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SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

/X/ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE

SECURITIES EXCHANGE ACT OF 1934

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2000

OR

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

Commission File No. 0-27436

TITAN PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

DELAWARE

94-3171940

(State or other jurisdiction of incorporation or organization)

(I.R.S. employer identification number)

400 OYSTER POINT BLVD., SUITE 505, SOUTH SAN FRANCISCO, CALIFORNIA 94080 (Address of principal executive offices, including zip code)

(650) 244-4990

(Registrant's telephone number, including area code)

SECURITIES REGISTERED PURSUANT TO SECTION 12 (b) OF THE ACT: None

SECURITIES REGISTERED PURSUANT TO SECTION 12(g) OF THE ACT: Common Stock, \$.001 par value

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 twelve (12) months (or for such shorter period that the registrant was required to file such report(s)), and (2) has been subject to the filing requirements for the past ninety (90) days. Yes /X/No /

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K 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. /

The aggregate market value of the voting stock held by non-affiliates of the registrant was approximately \$509 million, based on the last sales price of the common stock as of March 23, 2001.

As of March 23, 2001, 27,529,367 shares of common stock, \$.001 par value, of the registrant were issued and outstanding.

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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.

 $Spheramine(R)\,,\; CeaVac(R)\,,\; TriAb(R)\,,\; TriGem(TM)\,,\; Pivanex(R)\; and\; CCM(TM)\\ are\; trademarks\; of\; Titan\; Pharmaceuticals,\; Inc.\; Zomaril(TM)\; is\; a\; trademark\; of\; Novartis\; Pharma\; AG.\; This\; Form\; 10-K\; also\; includes\; trade\; names\; and\; trademarks\; of\; companies\; other\; than\; Titan\; Pharmaceuticals,\; Inc.\;$

(a) GENERAL DEVELOPMENT OF BUSINESS

Titan Pharmaceuticals, Inc. is a biopharmaceutical company developing proprietary therapeutics for the treatment of central nervous system (CNS) disorders, cancer, and other serious and life threatening diseases. Our product development programs focus on large pharmaceutical markets with significant unmet medical needs and commercial potential. We currently have nine products in development, seven of which are in clinical development, with two products in expanded human trials for safety and efficacy, known as Phase III clinical trials. We have five products in trials for preliminary efficacy and dosing and in trials for initial human safety and evidence of efficacy, known as Phase II and Phase I/II clinical trials, respectively. In addition to these programs, we have two products in preclinical development. We are independently developing our product candidates and also utilizing strategic partnerships, including collaborations with Novartis Pharma AG and Schering AG, as well as collaborations with several government-sponsored clinical cooperative groups. These collaborations help fund product development and enable us to retain significant economic interest in our products.

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 are conducted in 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.

(b) FINANCIAL INFORMATION ABOUT INDUSTRY SEGMENTS

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

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(c) NARRATIVE DESCRIPTION OF BUSINESS

PRODUCT DEVELOPMENT PROGRAMS

ZOMARIL (ILOPERIDONE) -- SCHIZOPHRENIA AND RELATED PSYCHOTIC DISORDERS

Our lead CNS therapeutic product candidate, Zomaril, is being developed for the treatment of schizophrenia, the most common form of psychosis. Approximately 2.5 million people in the U.S. are afflicted with the disease, and in 2000, drug therapy for schizophrenia totaled over \$5.0 billion in sales worldwide. While efficacious in reducing psychotic symptoms and allowing patients to function more normally, currently marketed drugs often cause one or more side effects that limit their usefulness, including weight gain and extrapyramidal symptoms such as involuntary muscle movements and rigidity, and cardiac arrhythmia. Zomaril acts by selectively binding with serotonin and dopamine receptors in the brain. This selective binding action helps to reverse the neurotransmitter imbalance believed to be the cause of the symptoms of schizophrenia. Novartis, our worldwide marketing partner in all countries except Japan, is funding clinical trials and will pay us a royalty on net product sales.

Zomaril is currently being evaluated in an extensive Phase III program administered by Novartis comprising over 3,300 patients at 208 sites in 24 countries. Novartis has informed us that the first and second of three planned efficacy studies have been completed, and the completion of the third study is expected in the second quarter of 2001, with projected New Drug Application (NDA) filing in the latter part of 2001. We have been advised by Novartis that in both completed efficacy studies, Zomaril statistically significantly reduced the symptoms of schizophrenia compared to placebo, and demonstrated an excellent safety and tolerability profile. Zomaril is also being investigated in three 12-month safety studies, as well as in a study with elderly patients, all of which have been completed and are in the final data analysis stage.

IMMUNOTHERAPEUTICS--CANCER THERAPY

We are engaged in the development of cancer immunotherapeutics utilizing monoclonal antibody technology licensed from the University of Kentucky Research Foundation. These monoclonal antibody therapeutics under development mimic specific antigens that are primarily present on the targeted cancer cell and are not commonly found on normal tissue. From a molecular biological perspective, the antibody is structurally similar to the cancer antigen. When injected into a patient, the vaccine acts as a trigger for the normal immune system's response of producing anti-cancer antigen antibodies to promote lymphocytes to attack cancer cells.

We are developing three such products that have collectively demonstrated an immune response in humans against antigens associated with colon cancer, breast cancer, ovarian cancer, small cell lung cancer, melanoma and

other cancers. We have established several collaborations with government-sponsored clinical cooperative groups to help fund and develop our cancer immunotherapy products. The products are:

CEAVAC - We believe this product has potential utility in the treatment of adenocarcinomas, notably, colorectal cancer, non-small cell lung cancer, breast cancer, pancreatic cancer and gastric cancer. The target, carcinoembryonic antigen (CEA), is present in the largest group of cancers, adenocarcinomas. We are sponsoring a randomized, double-blind, Phase III trial in approximately 620 patients in Dukes D colorectal cancer. Approximately 95% of the patients

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have been enrolled in this trial to date, which is evaluating the ability of CeaVac to improve survival when administered in combination with standard chemotherapy, consisting of 5-FU/Leucovorin. CeaVac will also be tested in a double-blind, Phase III trial in approximately 1,400 patients with Dukes C colorectal cancer, sponsored by the American College of Surgeons Oncology Group. These trials are intended to potentially serve as the basis for product license applications in these indications if the results are sufficiently positive. CeaVac in combination with TriAb will also be tested in a Phase II trial in patients with non-small cell lung cancer by the Radiation Therapy Oncology Group. We are also pursuing additional clinical trials through cooperative groups.

