsu	83,500(10)	*
Hubert Huckel, M.D.	137,500(11)	*
M. David MacFarlane, Ph.D.	26,250(12)	*
Ley S. Smith.	85,000(13)	*
Konrad M. Weis, Ph.D.	139,240(14)	*
Kevin Douglas and The Douglas Family Trust	1,847,100(15)	6.4%
1101 Fifth Avenue, Suite 360		
San Rafael, CA 94901		
All executive officers and directors as a group (12) persons	4,533,197	15.6%

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 5, 2004 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 1,512,918 shares issuable upon exercise of outstanding options.
- (4) Includes 57,166 shares issuable upon exercise of outstanding options.
- (5) Includes 552,100 shares issuable upon exercise of outstanding options.
- (6) Includes 226,583 shares issuable upon exercise of outstanding options.
- (7) Includes 663,570 shares issuable upon exercise of outstanding options.
- (8) Includes 78,333 shares issuable upon exercise of outstanding options.
- (9) Includes 264,968 shares issuable upon exercise of outstanding options.
- (10) Includes 55,833 shares issuable upon exercise of outstanding options.
- (11) Includes (i) 98,000 shares issuable upon exercise of outstanding options, and (ii) 3,000 shares held by Dr. Huckel's wife.
- (12) Includes 16,250 shares issuable upon exercise of outstanding options.
- (13) Includes 75,000 shares issuable upon exercise of outstanding options.

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- (14) Includes 103,666 shares issuable upon exercise of outstanding options.
- (15) Derived from a Schedule 13G/A filed by Kevin Douglas and The Douglas Family Trust on February 13, 2004.

### **Equity Compensation Plan Information**

The following table sets forth aggregate information regarding our equity compensation plans in effect as of December 31, 2003:

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	3,835,228	\$ 10.40	1,748,066		
Equity compensation plans not approved by security holders(1)(2)	2,116,262	\$ 7.57	390,063		
Total	5,951,490	\$ 9.39	2,138,129		

- (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 during the fiscal years ended December 31, 2003 and 2002 were:

	2003	2002
A PAR	177.500	140.201
Audit Fees	175,500	140,381
Audit-Related Fees	9,900	95,783
Tax Fees	63,900	76,740
All Other Fees		
Total	249,300	312,904

**Audit Fees**—This category includes aggregate fees billed by our independent auditors for the audit of Titan's annual financial statements, 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.

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**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, 2003 and 2002, Ernst & Young 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 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.

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.

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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.

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### 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.

# 3. 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 August 1, 2002
- †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)

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- †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)

- 14 Code of Business Conduct and Ethics.
- 23.2 Consent of Ernst & Young LLP, Independent Auditors.
- 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.
- (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.

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- (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.

# (b) Reports on Form 8-K

We filed a current report on Form 8-K with the SEC on October 15, 2003 to announce the acquisition of Developmental Therapeutics, Inc., a privately-held Delaware corporation which has the exclusive worldwide license to a U.S. patent covering 3,5-diiodothyropropionic acid or DITPA.

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### TITAN PHARMACEUTICALS, INC.

# INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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### REPORT OF ERNST & YOUNG LLP, INDEPENDENT AUDITORS

The Board of Directors and Stockholders

Titan Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of Titan Pharmaceuticals, Inc. as of December 31, 2003 and 2002, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three 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 auditing standards generally accepted in the 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 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 2002, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2003, in conformity with accounting principles generally accepted in the United States.

/s/ Ernst & Young LLP

Palo Alto, California February 20, 2004

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# TITAN PHARMACEUTICALS, INC.

### CONSOLIDATED BALANCE SHEETS

		December 31,				
		2003		2002		
		(in thousands				
Assets						
Current assets:		6.022	Φ.			
Cash and cash equivalents	\$	6,832	\$	7,155		
Marketable securities		39,723		66,295		
Related party receivables		123		316		
Prepaid expenses, other receivables and current assets	_	1,241		881		
Total current assets		47,919		74,647		
Property and equipment, net		789		979		
Investment in other companies		300		300		
	\$	49,008	\$	75,926		
Liabilities and Stockholders' Equity						
Current liabilities:			_			
Accounts payable	\$	1,505	\$	1,901		
Accrued clinical trials expenses		634		1,203		
Other accrued liabilities		1,202		841		

Total current liabilities	3,341	3,945
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, 2003 and 2002	_	_
Common stock, at amounts paid in, \$0.001 par value per share; 50,000,000 shares authorized, 28,903,043 and 27,642,085 shares issued and outstanding at December 31, 2003 and 2002,		
respectively	195,331	191,680
Additional paid-in capital	9,047	9,161
Deferred compensation	(211)	(621)
Accumulated deficit	(159,741)	(129,852)
Accumulated other comprehensive income	_	372
Total stockholders' equity	44,426	70,740
	\$ 49,008	\$ 75,926

See accompanying notes.

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# TITAN PHARMACEUTICALS, INC.

# CONSOLIDATED STATEMENTS OF OPERATIONS

	Year ended December 31,						
	2003		2002			2001	
		(in thousa	nds,	except per shar	e am	ount)	
Revenue:							
Contract revenue	\$	28	\$	2,696	\$	1,224	
License revenue		61		_		2,600	
Grant revenue	_		_	196	_	748	
Total revenue		89		2,892		4,572	
Operating expenses:	_						
Research and development		22,258		29,819		23,339	
Acquired research and development		3,896		_		_	
General and administrative		5,109		5,076		5,383	
			_		_		
Total operating expenses	_	31,263	_	34,895	_	28,722	
Loss from operations		(31,174)		(32,003)		(24,150)	
Other income (expense):							
Interest income		1,278		4,221		6,763	
Other income (expense)	_	7	_	(400)	_	(77)	
Other income, net		1,285		3,821		6,686	
Net loss	\$	(29,889)	\$	(28,182)	\$	(17,464)	
Basic and diluted net loss per share	\$	(1.07)	\$	(1.02)	\$	(0.63)	
Weighted average shares used in computing basic and diluted net loss per share		27,907		27,642		27,595	