- TRIAB--We believe this product has potential utility in the treatment of breast, ovarian, colon and non-small cell lung cancer. TriAb is a monoclonal antibody that generates an immune response to the Human Milk Fat Globule (HMFG) protein, present on the aforementioned cancers, as well as other cancers. Phase I/II trials of TriAb in patients with advanced breast cancer have demonstrated strong immune response against HMFG in the majority of patients. In addition, trials of TriAb in patients with advanced breast cancer undergoing autologous stem cell transplants have demonstrated prompt and vigorous immune responses, and patients with good immune responses have demonstrated a decrease in tumor relapse rates. Based on this preliminary data, we are evaluating TriAb in Phase II studies as a treatment for advanced breast cancer both as a single agent as well as in combination with CeaVac and chemotherapy or hormonal therapy.
- TRIGEM--We believe this product has potential utility in the treatment of melanoma, small cell lung cancer and sarcoma. TriGem is a novel monoclonal antibody that has demonstrated the ability to generate an immune response in cancer patients to the GD2 ganglioside, an antigenic glycosphingolipid present in melanoma, lung cancer, and other cancers. Published clinical trial data have demonstrated the ability of TriGem to elicit strong anti-cancer immune responses in patients with advanced malignant melanoma. This immune response was associated with favorable survival and disease progression compared to recent historical data in similar patient groups. The Southwest Oncology Group and other cooperative groups have expressed an interest in working with this product and we are discussing clinical development plans with these groups.
- BIVALENT VACCINE (CEAVAC + TRIAB) --We believe this product allows targeting of tumor cells expressing both the CEA and HMFG tumor associated antigens without adding toxicity. We have initiated studies with this combination vaccine in conjunction with chemotherapy or hormonal therapy for patients with metastatic breast cancer.

PIVANEX--ANTI-CANCER THERAPY BASED UPON CELLULAR DIFFERENTIATION

Pivanex is a novel analog of butyric acid and has demonstrated in laboratory tests the ability to destroy cancer cells through the mechanism of cellular differentiation. Traditional cytotoxic chemotherapeutics tend to kill cancer cells preferentially because cancer cells divide more often and more rapidly than most normal cells. Unfortunately, these agents may also kill rapidly dividing normal cells, such as blood cells and cells of the intestine lining, which leads to the common side effects of anemia, nausea, vomiting and risk of infection. Unlike traditional cytotoxic chemotherapy, differentiation therapy represents a relatively new direction in cancer research, and involves the development of agents that, in contrast to the function of cytotoxic agents, induce cancer cells to differentiate and undergo terminal cellular senescence. Differentiation therapy may also lead to apoptosis, or what is known as normal "programmed cell death,"

are currently studying Pivanex in a Phase II clinical trial in patients with non-small cell lung cancer, and are initiating a Phase II trial in patients with liver tumors.

GALLIUM MALTOLATE--ANTI-CANCER THERAPY AND OTHER TREATMENTS

Gallium maltolate is an orally administered active form of gallium, a semi-metallic element. Intravenously administered gallium has demonstrated preliminary evidence of clinical activity in several cancers, including multiple myeloma, lymphoma, urothelial carcinoma and prostate cancer. Intravenous gallium, as gallium nitrate, received FDA approval in 1991 for hypercalcemia of malignancy. Gallium combines the highly desirable properties of naturally concentrating at sites of malignancy and then acting at these sites to inhibit abnormal cell proliferation. Recently published data from laboratory experiments suggest that gallium may also be effective in treating HIV infection. The mechanism of action may relate to gallium's strong ability to inhibit ribonucleotide reductase, an enzyme essential for DNA synthesis. Because gallium acts on a human enzyme essential to viral replication rather than the virus itself, the ability of the virus to develop drug resistance may be substantially reduced.

Phase I single dose and multiple dose trials of gallium maltolate in normal subjects have demonstrated a good safety profile while achieving potential therapeutic serum drug levels. Observed pharmacokinetic parameters suggest feasibility for once per day or twice per day oral dosing. A Phase II clinical trial in prostate cancer and multiple myeloma is planned for initiation in second quarter 2001. Additionally, we are planning to commence Phase I/II trials in patients with lymphoma, bladder cancer, and in HIV-positive patients late this year.

SPHERAMINE--PARKINSON'S DISEASE

We are engaged in the development of cell-based therapeutics for the treatment of neurologic diseases. Our proprietary technology 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 in order to treat the neurologic disease.

This cell-coated microcarrier (CCM) technology can facilitate site-specific delivery of missing or deficient neurotransmitters and growth factors to diseased or injured areas of the brain by increasing the survival and successful engraftment of implanted cells. Our first product under development based on this technology is Spheramine, consisting of microcarriers coated with dopamine-producing human retinal pigment epithelial cells, for the treatment of Parkinson's disease. Preliminary evidence of efficacy of Spheramine has been demonstrated in a validated primate model of Parkinson's disease (MPTP monkey model). Based on these promising results and successful initial safety testing in primates, we initiated Phase I/II clinical testing of this product in an open-label evaluation of safety and efficacy. This study is being performed at Emory University. In January 2001, we announced treatment of the first cohort of six patients with moderately severe to severe Parkinson's disease receiving Spheramine. These patients have now been 3 to 11 months post treatment and preliminary results from this Phase I/II study will be presented at the American Academy of Neurology meeting in May 2001. Early results from our Phase I/II study have been encouraging, and consistent with results seen in the preclinical studies with the validated primate model.

In January 2000, we entered into an agreement with Schering AG, under which Schering and Titan will collaborate on manufacturing and clinical development of cell therapy for the treatment of Parkinson's disease. Under the agreement, we will perform clinical development activities for which we will receive funding. Schering will fully fund, and manage in collaboration with us, all future pilot and pivotal clinical studies, and manufacturing and development activities. Under this agreement, Schering received exclusive,

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worldwide development, manufacturing and commercialization rights, and, in addition to the above payments and milestone payments, agreed to pay us a royalty on product sales. Schering also retains the right to make an equity investment in Titan, up to a specified amount, upon initiation of pivotal clinical studies. In addition to the collaborative development of Spheramine for Parkinson's disease, Titan and Schering may also mutually explore other potential therapeutic applications of our CCM technology. Titan has continued to investigate other potential applications of the CCM technology with various different cells and disease states such as glioma, Alzheimer's disease, and stem cell applications.

LONG-TERM DRUG DELIVERY SYSTEM

We are developing a sustained drug delivery technology with application in the treatment of a number of neurologic disorders in which conventional treatment is limited by variability of drug concentration in blood and poor patient compliance. The technology, which has been licensed from the Massachusetts Institute of Technology (MIT), consists of a polymeric drug delivery system that potentially can provide controlled drug release over extended periods (i.e., from three months to more than one year). The technology involves imbedding the drug of interest in a polymer, which is then implanted subcutaneously to provide systemic delivery 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 highly desirable by avoiding peak and trough level dosing that poses problems for many CNS and other therapeutic agents.

Additional pre-clinical experiments were completed during 2000 on a product being developed for the potential treatment of drug addiction, demonstrating long-term drug delivery using the proprietary polymeric drug delivery system. This study, which was supported by an SBIR Phase I grant from the National Institutes of Health (NIH), demonstrated proof of concept in animal models by delivering sustained therapeutic drug levels for periods of greater than three months, without systemic adverse effects.

We are conducting further pre-clinical evaluation, including toxicology studies directed at filing an Investigational New Drug (IND) application for pilot clinical trials in the treatment of drug addiction by late 2001, and we are also developing products for the treatment of alcohol addiction and Parkinson's disease.

GENE THERAPY PRODUCTS--CANCER

We are currently developing RB94, a gene therapy product for the treatment of cancer, under an exclusive worldwide license from the Baylor College of Medicine. RB94 combines a truncated variant (p94) of the RB gene, a tumor suppressor gene, with a viral vector. We believe the form of the RB protein encoded by the RB94 gene therapy product is more effective at causing suppression of tumor cells than the full-length RB protein, based on data demonstrating in vitro suppression of numerous tumor types tested to date, including tumors of the bladder, prostate, cervix, bone, breast, lung and fibrous tissue. In addition, preliminary experiments indicate the modified gene is effective in suppressing some cancer cell lines in vitro that continue to contain the functional native RB gene.

We are currently testing RB94 in pre-clinical studies of solid tumors in mouse models, and expect to conduct additional pre-clinical testing in preparation for pilot clinical trials in late 2001.

Through a cross-license agreement with Selective Genetics, we acquired rights to develop cancer therapies using Selective's proprietary cancer cell targeting technology in conjunction with RB94. We plan to combine these technologies to potentially enable systemic anti-cancer gene therapy.

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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.

ZOMARIL (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, the scientific name for Zomaril, 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 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 Zomaril. 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 net sales of the product, providing Titan with a net royalty of 8% on the first \$200 million sales annually and 10% on all sales above \$200 million on an annual basis.

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 analogs. The Kentucky agreement requires 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 net sales of licensed products by any sublicensees or us. 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 net sales of licensed products by any sublicensees or us. Our minimum annual

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 analogs 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. Our minimum annual royalty is \$60,000.

We must also satisfy certain other terms and conditions set forth in the Bar-Ilan agreement in order

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to retain our license rights, including:

- the use of reasonable best efforts to bring any products developed under the Bar-Ilan agreement to market,
- the timely commencement of toxicology testing on small and large animals,
- the development of and compliance with a detailed business plan, and
- the timely payment of royalty fees.

All of the above conditions have been met to date.

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 net sales of products and processes incorporating the licensed technology. We must also pay all costs and expenses incurred in patent prosecution and maintenance.

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 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 an agreement with Schering AG, under which 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 may terminate this sublicense for any reason by providing 90 days prior notice to us.

LONG-TERM DRUG DELIVERY SYSTEM

In October 1995, we acquired from 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 the condition that an IND be filed with the FDA by December 31, 2001. 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.

GENE THERAPY PRODUCTS

In October 1992, we acquired an exclusive, worldwide license under United States and foreign

gene, including its use in conferring senescence to tumors that form the basis of RB94. The Baylor license provides for royalties based on net sales of products and processes incorporating the licensed technology, subject to certain minimum annual amounts and a percentage of sublicensing income arising from the license of such products and processes. Under the Baylor license, we must:

- use reasonable best efforts to bring any products developed under the Baylor license to market.
- develop and comply with a detailed business plan,
- fund research pursuant to the Baylor research agreement,
- commence a cancer therapy research program,
- make timely payment of royalty fees, and
- pay all costs and expenses incurred in patent filing, prosecution and maintenance.

We are a party to several license agreements with the University of Illinois at Chicago, which granted us the exclusive worldwide license under certain issued patents and patent applications, including those relating to methods for preventing multi-drug resistance and the human MDR1 gene. The exclusive nature of the Chicago licenses is subject in certain instances to certain reservations, including the use of all or part of the licensed technology for research, education and other non-commercial purposes. In addition, our rights under the MDR1 license are subject to a non-exclusive right granted to Glaxo-Wellcome to transfect cell lines with the MDR1 gene, and to use the transfectants for research purposes. Glaxo-Wellcome does not, however, have the right to sell or transfer the transfectants or any derivatives thereof, without the written authorization of the University of Illinois at Chicago.

In September 1999, we granted an exclusive worldwide sublicense to GenTest Inc. for the right to manufacture, distribute and sell products developed under the University of Illinois at Chicago patent rights related to cDNA-expressed MDR1 protein. In July 2000, we granted an exclusive worldwide sublicense to Epidauros Biotechnologies AG for the right to manufacture, distribute and sell products developed under the University of Illinois at Chicago patent rights related to the use of MDR1 gene in pharmacogenomics.

We acquired an exclusive license from MIT under an issued patent relating to the use of MDR genes for creating and selecting drug resistant mammalian cells. The MIT MDR license is subject to prior grants of:

- an irrevocable, royalty-free, non-exclusive license granted to the United States government,
- non-exclusive licenses granted to Eli Lilly, Inc. and Genetics Institute, Inc. for research purposes, and
- non-exclusive, commercial licenses that may be granted pursuant to options granted to Eli Lilly and Genetics Institute to use aspects of the licensed technology but only to make products that do not incorporate genes claimed in the patent, proteins expressed by such genes or antibodies and inhibitors to such genes.

The MIT MDR license provides for the payment of royalties based on net sales of products and processes incorporating the licensed technology, subject to certain minimum annual amounts, a percentage of sublicensing income arising from the license of such products and processes, and the issuance of Ingenex's common stock to MIT. Under the MIT MDR license, we must also:

- use reasonable best efforts to bring any products developed under the MIT MDR license to market,
- develop and comply with a detailed business plan and

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make timely payment of license and royalty fees.

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."

ZOMARIL (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 Zomaril 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 analogs. U.S. patents have been issued that relate to aspects of these technologies. Prosecution of patent applications relating to these technologies continues satisfactorily, as does prosecution of various divisional and continuation applications and their foreign counterparts for all the antibodies, although it is uncertain whether additional patents will be granted. Unless its term is extended, the U.S. patent that covers certain aspects of CeaVac and its use will expire in 2015.

PTVANEX

We are the exclusive licensee under the Bar-Ilan agreement of an issued U.S. patent and certain foreign patents, and patent applications relating to certain aspects of our Pivanex product candidate. Prosecution of various divisional and continuation applications and their foreign counterparts continues satisfactorily, although it is uncertain whether additional patents will be granted.

GALLIUM COMPLEXES

We are the exclusive licensee under the license agreement with Dr. Lawrence Bernstein on several issued U.S. patents and patent applications covering the pharmaceutical compositions, application and administration of gallium complexes.

CELL THERAPY PRODUCTS

We are the exclusive licensee under a license agreement with NYU of U.S. and foreign patent applications relating to our CCM technology. The Patent and Trademark Office has issued three U.S. patents on the core subject material underlying the NYU license. Unless its term is extended, the U.S.