# TITAN PHARMACEUTICALS, INC

# CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY

# (in thousands)

	Preferred Stock		Common Stock					Accumulated		
	Shares	Amount	Shares	Amount	Additional Paid-In Capital	Deferred Compensation	Accumulated Deficit	Other Comprehensive Income	Total Stockholders' Equity	
Balances at December 31, 2000	222	<b>\$</b> —	27,234	\$190,763	\$ 8,744	\$ (1,254)	\$ (84,206)	\$ 691	\$ 114,738	
Comprehensive loss:										
Net loss Unrealized gain on marketable securities							(17,464)	1,200	(17,464) 1,200	
Comprehensive loss									(16,264)	
Issuance of common stock upon exercise of options and warrants			461	1,028					1,028	
Rescission of stock option			.01	1,020					1,020	
exercises			(53)	(107)	149				42	
Compensation related to stock options					124	(83)	)		41	
Amortization of deferred						(65)				
compensation	_					542			542	
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									(25,701)	
exercise of options, net of issuance										
costs of \$6 Compensation related to stock			_	(4)					(4)	
options					144	(141)	)		3	
Amortization of deferred compensation						315			315	
Balances at December 31, 2002	222	<u> </u>	27.642	<b>\$191,680</b>	\$ 9,161	\$ (621)	\$ (129,852)	\$ 372	\$ 70,740	
Comprehensive loss:		,	,	, -, -, -, -	7 7,202	7 (0-2)	+ (===,===)	,	, ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	
Net loss							(29,889)		(29,889)	
Unrealized loss on marketable securities								(372)	(372)	
Comprehensive loss									(30,261)	
Issuance of common stock to									(30,201)	
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			13	113	(114)	) 114			_	
Amortization of deferred compensation						296			296	
Balances at December 31, 2003	222	•	28 002	<b>\$195,331</b>	\$ 9,047	\$ (211)	\$ (159,741)	<b>\$</b> —	\$ 44,426	
Datances at December 31, 2003		φ —	20,703	φ193,331	φ 2,04/	ψ (211)	φ (133,/41)	Ψ —	φ ++,420	

# TITAN PHARMACEUTICALS, INC.

# CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years ended December 31,					
		2003		2002		2001
		(ir	thous	housands of dollars)		
Cash flows from operating activities:						
Net loss	\$	(29,889)	\$	(28,182)	\$	(17,464)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:						
Depreciation and amortization		439		374		272
(Gain) loss on investment activities		(51)		309		_
Acquired research and development		3,873		_		_
Non-cash compensation related to stock options		296		318		732
Changes in operating assets and liabilities:						
Prepaid expenses, receivables and other current assets		(166)		(291)		(580)
Accounts payable		(675)		1,007		(410)
Accrued clinical trials and other liabilities		(265)		(826)		1,711
Deferred contract revenue	_			(2,000)	_	2,000
Net cash used in operating activities		(26,438)		(29,291)		(13,739)
Cash flows from investing activities:						
Purchases of property and equipment, net		(248)		(778)		(254)
Investment in other companies		91		_		(600)
Purchases of marketable securities		(47,660)		(25,114)		(72,733)
Proceeds from maturities of marketable securities		64,819		43,718		55,750
Proceeds from sales of marketable securities		9,000		12,852		16,127
Net cash used in investing activities		26,002		30,678		(1,710)
Cash flows from financing activities:						
Issuance of common stock, net	_	113		(4)	_	921
Net cash (used in) provided by financing activities		113		(4)		921
Net increase (decrease) in cash and cash equivalents		(323)		1,383		(14,528)
Cash and cash equivalents at beginning of year		7,155		5,772		20,300
cush and cush equivalents at regimming of year	_	7,133		3,772		20,500
Cash and cash equivalents at end of year		6,832		7,155		5,772
Marketable securities at end of year		39,723		66,295		99,279
Cash, cash equivalents and marketable securities at end of year	\$	46,555	\$	73,450	\$	105,051
Schedule of non-cash transaction:						
Issuance of common stock to acquire technologies, net	\$	3,538	\$	_	\$	_

See accompanying notes.

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### 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, cancer, and cardiovascular disease. 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, 2003, we owned 81% of Ingenex, assuming the conversion of all preferred stock to common stock, and 79% 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 Titan had applied the

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provisions of SFAS 123 to estimate and recognize compensation expense for our stock-based employee compensation.

	Year Ended December 31,						
		2003		2002		2001	
Net loss, as reported	\$	(29,889)	\$	(28,182)	\$	(17,464)	
Add: Stock-based employee compensation expense included in reported net							
loss		296		318		1,088	
Deduct: Stock-based employee compensation expense determined under fair							
value method for all stock option grants		(2,319)		(8,489)		(10,225)	
					_		
Pro forma net loss	\$	(31,912)	\$	(36,353)	\$	(26,601)	
			_		_		
Basic and diluted net loss per share, as reported	\$	(1.07)	\$	(1.02)	\$	(0.63)	
Pro forma basic and diluted net loss per share	\$	(1.14)	\$	(1.32)	\$	(0.96)	
^							

# 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 \$40,000 in 2003, \$9,000 in 2002, and none in 2001 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

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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 LLC for 714,286 shares of Series A Preferred stock, and at December 31, 2003, these shares represent 6.6% 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.

### 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 Titan has continuing performance obligations and has 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 and 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 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, 2003, 2002, and 2001, outstanding preferred stock, options and warrants totaled 6.1 million, 6.4 million, and 4.4 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, 2003, 2002, and 2001 was \$30.3 million, \$29.7 million, and \$16.3 million, respectively. Comprehensive loss has been disclosed in the Statement of Stockholders' Equity for all periods presented.

## Recent Accounting Pronouncements

In November 2003, the EITF discussed several of the recommendations on the proposed models for evaluating impairment of equity and debt securities discussed on Issue No. 03-01, "The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments." Although the Task Force requested further revisions to the underlying impairment models at the November meeting, it reached a consensus that certain quantitative and qualitative disclosures are required for debt and marketable equity securities classified as available-for-sale or held-to-maturity under SFAS No. 115 and SFAS No.124 that are impaired at the balance sheet date but for which an other-than-temporary impairment has not been recognized. For those investments with unrealized losses that have not been recognized as other-than-temporary impairments, additional disclosure is required. The disclosure requirement is effective for fiscal years ending after December 15, 2003 (see Note 2).