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patents that cover certain aspects of our Spheramine product and its use will expire between 2014 and 2017. An Australian patent on the core material of a patent application underlying the NYU license was granted in May 1996. Prosecution of various divisional and continuation applications and their foreign counterparts continues satisfactorily, although it is uncertain whether additional patents will be granted.

LONG-TERM DRUG DELIVERY SYSTEM

We are the exclusive licensee under the MIT license to three United States and certain European patents relating to a long-term drug delivery system.

GENE THERAPY PRODUCT--RB94

We are the exclusive licensee under the Baylor license of U.S. and foreign patent applications relating to the RB gene, including its use in conferring senescence to tumors that form the basis of RB94. We are aware of the existence of a prior art reference, European Patent Application 0 259 031 (EP 0 259 031), which discloses a DNA sequence corresponding to the sequence of the RB94 DNA molecule that is claimed in a U.S. patent licensed to us from Baylor College of Medicine. The Baylor patent also contains claims directed to specific expression vectors containing these DNA molecules. Although a patent is presumed valid, we cannot assure that the claims of the Baylor patent, if challenged, will not be found invalid.

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 targeted by us. 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.

CENTRAL NERVOUS SYSTEM THERAPEUTICS

ZOMARIL

With respect to Zomaril, 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 PLC, and Geodon sold by Pfizer. Competition among these companies is already intense and Zomaril, expected to be the fifth or sixth such product on the market, will face significant competition. The success of Zomaril will depend on how it can be differentiated from products already on the market on the basis of efficacy, side-effect profile, cost, availability of formulations and dose requirements, among other things.

SPHERAMINE

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

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central nervous system. In addition, several well-funded public and private companies are actively pursuing alternative cell transplant technologies, including StemCells, Inc. and Diacrin, Inc. NeuroCell-PD, a product under development by Diacrin, Inc. involves using antibodies to eliminate the need for immunosuppression when transplanting fetal pig cells into Parkinson's patients, and would directly compete with Spheramine.

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. Additionally, companies such as Medtronic are developing implantable pumps that could be used to infuse drugs into the central nervous system.

CANCER THERAPEUTICS

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.

RB94

With regard to our gene therapy products, we are aware of several development stage and established enterprises that are exploring the field of human gene therapy or are actively engaged in research and development in this area, including Genetix Pharmaceuticals, Inc. and two research organizations receiving funding from the NIH. We are aware of other commercial entities that have produced gene therapy products used in human trials. Further, it is expected that competition in this field will intensify.

GALLIUM COMPLEXES

We are aware that intravenously administered gallium nitrate is approved to treat hypercalcemia related to malignancy and may have potential for treatment of certain cancers. Other intravenous products including the bisphosphonates are available or are in development in the U.S. or Europe to treat osteoporosis, Paget's disease, primary hyperparathyroidism, hypercalcemia of malignancy and metastatic bone disease. Our product, gallium maltolate, is an orally administered drug and may have potential advantages in the treatment of cancer.

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 be directly competitive with the technologies being developed by us.

See "Risk Factors-We face intense competition."

MANUFACTURING

We utilize contract manufacturing organizations to manufacture our products for preclinical $% \left(1\right) =\left(1\right) +\left(1\right)$

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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 others. In most cases, such proof entails extensive clinical and pre-clinical laboratory tests.

The procedure for obtaining FDA approval to market a new drug involves several steps. Initially, the manufacturer must conduct pre-clinical animal testing to demonstrate that the product does not pose an unreasonable risk to human subjects in clinical studies. Upon completion of such animal testing, an IND application 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 fails to act within 30 days), the clinical trials may begin.

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

The results of the pre-clinical and clinical testing on new drugs are submitted to the FDA in the form of an 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 NIH, covering deliberate transfers of recombinant DNA into human subjects conducted within NIH laboratories or with NIH funds, which provide 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

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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 those countries. 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 46 full-time employees. None of our employees are represented by a labor union. We have not experienced any work stoppages and consider our relations with our employees to be good. See "Risk Factors-We may not be able to retain our key management and scientific personnel."

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, 2000, we had an accumulated deficit of approximately \$84.2 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. 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, Zomaril is furthest in development and any significant delays in its development, regulatory approval or commercialization may seriously harm our business.

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 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. We depend on third-party laboratories and medical institutions conducting preclinical studies and clinical trials for our products to maintain both good laboratory and good clinical practices, which are outside our direct control. 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, which are similarly outside our direct control.

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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 meet the 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 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. Several of our product candidates, including Zomaril and CeaVac, are currently in Phase II and Phase III human clinical trials. We may not be able to demonstrate that any of our product candidates will be safe or effective in these advanced trials that involve larger numbers of patients. Our product development programs may 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 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:

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- obtain and keep patent protection for our products and technologies on an international basis;
- enforce our patents to prevent others from using our inventions;
- maintain and prevent others from using our trade secrets; and
- operate and commercialize products without infringing on the patents or proprietary rights of others.

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

If we sue others for infringing our patents, a court may determine that such patents are invalid or unenforceable. Even if the validity of our patent rights is upheld by a court, a court may not prevent the alleged infringement of our patent rights on the grounds that such activity is not covered by our patent claims.

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

- pay substantial damages;
- stop using our technologies and methods;
- stop certain research and development efforts;

- develop non-infringing products or methods; and
- obtain one or more licenses from third parties.

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

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 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 and is expected to increase. 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

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capabilities, experience in obtaining regulatory approvals and manufacturing, marketing, financial and managerial resources than we have. We also compete with universities and other research institutions in the development of products, technologies and processes, as well as the recruitment of highly qualified personnel. Our competitors may succeed in developing technologies or products that are more effective than the ones we have under development or that render our proposed products or technologies noncompetitive or obsolete. In addition, certain of such competitors may achieve product commercialization or patent protection earlier than us. For example, with respect to Zomaril, several competing products are already on the market and Zomaril, expected to be the fifth or sixth such product, will face significant competition.

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 Zomaril is almost entirely dependent upon Novartis conducting the Phase III trials and completing the regulatory approval process and implementing the marketing program necessary to commercialize Zomaril if the product is approved by the FDA. Beyond our contractual rights, we cannot control the amount or timing of resources that Novartis devotes to these matters. In addition, we receive substantial government funding for our Spheramine and 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 seriously harmed. 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 any such third-party 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. Schering AG, our collaborator for the development and commercialization of Spheramine, may terminate their sublicense agreement with us for any reason by providing 90 days prior notice to us.

WE MUST MEET PAYMENT AND OTHER OBLIGATIONS UNDER OUR LICENSE AND SPONSORED RESEARCH AGREEMENT. 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

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enter into additional collaborative arrangements to manufacture or market any proposed products or, in lieu thereof, establish our own manufacturing operations or sales force.

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 small 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, 2000, we had approximately \$117.5 million of cash, cash equivalents, and marketable securities that we believe will enable us to fund our operations through 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 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 any needed financing, we will be required to reduce, defer or discontinue our product development programs. We may be required to obtain funds on terms that are not acceptable, if at all.

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 securities.

- variations in our anticipated or actual operating results;
- sales of substantial amounts of our 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.

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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.

In the past, companies that have experienced volatility in the market prices of their stock have been the object of securities class action litigation. If we were the object of securities class action litigation, it could result in substantial costs and a diversion of management's attention and resources.

ITEM 2. PROPERTIES

We have a four-year lease, expiring in June 2002, for approximately 10,000 square feet of office space in South San Francisco, California. We also have a five-year lease, expiring in October 2003, for approximately 4,200 square feet of office and laboratory space in Somerville, New Jersey.

TTEM 3. LEGAL PROCEEDINGS

In March 2000, a former investor relations consultant commenced an action in the Supreme Court of the State of New York, New York County, alleging that Titan purportedly breached an agreement dated February 24, 1997, by failing to delivery certain warrants to the plaintiffs. We are vigorously defending the pending action.

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.

(a) PRICE RANGE OF SECURITIES

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

<TABLE> <CAPTION>

| | HIGH | LOW |
|--------------------------------------|----------|----------|
| <\$> | <c></c> | <c></c> |
| Fiscal Year Ended December 31, 2000: | | |
| First Quarter | \$53.000 | \$15.000 |
| Second Quarter | \$45.000 | \$18.875 |
| Third Quarter | \$65.300 | \$33.000 |
| Fourth Quarter | \$64.750 | \$31.400 |
| Fiscal Year Ended December 31, 1999: | | |
| First Quarter | \$4.750 | \$3.250 |
| Second Quarter | \$4.938 | \$2.750 |
| Third Quarter | \$13.563 | \$4.313 |
| Fourth Quarter | \$19.500 | \$6.750 |
| | | |

 | |

(b) APPROXIMATE NUMBER OF EQUITY SECURITY HOLDERS

The number of record holders of our common stock as of March 23, 2001 was approximately 175. Based on the last ADP search, we believe there are in excess of 10,000 beneficial holders of the 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 more detailed 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."

| VEAD | רשחואש | DECEMBER | 21 | |
|------|--------|----------|----|--|

| | 2000 | 1999 (IN THOUSANDS, | 1998 EXCEPT PER | 1997 SHARE DATA) | 1996 |
|-------------------------------------|-------------|------------------------|--------------------|---------------------|---------------|
| <s></s> | <c></c> | <c></c> | <c></c> | <c></c> | <c></c> |
| STATEMENT OF OPERATIONS DATA: | | | | | |
| Total revenue (1) | \$ 1,880 | <i>\$ 337</i> | <i>\$</i> - | \$ 17,500 | <i>\$ 259</i> |
| Operating expenses: | | | | | |
| Research and development | 16,744 | 9,429 | 7,813 | 9,310 | 5,567 |
| Acquired in-process research and | | | | | |
| development (2) | 4,969 | 136 | _ | 9,500 | _ |
| General and administrative | 4,070 | 2,794 | 3,708 | 6,514 | 5,264 |
| Other income (expense), net (3) | 5,115 | 726 | 907 | 8,415 | (2, 294) |
| Net (loss) income | \$ (18,788) | \$ (11,296) | \$ (10,614) | \$ 592 | \$ (12,856) |
| Basic net (loss) income per share | \$(0.73) | \$(0.70) | \$(0.81) | \$0.05 | \$(1.67) |
| Diluted net (loss) income per share | \$(0.73) | \$(0.70) | \$(0.81) | \$0.04 | \$(1.67) |
| Shares used in computing: | | | | | |
| Basic net (loss) income per share | 25,591 | 16,112 | 13,109 | 13,002 | 10,936 |
| Diluted net (loss) income per share | | | | | |

 25, 591 | 16,112 | 13, 109 | 13,477 | 10,936 |(1) Revenues for 1997 include \$17.4 million from fees related to the sublicense of Zomaril to Novartis.

(2) Acquired in-process research and development reflects the acquisition of GeoMed in 2000, the acquisition of a minority interest in Theracell in 1999, and the acquisition of an exclusive worldwide license for iloperidone in 1997.

(3) Other income for 1997 includes a gain of \$8.4 million from the sale of a research technology.

<TABLE> <CAPTION>

AS OF DECEMBER 31,

| | 2000 | 1999 | 1998 (IN THOUSANDS) | 1997 | 1996 |
|--|-----------|----------|------------------------|----------|---------|
| <s></s> | <c></c> | <c></c> | <c></c> | <c></c> | <c></c> |
| BALANCE SHEET DATA: | | | | | |
| Cash, cash equivalents, and marketable | | | | | |
| securities | \$117,523 | \$46,454 | \$11,655 | \$24,387 | \$1,377 |
| Working capital | 115,386 | 45,128 | 10,215 | 23,642 | 12,174 |
| Total assets | 118,442 | 47,362 | 12,228 | 25,594 | 16,366 |
| Long-term debt | - | _ | _ | _ | 1,200 |
| Total stockholders' equity | 114,738 | 44,302 | 9,406 | 17,178 | 11,411 |
| | | | | | |

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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," "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.

 $Spheramine\left(R\right),\ CeaVac\left(R\right),\ TriAb\left(R\right),\ TriGem\left(TM\right),\ Pivanex\left(R\right)\ and\ CCM\left(TM\right)\\ are\ trademarks\ of\ Titan\ Pharmaceuticals,\ Inc.\ Zomaril\left(TM\right)\ is\ a\ trademark\ of\ Novartis\ Pharma\ AG.$

OVERVIEW

We are a biopharmaceutical company developing proprietary therapeutics for the treatment of central nervous system (CNS) disorders, cancer and other

Our most advanced product candidate, Zomaril (iloperidone), is a novel antipsychotic agent under development for the treatment of patients with schizophrenia. Zomaril is currently in Phase III clinical testing through a licensing and development agreement with Novartis Pharma AG. We have been advised by Novartis that in two completed efficacy studies, Zomaril statistically significantly reduced the symptoms of schizophrenia compared to placebo, and demonstrated an excellent safety and tolerability profile. Also in the CNS arena, we are developing a unique cell based therapeutic, Spheramine, for the treatment of patients with Parkinson's disease. In January 2001, we announced treatment of the first cohort of six patients with moderately severe to severe Parkinson's disease receiving Spheramine. Preliminary results from this Phase I/II study will be presented later in the year at scientific meetings. We have entered into a collaboration with Schering AG for the development, manufacture and commercialization of this treatment for Parkinson's disease, and Schering is funding the manufacturing, development and further clinical studies of the product and will make milestone payments and pay a royalty on net product sales in exchange for worldwide commercialization rights. Our cancer portfolio includes three therapeutic monoclonal antibodies-CeaVac, TriAb, and TriGem-that are designed to stimulate a patient's immune system against cancer cells. CeaVac is currently being evaluated in a large multi-center double-blind placebo-controlled Phase III clinical trial in patients with metastatic colorectal cancer. TriAb is currently being evaluated in a double-blind placebo-controlled Phase II clinical study in patients with breast cancer. TriGem is being studied in a Phase II trial of malignant melanoma. We are also currently conducting a Phase II clinical trial with Pivanex, a novel synthetic analog of butyric acid, for the treatment of patients with non-small cell lung cancer. Gallium maltolate, an orally administered form of qallium, will be tested in a Phase II study in patients with prostate cancer and multiple myeloma. Additionally, we are planning a Phase I/II study with gallium maltolate in HIV patients. Our other programs in pre-clinical development include a cancer gene therapy product and a long-term drug delivery technology.