In January 2003, the FASB issued Interpretation No. 46 (or FIN 46), "Consolidation of Variable Interest Entities." FIN 46 addresses consolidation of variable interest entities ("VIEs") that do not have sufficient equity investment at risk to permit the entity to finance its activities without additional subordinated financial support, or in which the equity investors lack an essential characteristic of a controlling financial interest. In December 2003, the FASB completed deliberations of proposed modifications to FIN 46 ("Revised Interpretation") resulting in multiple effective dates based on the nature as well as the creation date of the VIE. VIEs created after January 31, 2003, but prior to January 1, 2004, may be accounted for either based on the original interpretation of the Revised Interpretation. VIEs created after January 1, 2004 must be accounted fro under the Revised Interpretation. Special purpose entities ("SPEs") created prior to February 1, 2003 may be accounted for under the original or revised interpretation's provisions no later than our first quarter of fiscal 2004. Non-SPEs created prior to February 1, 2003, should be accounted for uner the revised interpretation's provisions no later than our first quarter of 2004. We do not currently have any arrangements with

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variable interest entities that will require consolidation of there financial information in our financial statements.

In November 2002, the EITF reached a consensus on Issue No. 00-21, "Revenue Arrangements with Multiple Deliverables." EITF Issue No. 00-21 provides guidance on how to account for arrangements that involve the delivery or performance of multiple products, services and/or rights to use assets. The provisions of EITF Issue No. 00-21 apply to revenue arrangements entered into in fiscal periods beginning after June 15, 2003. The adoption of EITF Issue No. 00-21 did not have a material impact on our financial position and results of operations.

Also in November 2002, the FASB issued Interpretation No. 45 (or FIN 45), "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others." FIN 45 elaborates on the existing disclosure requirements for most guarantees, including certain indemnification agreements. It also clarifies that at the time a company issues a guarantee, the company must recognize an initial liability for the fair value of the obligation it assumes under that guarantee and must disclose that information in its interim and annual financial statements. The initial recognition and measurement provisions apply on a prospective basis to guarantees issued or modified after December 31, 2002. The disclosure requirements are effective for financial statements of interim or annual periods ending after December 15, 2002. The adoption of FIN 45 did not have a material impact on our results of operations and financial position. See Note 10, "Guarantees and Indemnifications," below for a discussion related to these agreements.

# 2. Cash, Cash Equivalents and Marketable Securities

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

2003 2002

Gross

Gross Unrealized Gross Unrealized Gross Unrealized Fair

Classified as:	Am	ortized Cost		Gain		(Loss)	F	air Value	A	Amortized Cost	Unrealized Gain		(Loss)	V	Value
Cash	\$	253	\$	_	\$	_	\$	253	\$	576	\$ _	\$	_ :	\$	576
Cash equivalents:							Ι								
Money market funds		5,082		_		_		5,082		6,579	_		_		6,579
Commercial paper	_	1,497	_		_		_	1,497	_			_		_	
Total cash equivalents		6,579		_		_		6,579		6,579			_		6,579
Marketable securities:															
Securities of the U.S. government and its agencies		33,178		47		(17)		33,208		40,064	258		(17)		40,305
Corporate notes and bonds		4,246		9		(38)		4,217		18,571	161		(38)		18,694
Commercial paper		2,299		_		(1)		2,298		7,288	8		_		7,296
Total marketable securities		39,723		56		(56)		39,723		65,923	427	Ξ	(55)		66,295
Total cash, cash equivalents and marketable securities	\$	46,555	\$	56	\$	(56)	\$	46,555	\$	73,078	\$ 427	\$	(55)	\$	73,450
Securities available-for-sale:			_						_			_			
Maturing within 1 year	\$	30,353					\$	30,353	\$	58,275			:	\$	58,505
Maturing between 1 to 2 years	\$	15,949					\$	15,949	\$	14,227				\$	14,369

Gross realized losses on sales of marketable securities were \$17,000 for the year ended December 31, 2003. There were no gross realized gains in 2003. For the year ended December 31, 2002, there were \$119,000 of gross realized gains and \$3,000 of gross realized losses. For the year ended December 31, 2001, there were \$149,000 of gross realized gains and no gross realized losses.

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The aggregate amount of unrealized losses and the related fair value of investments with unrealized losses at December 31, 2003 were approximately \$56,000 and \$3.8 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.

## 3. Property and Equipment

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

	2003		2002	
Furniture and office equipment	\$	530	\$	525
Leasehold improvements		368		318
Laboratory equipment		428		365
Computer equipment		810		728
		2,136		1,936
Less accumulated depreciation and amortization		(1,347)		(957)
•			_	
Property and equipment, net	\$	789	\$	979

Depreciation and amortization expense was \$436,000, \$374,000, and \$272,000 for the years ended December 31, 2003, 2002, and 2001, 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 \$2.6 million, \$1.3 million, and \$1.6 million in the years ended December 31, 2003, 2002, and 2001, respectively.

At December 31, 2003, the annual aggregate commitments we have under these agreements, including minimum license payments, are as follows (in thousands):

2004 \$ 319

2005	324
2005 2006	329
2007	334
2008	334
	\$ 1,640

After 2008, 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.

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### 6. Iloperidone Sublicense to Novartis Pharma AG

We entered into an agreement with 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, Titan 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 Titan a royalty on future net sales of the product, providing Titan 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.

### 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, 2003, we recognized \$2.8 million under this agreement to date. 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 late-stage Parkinson's disease following the successful completion of Titan's Phase I/II clinical study of Spheramine. As a result, Titan 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. Titan 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. Titan acquired DTI in a stock transaction for 1,187,500 shares of Titan 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 Titan 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 Titan 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.

#### Lease Commitments

We lease facilities under operating leases that expire at various dates through June 2007. We also lease certain office equipment under operating and capital leases that expire at various dates through February 2007. Rental expense was \$825,000, \$765,000, and \$584,000 for years ended December 31, 2003, 2002, and 2001, respectively.

The following is a schedule of future minimum lease payments at December 31, 2003 (in thousands):

2004		924
2005		959
2006		893
2004 2005 2006 2007		345
		_
	\$ 3	,121

### 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, 2003.

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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, 2003. 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 Titan's common stock, on a one-to-one basis, only if certain development milestones are achieved within 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. Holders of Series C Preferred are not entitled to vote but 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.

In October 2003, we acquired DITPA through the acquisition of Developmental Therapeutics, Inc. (DTI) in a stock transaction for 1,187,500 shares of Titan 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, 2003, shares of common stock reserved by us for future issuance consisted of the following (shares in thousands):

Stock options	8,090
Preferred stock	222
DTI merger contingent shares	750
	9,062

## 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

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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. 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 option granted under the 2001 NQ Plan were 100% of the fair market value of our common stock on the date of grant.

In December 2001, Titan entered into agreements with certain officers and directors of the company to rescind stock options that were previously granted and exercised. These agreements resulted in the rescission of 88,000 stock options that were exercised and, as a result, a total compensation charge of \$149,000 was recorded in general and administrative expense and the reinstated options were subsequently cancelled. A total of 53,000 shares of common stock were returned and retired from shares outstanding as of December 31, 2001, and \$107,000 was refunded to the individuals.

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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, 2000	1,157	3,666	\$	12.95
Increase in shares reserved	1,000	_		_
Options granted	(1,300)	1,300	\$	15.21

Options exercised		(404)	\$ 3.26
Options cancelled	434	(434)	\$ 26.35
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	<del>_</del>	<del></del>	
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	<del>_</del>	(73)	\$ 1.57
Options cancelled	864	(864)	\$ 8.67
Balance at December 31, 2003	2,138	5,952	\$ 9.39

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 2003, 2002 and 2001, the number of Substitute Options cancelled was immaterial.

Options for 3.9 million and 2.6 million shares were exercisable at December 31, 2002 and 2001, respectively. The options outstanding at December 31, 2003 have been segregated into three ranges for additional disclosure as follows (option shares in thousands):

		Options Outstanding	;				
					Option	s Exercisa	ble
Range of Exercise Prices	Number Outstanding			Weighted Average ercise Price	Number Exercisable	Weighted Average Exercise Price	
\$0.08 - \$3.77	2,088	7.43	\$	2.14	1,186	\$	2.28
\$3.79 - \$11.63	2,355	6.27	\$	8.39	2,146	\$	8.29
\$11.95 - \$46.50	1,509	6.30	\$	20.99	1,459	\$	20.44
\$0.08 - \$46.50	5,952	6.69	\$	9.39	4,791	\$	10.50

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 had 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 2003, 2002, and 2001: weighted-

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average volatility factor of 0.70, 0.79, and 0.86, respectively; no expected dividend payments; weighted-average risk-free interest rates in effect of 2.2%, 2.4%, and 3.9%, respectively; and a weighted-average expected life of 3.01, 3.54, and 2.99 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, 2003, 2002, and 2001 was \$0.89, \$2.32, and \$8.44, 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 Parties 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. In 2002 and 2001, we provided certain relocation loans to employees in connection with employment. Also in February 2001, we provided a loan to a vice president officer in the principal amount of \$373,000 bearing interest at prime rate. The loan was due and payable on August 7, 2002 and as of December 31, 2002, the principal balance was paid in full.

### 15. Income Taxes

As of December 31, 2003, we had net operating loss carryforwards for federal income tax purposes of approximately \$157.4 million that expire at various dates through 2023, and federal research and development tax credits of approximately \$4.2 million that expire at various dates through 2023. We also had net operating loss carryforwards for state income tax purposes of approximately \$56.5 million that expire at various dates through 2013, and state research and development tax credits of approximately \$3.2 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.

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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,			
	2	2003		2002	
Deferred tax assets:					
Net operating loss carryforwards	\$	59,000	\$	45,300	
Research credit carryforwards		6,400		2,100	
Other, net		4,200		4,600	
			_		
Total deferred tax assets		69,600		52,000	
Deferred tax liabilities:					
Unrealized gain on investments		(50)		(100)	
Valuation allowance		(69,550)		(51,900)	
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 \$17.6 million, \$11.1 million, and \$5.9 million during 2003, 2002, and 2001, respectively. The valuation allowance at December 31, 2002 includes \$3.7 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 Juarter	_	Second Quarter	Third Quarter	_	Fourth Quarter
	(i	n tho	usands, except p	oer share amoun	t)	
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)

2002				
Total revenue	\$ 2,347 \$	151 \$	158 \$	236
Net loss	\$ (4,950) \$	(7,032) \$	(7,296) \$	(8,904)
Basic and diluted net loss per share	\$ (0.18) \$	(0.25) \$	(0.26) \$	(0.32)

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# **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 12, 2004	By:	/s/ LOUIS R. BUCALO

Louis R. Bucalo, M.D., Chairman, President and Chief Executive Officer

Signature	Title	Date
/s/ LOUIS R. BUCALO	Chairman, President and Chief Executive Officer	March 12, 200
Louis R. Bucalo, M.D.	(principal executive officer)	
/s/ ERNST-GÜNTER AFTING	Director	March 12, 200
Ernst-Günter Afting, M.D., Ph.D.		
/s/ VICTOR J. BAUER	Director	March 12, 200
Victor J. Bauer, Ph.D.		
/s/ SUNIL BHONSLE	Executive Vice President, Chief Operating Officer and	March 12, 200
Sunil Bhonsle	— Director	
/s/ EURELIO M. CAVALIER	Director	March 12, 200
Eurelio M. Cavalier		
/s/ MICHAEL K. HSU	Director	March 12, 200
Michael K. Hsu		
/s/ HUBERT E. HUCKEL	Director	March 12, 200-
Hubert E. Huckel, M.D.		
/s/ M. DAVID MACFARLANE	Director	March 12, 200-
M. David MacFarlane, Ph.D.		
/s/ LEY S. SMITH	Director	March 12, 200-
Ley S. Smith		
/s/ KONRAD M. WEIS	Director	March 12, 200-
Konrad M. Weis, Ph.D.	_	

Robert E. Farrell

### **OuickLinks**

## **PARTI**

Item 1. Business

Item 2. Properties

Item 3. Legal Proceedings

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

### **PART II**

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

Item 6. Selected Financial Data

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

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

Item 8. Consolidated Financial Statements and Supplementary Data.