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RESULTS OF OPERATIONS

COMPARISON OF YEARS ENDED DECEMBER 31, 2000 AND 1999

Revenues in 2000 were \$1.9 million compared to \$0.3\$ million for 1999, an increase of \$1.6 million. The increase in revenue is primarily due to our corporate partnership with Schering AG for the development and commercialization of Spheramine for the treatment of Parkinson's disease.

Ongoing research and development expenses for 2000 were \$16.7 million, compared to \$9.4 million for 1999, an increase of \$7.3 million. The planned increase in ongoing research and development expenditures from 1999 to 2000 was a result of the expansion of our randomized, placebo-controlled Phase III clinical study of CeaVac in Dukes D colorectal cancer, commencement of our Phase I/II clinical study of Spheramine in Parkinson's disease, advancement of our preclinical development programs and increased manufacturing and development activity for all of our product candidates. Also in year 2000 we recorded a \$5.0 million acquired in-process research and development expense in connection with the acquisition of gallium maltolate, a novel and proprietary agent for the potential treatment of cancer and other conditions, including HIV infection. The entire purchase price was charged to acquired in-process research and development on the acquisition date in accordance with generally accepted accounting principles. See Note 8 to the Consolidated Financial Statements beginning on page F-1 in this report.

General and administrative expenses for 2000 were \$4.1 million compared to \$2.8 million for 1999, an increase of \$1.3 million. The increase was in support of our expanded clinical operations, infrastructure development and non-cash compensation charges related to stock options.

Other income, net, for 2000 was \$5.1 million compared to \$0.7 million for 1999, an increase of \$4.4 million. Other income, net, for 2000 and 1999 primarily consisted of interest income. The increase in interest income resulted from a significantly larger cash and marketable securities position in 2000.

As a result of the foregoing, we had a net loss of \$18.8\$ million in 2000 compared to a net loss of \$11.3\$ million in 1999.

None of our products have been commercialized, and we do not expect to generate any revenue from product sales or royalties until at least the fourth quarter of 2002. With the advancement in clinical development of our products, we anticipate research and development expenses will increase in the near future, while general and administrative costs necessary to support such research and development activities will increase at a controlled rate. We will also seek 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 1999 of \$0.3 million consisted primarily of U.S. government grants. There were no revenues for 1998.

Research and development expenses for 1999 were \$9.6 million, including \$0.1 million of acquired in-process research and development related to the acquisition of the minority interest of Theracell, compared to \$7.8 million for 1998, an increase of \$1.8 million. The planned increase compared to 1998 was attributable to patient enrollment in the clinical trial with CeaVac in colorectal cancer and the final phases of the pre-clinical program for Spheramine in preparation for Phase I/II clinical trial. General and

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administrative expenses for 1999 were \$2.8 million compared to \$3.7 million for 1998, a decrease of \$0.9 million. The decrease was attributable to ongoing efforts to contain non-research operating costs.

Other income for 1999 was \$0.7 million compared to \$0.9 million for 1998, a decrease of \$0.2 million. Other income for 1999 and 1998 primarily consisted of interest income.

As a result of the foregoing, we had a net loss of \$11.3 million in 1999 compared to a net loss of \$10.6\$ million in 1998.

LIQUIDITY AND CAPITAL RESOURCES

We have funded our operations since inception primarily through our initial public offering and private placements of our securities, as well as proceeds from warrant and option exercises, corporate licensing and collaborative agreements, and government sponsored research grants. At December 31, 2000, we had \$117.5 million of cash, cash equivalents, and marketable securities.

In November 2000, we completed a private placement of 1.2 million shares of our common stock for net proceeds of approximately \$40.9 million, after deducting fees and commissions and other expenses of the offering.

In March 2000, we completed a private placement of 1.2 million shares of our common stock for net proceeds of approximately \$38.8 million, after deducting fees and commissions and other expenses of the offering.

In October 1999, we called for the redemption on November 19, 1999 (the Redemption Date) of our outstanding Class A Warrants for cash at the redemption price of \$0.05 per warrant. Rather than surrendering the warrants for redemption, warrant holders had the option to purchase our common stock by exercising the warrant at a price of \$6.02 per share before the Redemption Date. The warrant call resulted in 7.1 million, or 99.4\$, of our outstanding Class A Warrants being exercised with net proceeds of \$39.4 million, after deducting advisory fees and other related expenses.

In January 1999, we completed a private placement of 2.3 million shares of our common stock for net proceeds of \$5.8 million, after deducting fees and commissions and other expenses of the offering.

Our operating activities used \$13.2 million, \$10.9 million and \$13.2 million of cash in 2000, 1999 and 1998, respectively. 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. The aggregate commitments we have under these agreements, including minimum license payments, for the next 12 months is approximately \$0.7 million. 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 and meeting project-funding milestones. We also have lease commitments under non-cancelable operating leases of \$0.8 million until 2003.

We expect to continue to incur substantial additional operating losses from costs related to continuation and expansion of product and technology development, clinical trials, and administrative activities. We believe that we currently have sufficient working capital to sustain our planned operations through 2005.

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RECENT ACCOUNTING PRONOUNCEMENT

In June 1998, the Financial Accounting Standards Board issued SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities" (SFAS 133), which establishes accounting and reporting standards for derivative instruments, including certain derivative instruments embedded in other contracts, and for

hedging activities. In June 1999, the FASB issued SFAS No. 137, "Accounting for Derivative Instruments and Hedging Activities—Deferral of the Effective Date of FASB Statement No. 133." We are required to adopt SFAS 133 effective January 1, 2001. Because we do not hold any derivative instruments and do not engage in hedging activities, management does not believe the adoption of SFAS 133 will have an impact on our financial position or results of operations.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our portfolio of marketable securities creates an exposure 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. 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, 2000 (in thousands, except interest rate):

| <table></table> | | | | | |
|---------------------------------|----------|----------|----------|----------|------------|
| <caption></caption> | | | | | ECHTIM HED |
| CASH EQUIVALENTS AND MARKETABLE | 0001 | 0000 | 0000 | | ESTIMATED |
| SECURITIES: | 2001 | 2002 | 2003 | TOTAL | FAIR VALUE |
| <\$> | <c></c> | <c></c> | <c></c> | <c></c> | <c></c> |
| Variable rate securities | \$17,835 | - | - | \$17,835 | \$17,835 |
| Average interest rate | 6.330% | - | - | 6.330% | |
| Fixed rate securities | \$41,650 | \$39,225 | \$12,300 | \$93,175 | \$95,258 |
| Average interest rate | | | | | |

 6.232% | 6.874% | 5.563% | 6.414% | |

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.

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ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF REGISTRANT.

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

| <table> <caption></caption></table> | | |
|--|---------|--|
| NAME | AGE | POSITION |
| <\$> | <c></c> | <c></c> |
| Louis R. Bucalo, M.D. (1) | . 42 | Chairman, President and Chief Executive Officer |
| Sunil Bhonsle | . 51 | Executive Vice President and Chief Operating Officer |
| Richard C. Allen, Ph.D | . 58 | Executive Vice President, Cell Therapy |
| Robert E. Farrell | . 51 | Executive Vice President and Chief Financial Officer |
| Jan D. Wallace, M.D | . 59 | Executive Vice President, Clinical Development and |
| | | Regulatory Affairs |
| Victor Bauer, Ph.D | . 65 | Executive Director, Corporate Development and Director |
| Ernst-Gunter Afting, M.D., Ph.D. (2) (3) | . 58 | Director |
| Eurelio M. Cavalier (1) | . 68 | Director |
| Michael K. Hsu (2) | . 51 | Director |
| Hubert Huckel, M.D. (1) (2) (3) | . 69 | Director |
| Ley S. Smith (1) | . 66 | Director |
| Konrad M. Weis, Ph.D. (1)(3) | . 72 | Director |
| | | |

 | |

- (1) Member of Executive Committee
- (2) Member of Audit Committee
- (3) Member of Compensation Committee

Louis R. Bucalo, M.D. is a 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. 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

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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.

Jan D. Wallace, M.D., has served as our Executive Vice President of Clinical Development and Regulatory Affairs since March 2000. From March 1998 until joining Titan, Dr. Wallace served as Senior Vice President, Clinical and Regulatory Affairs, for Elan Pharmaceuticals. From May 1992 until March 1998, he served as Vice President, Clinical and Regulatory Affairs, of Athena Neurosciences, Inc. Prior thereto, Dr. Wallace spent approximately five years at Warner-Lambert/Parke Davis, employed in various executive positions.

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.

Ernst-Gunter 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.

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.
He serves on the Advisory Board of COR Therapeutics and Indiana Heart Institute.

Michael K. Hsu has served on our Board of Directors since March 1993. He is currently a General Partner of EndPoint Merchant Group, a merchant bank specializing in making investments into the healthcare and life science industries. Mr. Hsu 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.

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,

Center. He currently serves on the Board of Directors of BioStar, Inc., MDS, Inc., Crescendo Pharmaceuticals, Illuminis and is a member of the Regional Board of National City Corp.

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

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

DIRECTOR COMPENSATION

Directors are entitled to receive options pursuant to our Amended 1998 Stock Option Plan. During 2000, each of our current directors received a bi-annual (i.e. every two years) option grant to purchase 15,000 shares of our common stock at an exercise price of \$43.625. In addition, each director received an option grant to purchase 5,000 shares of our common stock at an exercise price of \$43.625 for each committee served. Upon being elected director in July 2000, Mr. Ley S. Smith received an option grant to purchase 10,000 shares of our common stock at an exercise price of \$33.75. Directors are reimbursed for their expenses in attending Board of Directors meetings. Directors are not precluded from serving us in any other capacity and receiving compensation therefor.

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

We are a party to a consulting agreement with Dr. Jaffe, a former director of Titan, pursuant to which he receives fees of \$35,000 annually.

BOARD COMMITTEES AND DESIGNATED DIRECTORS

The Board of Directors has an Executive Committee, a Compensation Committee and an Audit 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. The Compensation Committee makes recommendations to the Board concerning salaries and incentive compensation for our officers and employees and administers our stock option plans. The Audit Committee reviews the results and scope of the audit and other accounting related matters.

The Board of Directors met four times during 2000 and also took action by unanimous written consent. The Executive Committee met four times and also took action by unanimous written consent, the Compensation Committee met two times and also took action by unanimous written consent, and the Audit Committee met one time. Each of our current directors attended at least 75% of the aggregate of (i) the meetings of the Board of Directors and (ii) meetings of any Committees of the Board on which such person served which were held during the time such person served, except that Mr. Smith attended two out of three meetings held after he was appointed a director, and Mr. Cavalier attended five out of seven meetings.

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COMPLIANCE WITH SECTION 16(a) OF THE SECURITIES EXCHANGE ACT OF 1934

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

Based solely on our review of such forms furnished to us and written representations from certain reporting persons, we believe that all filing requirements applicable to our executive officers, directors and greater than 10% beneficial owners were complied with, except as follows: Dr. Afting filed a Form 4 three days late, Dr. Bauer filed a Form 4 approximately two weeks late, and Mr. Smith filed a Form 3 and Form 4 several weeks late.

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 and to executive officers whose annual compensation exceeded \$100,000 for the fiscal year ended December 31, 2000 (collectively, the "named executive officers") for services during the fiscal years ended December 31, 2000, 1999 and 1998:

| | ANNUAL COMPENSATION | | |
|---------------------------------------|---------------------|--------------|--|
| NAME AND PRINCIPAL POSITION | YEAR | SALARY | |
| <\$> | <c></c> | <c></c> | |
| Louis R. Bucalo | 2000 | \$261,891 | |
| President and Chief Executive Officer | 1999 | \$222,013 | |
| | 1998 | \$243,100 | |
| Sunil Bhonsle | 2000 | \$202,842 | |
| Executive Vice President and | 1999 | \$180,100 | |
| Chief Operating Officer | 1998 | \$194,800 | |
| Richard C. Allen | 2000 | \$202,842 | |
| Executive Vice President | 1999 | \$180,475 | |
| | 1998 | \$197,800 | |
| Robert E. Farrell | 2000 | \$195,211 | |
| Executive Vice President and | 1999 | \$173,425 | |
| Chief Financial Officer | 1998 | \$190,400 | |
| Jan D. Wallace | 2000 | \$232,929(1) | |
| Executive Vice President | | | |

 | || | | |
(1) Dr. Wallace joined Titan in March 2000.

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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, 2000. No stock appreciation rights were granted to these individuals during such year.