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

Item 9A. Controls and Procedures.

## **PART III**

Item 10. Directors and Executive Officers of Registrant.

Item 11. Executive Compensation.

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

Item 13. Certain Relationships and Related Transactions.

Item 14. Principal Accountant Fees and Services.

# **PART IV**

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

TITAN PHARMACEUTICALS, INC. INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

TITAN PHARMACEUTICALS, INC. CONSOLIDATED BALANCE SHEETS

TITAN PHARMACEUTICALS, INC. CONSOLIDATED STATEMENTS OF OPERATIONS

TITAN PHARMACEUTICALS, INC CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY (in thousands)

TITAN PHARMACEUTICALS, INC. CONSOLIDATED STATEMENTS OF CASH FLOWS

TITAN PHARMACEUTICALS, INC. NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

**SIGNATURES** 

#### OYSTER POINT MARINA PLAZA

## Sixth Amendment to Office Lease

THIS Sixth Amendment TO OFFICE LEASE (the "Sixth Amendment") is made and entered into as of August 1, 2002, by and between KASHIWA FUDOSAN AMERICA, INC., a California corporation ("Landlord") and TITAN PHARMACEUTICALS, INC., a Delaware corporation ("Tenant").

#### Recita1s

- A. Landlord and Tenant have heretofore entered into that certain lease dated February 14, 1996 (the "Lease") for premises originally described as Suite 505 (the "Premises"), initially containing approximately 3,866 rentable square feet of space in the building located at 400 Oyster Point Boulevard, South San Francisco, California (the "Building"), which forms part of the office building complex commonly known as Oyster Point Marina Plaza (the "Complex").
- B. The Lease has heretofore been amended by the following instruments (collectively the "Addenda"):
  - (i). First Amendment to Lease dated as of March 25, 1997;
  - (ii). Second Amendment to Lease dated as of May 22, 1998;
  - (iii). Third Amendment to Lease dated as of November 11, 2000;
  - (iv). Fourth Amendment to Lease dated as of April 9, 2001; and
  - (v). Fifth Amendment to Lease dated as of December 5, 2001.
- C. The parties mutually desire to amend the terms of the Lease to extend its Term, expand the Premises, and in certain other respects, all on and subject to the terms and conditions hereof.

## Agreement

Now, therefore, in consideration of the mutual terms and conditions herein contained and of other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

**1 EFFECT OF AMENDMENT.** Landlord and Tenant agree that, notwithstanding anything contained in the Lease to the contrary, the provisions set forth below will be deemed to be part of the Lease and shall supersede, to the extent they differ, any contrary provisions in the Lease. Terms defined in the Lease shall have the same meanings in this Sixth Amendment, unless a different definition is set forth in this Sixth Amendment. The term *Lease* as used herein shall be deemed to include the Addenda, each of which may also be referred to separately herein.

**2 EFFECTIVE DATE.** The amendments and changes specified in this Sixth Amendment shall become effective on October 1, 2002 (the "Effective Date"). Notwithstanding the foregoing, this Sixth Amendment shall constitute the fully-binding agreement and contract of the parties from and after the date of the parties execution and delivery of this Sixth Amendment to each other.

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3 SUMMARY TABLE. The Table set forth in  $\P$  4 of Fifth Amendment is hereby superseded and replaced in its entirety by the following table, which shall constitute the Table under  $\S$  1.2 of the Lease for all purposes from and after the Effective Date of this Sixth Amendment:

PERIODS	SUITE NO.	RSF	USF	MONTH BASE RENT	SHARE	TENANT'S SHARE COMPLEX	BASE YEAR
October 1, 2002 through June 30, 2003	505 504	18,774 3,821	- ,	. ,	528.50 8.100% 821.00 1.649%	4.042% 0.823%	2000
July 1, 2003 through June 30, 2004	505	18,774	16,325	\$ 56,3	322.00 8.100%	4.042%	2000

	504	3,821	3,323	\$ 4,012.05	1.649%	0.823%	
July 1, 2004 through June 30, 2005	505	18,774	16,325	\$ 61,015.50	8.100%	4.042%	2000
	504	3,821	3,323	\$ 4,203.10	1.649%	0.823%	
July 1, 2005 through June 30, 2006	505	18,774	16,325	\$ 64,770.30	8.100%	4.042%	2000
• ,	504	3,821	3,323	\$ 4,394.15	1.649%	0.823%	
July 1, 2006 through June 30, 2007	505	18,774	16,325	\$ 46,935.00	8.100%	4.042%	2000
	504	3,821	3,323	\$ 9,552.50	1.649%	0.823%	

In the event of any conflict between the terms contained in the Table and the terms contained in subsequent paragraphs of this Sixth Amendment, the terms of the Table shall control, except as may be expressly varied in any subsequent paragraph of this Sixth Amendment.

- **4 EXPANSION OF PREMISES.** Upon Substantial Completion of the Work specified in the Work Letter Agreement, as described in ~8 below, the Premises shall be expanded to include approximately 3,821 rentable square feet of space known as Suite 504 in the Building ("Suite 504") for all purposes under the Lease. The parties anticipate that Substantial Completion of Landlord's Work in Suite 504 will occur on or before October 1, 2002 (the "Target Date"). From and after the later to occur of the Target Date or Substantial Completion of Landlord's Work under the Work Letter Agreement specified in ¶ 8 below, Suite 504 shall become part of the Premises pursuant to the basic terms specified in the Table above regarding term, Base Rent, Tenant's Share of increases in Operating Expenses and Taxes, and the Base Year for the purposes of calculating Additional Rentable payable with respect to Suite 504.
- **5 EXTENSION OF LEASE TERM.** The Term of the Lease specified in § 1.4 of the Lease, as heretofore modified in the Addenda, is hereby extended for an additional period of one (1) year commencing on July 1, 2006, and the Expiration Date of the Lease is hereby amended accordingly to June 30, 2007, for the entire Premises (including Suite 504).
- **6 EXTENSION TERM BASE RENT.** The Base Rent for the Premises specified in § 1.5 of the Lease, as heretofore modified in the Addenda, shall be the amounts specified as Monthly Base Rent in the Table above for the various periods and spaces set forth in the Table from and after the Effective Date.
- **7 BASE YEAR.** As specified in the Table above, the Base Year for the purposes calculating Tenant's Share of Increased Operating Expenses and Increased Taxes under Article 4 of the Lease shall be calendar year 2000Jrom and after the Effective Date.
- **8 CONDITION OF PREMISES.** Except as otherwise expressly provided in the "Work Letter Agreement" which shall be executed by Landlord and Tenant concurrently with their execution of this Sixth Amendment substantially in the form attached hereto as Exhibit A with respect to Landlord's preparation of Suite 504 for Tenant's occupancy, Tenant shall accept the Premises, any existing Improvements in the Premises, and the Systems and Equipment serving the same in an "as is"

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condition on the Extension Term Commencement Date, and Landlord shall have no obligation to improve, alter, remodel, or otherwise modify the Premises in connection with Tenant's continued occupancy of the Premises from and after the Effective Date.

- 8.1 **Landlord's Preparation.** Landlord shall use reasonable diligence in completing and preparing the Premises for Tenant's occupancy in the manner and subject to the terms, conditions, and covenants set forth in the Work Letter Agreement. The facilities, materials, and work to be furnished, installed, and performed in the Premises by Landlord pursuant to the Work Letter Agreement are referred to as the "Work." Such other installations, materials, and work which may be undertaken by or for the account of Tenant to prepare, equip, decorate, and furnish the Premises for Tenant's occupancy are referred to as the "Tenant's Work."
- 8.1.1 **Readiness for Occupancy.** The Premises shall be deemed ready for occupancy on the earliest date on which all of the following conditions (the "Occupancy Conditions") have first been met:
  - (a) Substantial Completion of Work. The Work has been substantially completed; and it shall be so deemed notwithstanding the fact that minor or insubstantial details of construction, mechanical adjustment, or decoration remain to be performed, the noncompletion of which does not materially interfere with Tenant's beneficial use of the Premises for their intended purposes;
  - (b) Access and Services. Reasonable means of access and facilities necessary to Tenant's use and occupancy of the Premises, including corridors, elevators, stairways, heating, ventilating, air-conditioning, sanitary, water, and electrical facilities (but exclusive of parking facilities) have been installed and are in reasonably good operating order and available to Tenant; and
  - (c) Certificate of Occupancy or Completion. A certificate of occupancy, certificate of completion, final inspection card, or similar required governmental approval (temporary or final) has been issued by the City of South San Francisco permitting use of the Premises for office purposes.

. .

8.2 **Notice of Defects.** It shall be conclusively presumed upon Tenant's taking actual possession of the Premises that the same were in satisfactory condition (except for latent defects) as of the date of such taking of possession, unless within thirty (30) days after the Commencement Date Tenant shall give Landlord notice in writing specifying the respects in which the Premises were not in satisfactory condition.

**9 SECURITY DEPOSIT.** Tenant shall increase the Security Deposit specified in § 5.1 of the Lease from Six Thousand Two Hundred Dollars (\$6,200.00) to a total of Forty-Eight Thousand Dollars (\$48,000.00) in four installments of \$10,450.00, each, to be paid to Landlord on the following dates; September 1, 2002; December 1, 2002; March 1, 2003 and June 1, 2003.

**10 PARKING.** The number of parking spaces specified in § 28.1 of the Lease as available for Tenant's use is hereby amended to Sixty-Six (66).

**11 OPTION TO RENEW.** Tenant's Extension Option specified in § 1.7 of the Lease shall apply to the period following the Expiration Date of the Lease as amended in § 5 above.

12 RIGHT OF FIRST OFFER. From the Commencement Date through June 30, 2005; Tenant shall have the first right of offer on adjacent space on either side of the Premises (Suite 504-505), subject to the existing tenants, Greenspan and any third party occupying the suite adjacent to Suite 504, vacating the space and delivering it vacant and unencumbered to Landlord. The rent for the first right of offer shall be 95% of the Fair Market Value or Titan's rent schedule, whichever is greater. The term for the adjacent space shall be co-terminus with the term under the Lease. Tenant acknowledges that it has

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receive the first right of offer upon the expiration and vacation of Suite 504 by the U.S. Postal Service as specified in Amendment Four of the Lease.

**13 NO DISCLOSURE.** Tenant agrees that it shall not disclose any of the matters set forth in this Sixth Amendment or disseminate or distribute any information concerning the terms, details, or conditions hereof to any person, firm, or entity without obtaining the express written approval of Landlord.

14 NO OFFER. Submission of this Sixth Amendment is not an offer to enter into the same but a solicitation for such an offer by Tenant. Tenant agrees that its execution of this Sixth Amendment constitutes a firm offer to enter the same which may not be withdrawn for a period of thirty (30) working days after delivery to Landlord. Landlord shall not be bound by this Sixth Amendment until Landlord has executed and delivered the same to Tenant. This Sixth Amendment shall not be relied upon by any other party, individual, corporation, partnership, or other entity as a basis for terminating its lease with Landlord.

**15 DEFINED TERMS.** Terms used herein that are defined in the Lease shall have the meanings therein defined, unless a different definition is set forth in this Sixth Amendment. In the event of any conflict between the provisions of the Lease, and this Sixth Amendment, the terms of this Sixth Amendment shall prevail.

**16 SURVIVAL.** Warranties, representations, agreements, and obligations contained in this Sixth Amendment shall survive the execution and delivery of this Sixth Amendment and shall survive any and all performances in accordance with this Sixth Amendment.

17 COUNTERPARTS. This Sixth Amendment may be executed in any number of counterparts, which each severally and all together shall constitute one and the same Sixth Amendment.

**18 ATTORNEYS' FEES.** If any party obtains a judgement against any other party or parties by reason of breach of this Sixth Amendment, reasonable attorneys' fees and costs as fixed by the court shall be included in such judgement against the losing party or parties.

**19 SUCCESSORS.** This Sixth Amendment and the terms and provisions hereof shall inure to the benefit of and be binding upon the heirs, successors, and assigns of the parties.

**20 AUTHORITY.** Each of the individuals executing this Sixth Amendment represents and warrants that he or she is authorized to execute this Sixth Amendment on behalf of the party for whom he or she is executing this Sixth Amendment and that by his or her signature such party is legally bound by the terms, covenants, and conditions of this Sixth Amendment.

21 GOVERNING LAW. This Sixth Amendment shall be construed and enforced in accordance with the laws of the State of California.

22 CONTINUING VALIDITY OF LEASE. Except as expressly modified herein, the Lease remains in full force and effect.

**23 CONFLICTS.** In the event of any conflict between the provisions of this Sixth Amendment and those of the Lease or of the Addenda, the terms and conditions of this Sixth Amendment shall control.

**24 WHOLE AGREEMENT.** The mutual obligations of the parties as provided herein are the sole consideration for this Sixth Amendment, and no representations, promises, or inducements have been made by the parties other than as appear in this Sixth Amendment, which

supersedes any previous negotiations. There have been no representations made by the Landlord or understandings made between the parties other than those set forth in this Sixth Amendment. This Sixth Amendment may not be amended except in writing signed by all the parties.

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IN WITNESS WHEREOF, the parties have executed this Sixth Amendment as of the date first above written.

KASHIWA FUDOSAN AMERICA, INC., a California corporation

By: /s/ Haru Takehana

Haru Takehana, Vice President

Tenant:

TITAN PHARMACEUTICALS, INC., a Delaware corporation

By: /s/ Louis R. Bucalo

Louis R. Bucalo, M.D.

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Its: Chairman, CEO and President

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Exhibit 10.18

Agreement

Exhibit 14

## TITAN PHARMACEUTICALS, INC.

### CODE OF BUSINESS CONDUCT AND ETHICS

## For Employees, Officers and Directors

### Introduction

To further Titan's fundamental principles of honesty, loyalty, fairness and forthrightness we have established the Titan Pharmaceutical's, Inc. Code of Business Conduct and Ethics. Our Code strives to deter wrongdoing and promote the following six objectives:

- Honest and ethical conduct:
- Avoidance of conflicts of interest between personal and professional relationships;
- Full, fair, accurate, timely and transparent disclosure in periodic reports required to be filed by Titan with the Securities and Exchange Commission and in other public communications made by Titan;
- Compliance with the applicable government regulations;
- Prompt internal reporting of Code violations; and
- Accountability for compliance with the Code.

### Accounting Controls, Procedures & Records

Applicable laws and company policy require Titan to keep books and records that accurately and fairly reflect its transactions and the dispositions of its assets. In this regard, our financial executives shall:

- Provide information that is accurate, complete, objective, relevant, timely and understandable.
- Comply with rules and regulations of federal, state, provincial and local governments, and other appropriate private and public regulatory agencies.
- Act in good faith, responsibly, with due care, competence and diligence, without misrepresenting material facts or allowing independent judgment to be subordinated.

All directors, officers, employees and other persons are prohibited from directly or indirectly falsifying or causing to be false or misleading any financial or accounting book, record or account. Furthermore, no director, officer or employee of Titan may directly or indirectly:

- Make or cause to be made a materially false or misleading statement, or
- Omit to state, or cause another person to omit to state, any material fact necessary to make statements made not misleading in
  connection with the audit of financial statements by independent accountants, the preparation of any required reports whether
  by independent or internal accountants, or any other work which involves or relates to the filing of a document with the
  Securities and Exchange Commission.

## Bribery

The offering, promising, or giving of money, gifts, loans, rewards, favors or anything of value to any supplier, customer or governmental official is strictly prohibited.

### Communications

It is very important that the information disseminated about Titan be both accurate and consistent. For this reason, certain of our executive officers who have been designated as authorized spokespersons per our policy regarding compliance with Regulation FD are responsible for

our internal and external communications, including public communications with stockholders, analysts and other interested members of the

financial community. Employees should refer all outside requests for information to the authorized spokespersons.

### **Computer and Information Systems**

For business purposes, officers and employees are provided telephones and computer workstations and software, including network access to computing systems such as the Internet and e-mail, to improve personal productivity and to efficiently manage proprietary information in a secure and reliable manner. You must obtain the permission from our Information Technology Services department to install any software on any company computer or connect any personal laptop to the Titan network. As with other equipment and assets of Titan, we are each responsible for the appropriate use of these assets. Except for limited personal use of Titan's telephones and computer/e-mail, such equipment may be used only for business purposes. Officers and employees should not expect a right to privacy of their e-mail. All e-mails on company equipment are subject to monitoring by Titan.

### **Confidential or Proprietary Information**

Company policy prohibits employees from disclosing confidential or proprietary information outside Titan, either during or after employment, without company authorization to do so. Unless otherwise agreed to in writing, confidential and proprietary information includes any and all methods, inventions, improvements or discoveries, whether or not patentable or copyrightable, and any other information of a similar nature disclosed to the directors, officers or employees of Titan or otherwise made known to us as a consequence of or through employment or association with Titan (including information originated by the director, officer or employee). This can include, but is not limited to, information regarding our business, research, development, inventions, trade secrets, intellectual property of any type or description, data, business plans, marketing strategies and contract negotiations.

## **Conflicts of Interest**

Company policy prohibits conflicts between the interests of its employees, officers, directors and Titan. A conflict of interest exists when an employee, officer, or director's personal interest interferes or may interfere with the interests of the company. Conflicts of interest may not always be clear, so if an employee has a concern that a conflict of interest may exist, they should consult with higher levels of management, and in the case of officers and directors, they should consult with a member of the Audit Committee. When it is deemed to be in the best interests of Titan and its shareholders, the Audit Committee may grant waivers to employees, officers and directors who have disclosed an actual or potential conflict of interest. Such waivers are subject to approval by the Board of Directors.

## Fraud

Company policy prohibits fraud of any type or description.

## **Inside Information**

Company policy and applicable laws prohibit disclosure of material inside information to anyone outside Titan without a specific business reason for them to know. It is unlawful and against company policy for anyone possessing inside information to use such information for personal gain. Titan's

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policies with respect to the use and disclosure of material non-public information are more particularly set forth in Titan's Insider Trading Policy.

# **Political Contributions**

Company policy prohibits the use of company, personal or other funds or resources on behalf of Titan for political or other purposes which are improper or prohibited by the applicable federal, state, local or foreign laws, rules or regulations. Company contributions or expenditures in connection with election campaigns will be permitted where allowed by federal, state, local or foreign election laws, rules and regulations.

## Reporting and Non-Retaliation

Employees who have evidence of any violations of this code are encouraged and expected to report them to their supervisor, and in the case of officers and directors, they should report evidence of any such violations to a member of the Audit Committee. Such reports will be investigated in reference to applicable laws and company policy. Violations of this Code or any other unlawful acts by our officers, directors or employees may subject the individual to dismissal from employment and/or fines, imprisonment and civil litigation according to applicable laws.

We will not allow retaliation against an employee for reporting a possible violation of this Code in good faith. Retaliation for reporting a federal offense is illegal under federal law and prohibited under this Code. Retaliation for reporting any violation of a law, rule or regulation or a provision of this Code is prohibited. Retaliation will result in discipline up to and including termination of employment and may also result in criminal prosecution.

# Waivers

There shall be no waiver of any part of this Code for any director or officer except by a vote of the Board of Directors or a designated board committee that will ascertain whether a waiver is appropriate under all the circumstances. In case a waiver of this Code is granted to a director or officer, the notice of such waiver shall be posted on our website within five days of the Board of Director's vote or shall be otherwise disclosed as required by applicable law or the American Stock Exchange Rules. Notices posted on our website shall remain there for a period of 12 months and shall be retained in our files as required by law.

Approved By The Board of Directors March 3, 2004

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Exhibit 14

TITAN PHARMACEUTICALS, INC. CODE OF BUSINESS CONDUCT AND ETHICS

**EXHIBIT 23.2** 

## CONSENT OF ERNST & YOUNG LLP, INDEPENDENT AUDITORS

We consent to the incorporation by reference in the Registration Statements on Forms S-8 No. 333-42533, No. 333-86001, No. 333-62734 and No. 333-100011 (pertaining to the 1995 Stock Option Plan and the 1998 Stock Option Plan, as amended and restated, and the 2002 Stock Option Plan), and Forms S-3 No. 333-33710, No. 333-51250, No. 333-53538 and No. 333-112513 of Titan Pharmaceuticals, Inc. of our report dated February 20, 2004 with respect to the consolidated financial statements of Titan Pharmaceuticals, Inc. included in this Annual Report on Form 10-K for the year ended December 31, 2003.

/s/ Ernst & Young LLP

Palo Alto, California March 10, 2004

QuickLinks

EXHIBIT 23.2

CONSENT OF ERNST & YOUNG LLP, INDEPENDENT AUDITORS

**EXHIBIT 31.1** 

## CERTIFICATION PURSUANT TO RULE 13a-14(A) OF THE EXCHANGE ACT

I, Louis R. Bucalo, M.D., Chairman, President and Chief Executive Officer of Titan Pharmaceuticals, Inc., certify that:

- 1. I have reviewed this annual report on Form 10-K of Titan Pharmaceuticals, Inc.;
- Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact
  necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading
  with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation;
  - (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 12, 2004	/s/ LOUIS R. BUCALO
	Louis R. Bucalo, M.D.  Chairman, President and Chief Executive Officer

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EXHIBIT 31.1

CERTIFICATION PURSUANT TO RULE 13a-14(A) OF THE EXCHANGE ACT

## CERTIFICATION PURSUANT TO RULE 13a-14(A) OF THE EXCHANGE ACT

- I, Robert E. Farrell, J.D., Executive Vice President and Chief Financial Officer of Titan Pharmaceuticals, Inc., certify that:
  - 1. I have reviewed this annual report on Form 10-K of Titan Pharmaceuticals, Inc.;
  - Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact
    necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading
    with respect to the period covered by this report;
  - 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
  - 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
    - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    - (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation;
    - (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
  - 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 12, 2004	/s/ ROBERT E. FARRELL
	Robert E. Farrell, J.D.  Executive Vice President and Chief Financial Officer

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EXHIBIT 31.2

CERTIFICATION PURSUANT TO RULE 13a-14(A) OF THE EXCHANGE ACT

**EXHIBIT 32** 

### **CERTIFICATIONS PURSUANT TO 18 U.S.C. SECTION 1350**

In connection with the Annual Report of Titan Pharmaceuticals, Inc. (the "Company") on Form 10-K for the period ended December 31, 2003 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Louis R. Bucalo, M.D., Chairman, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. section 1350, as adopted pursuant to section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company for the period certified.

Signed at the City of South San Francisco, in the State of California, this 12th day of March, 2004.

 /s/ LOUIS R. BUCALO	
Louis R. Bucalo, M.D.	

In connection with the Annual Report of Titan Pharmaceuticals, Inc. (the "Company") on Form 10-K for the period ended December 31, 2003 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Robert E. Farrell, J.D., Executive Vice President and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. section 1350, as adopted pursuant to section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company for the period certified.

Signed at the City of South San Francisco, in the State of California, this 12th day of March, 2004.

/s/ ROBERT E. FARRELL
Robert E. Farrell, J.D.

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**EXHIBIT 32** 

CERTIFICATIONS PURSUANT TO 18 U.S.C. SECTION 1350