<TABLE> <CAPTION>

| | | INDIVIDUAL GRANT | | | |
|-----------------------------|--|--|---------------------------------------|------------------------|--|
| NAME | NUMBER OF SECURITIES UNDERLYING OPTIONS GRANTED | % OF TOTAL OPTIONS GRANTED TO EMPLOYEES LAST FISCAL YEAR | EXERCISE OR BASE PRICE (\$/SH) (1) | EXPIRATION DATE | |
| <s> Louis R. Bucalo</s> | <c></c> | <c> 3.32%</c> | <c> \$43.625</c> | <c> 08/28/2010</c> | |
| Jan D. Wallace | 20,000 230,000 | 38.14% | \$38.750 | 03/10/2010 | |

(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. We may also finance the option exercise by loaning the optionee sufficient funds to pay the exercise price for the purchased shares, together with any federal and state income tax liability incurred by the optionee in connection with such exercise.

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, 2000 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.

<TABLE> <CAPTION>

| | SHARES ACOUIRED ON | NUMBER OF SECURITIES UNDERLYING UNEXERCISED OPTIONS AT FY-END | | VALUE OF UNEXERCISED IN-THE-MOOPTIONS AT FY-END (1) | |
|--------------------|-----------------------|--|---------------|---|------------------|
| NAME | EXERCISE | EXERCISABLE | UNEXERCISABLE | EXERCISABLE | UNEXERCISABLE |
| <s></s> | <c> -</c> | <c></c> | <c></c> | <c></c> | <c></c> |
| Louis R. Bucalo | -0- | 974,034 | 273,140 | \$27,678,361 | \$5,812,766 |
| Sunil Bhonsle | -0- | 517,743 | 117,556 | \$15,199,672 | \$2,666,405 |
| Richard C. Allen | -0- | 377,350 | 84,334 | \$11,690,184 | \$1,912,864 |
| Robert E. Farrell | 86,930 | 136,103 | 42,167 | \$3,702,325 | <i>\$956,432</i> |
| Jan D. Wallace | | | | | |

 -0- | 0 | 230,000 | \$0 | \$0 |(1) Based on the fair market value of our common stock at year-end, \$35.37 per share, less the exercise price payable for such shares.

EMPLOYMENT AGREEMENTS

February 2004 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

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index, and bonuses of up to 20% at the discretion of the Board of Directors. An employment agreement with Dr. Wallace provides for a base annual salary of \$290,000 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), we are obligated to make severance payments equal to the base annual salary for six months. All of the agreements contain confidentiality provisions.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT.

The following table sets forth, as of March 23, 2001, certain information concerning the beneficial ownership of our common stock by (i) each stockholder known by us to own beneficially five percent or more of our outstanding common stock; (ii) each director; (iii) each executive officer; and (iv) all of our executive officers and directors as a group, and their percentage ownership and voting power.

<TABLE>

| NAME AND ADDRESS OF BENEFICIAL OWNER (1) | SHARES BENEFICIALLY OWNED (2) | PERCENT OF SHARES BENEFICIALLY OWNED |
|--|-------------------------------|---|
| <\$> | <c></c> | <c></c> |
| Louis R. Bucalo, M.D | 1,334,125(3) | 4.8% |
| Ernst-Gunter Afting, M.D., Ph.D | 41,166(4) | * |
| Richard C. Allen, Ph.D | 402,781(5) | 1.5% |
| Victor J. Bauer, Ph.D | 90, 781 (6) | * |
| Sunil Bhonsle | 562,186(7) | 2.0% |
| Eurelio M. Cavalier | 23, 333 (8) | * |
| Robert E. Farrell | 219, 365 (9) | * |
| Michael K. Hsu | 63,500(10) | * |
| Hubert Huckel, M.D | 104, 399 (11) | * |
| Ley S. Smith | 5, 833 (12) | * |
| Jan D. Wallace, M.D | 72, 081 (12) | * |
| Konrad M. Weis, Ph.D | 76, 740 (13) | * |
| The TCW Group, Inc. | | |
| 865 South Figueroa Street | | |
| Los Angeles, CA 90017 | 1,458,323(14) | 5.3% |
| The PNC Financial Services Group, Inc. | | |
| One PNC Plaza | | |
| 249 Fifth Avenue | | |
| Pittsburgh, PA 15222-2707 | 1,388,600(15) | 5.0% |
| All executive officers and directors | | |
| as a group (12) persons | 2,996,290 | 10.9% |
| | | |

 | || | | |

- * 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 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.

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- (3) Includes 1,033,894 shares issuable upon exercise of outstanding options.
- (4) Includes 9,666 shares issuable upon exercise of outstanding options.
- (5) Includes 323,016 shares issuable upon exercise of outstanding options.
- (6) Includes 75,781 shares issuable upon exercise of outstanding options.
- (7) Includes 384,292 shares issuable upon exercise of outstanding options.

- (8) Includes 8,333 shares issuable upon exercise of outstanding options.
- (9) Includes 36,165 shares issuable upon exercise of outstanding options.
- (10) Includes 43,499 shares issuable upon exercise of outstanding options.
- (11) Includes 12,999 shares issuable upon exercise of outstanding options. Includes 49,900 shares held by a family partnership for which Dr. Huckel serves as general partner.
- (12) Represents shares issuable upon exercise of outstanding options.
- (13) Includes 46,283 shares issuable upon exercise of outstanding options.
- (14) The given information is derived from a Schedule 13G filed by The TCW Group, Inc. on February 12, 2001.
- (15) The PNC Financial Services Group, Inc. includes the following subsidiaries: PNC Bancorp, Inc; PNC Bank, National Association; BlackRock Advisors, Inc.; and BlackRock Financial Management, Inc. The foregoing information is derived from a Schedule 13G filed by The PNC Financial Services Group, Inc. on February 12, 2001.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS.

In January 1999, we completed a private placement of 2,254,545 shares of our common stock. Dr. Hubert Huckel and Mr. Michael Hsu, directors of Titan, participated in the offering by purchasing 100,000 and 5,272 shares, respectively.

In February 2001, we loaned Robert E. Farrell, our Executive Vice President and Chief Financial Officer, approximately \$373,000 to finance certain federal and state income tax liabilities incurred by Mr. Farrell in connection with his exercise of stock options. The loan bears interest at a rate of 8.50% per year and is due and payable in August 2001.

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PART IV

ITEM 14. 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

<TABLE>

(S> <C.

- 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)
- 4.4 Form of Underwriter's Unit Purchase Option (1)
- 4.5 Form of Investor Rights Agreement between the Registrant and the holders of Series A and Series B Preferred Stock (1)
- 4.6 Form of Placement Agent's Unit Purchase Option (4)
- 4.7 Certificate of Designation of Series C Preferred Stock (8)
- 10.1 1993 Stock Option Plan (1)
- 10.2 1995 Stock Option Plan (1)
- 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 (2)
- +10.19 License Agreement between Theracell, Inc. and the University of South Florida dated March 15, 1996 (3)
- +10.20 License Agreement between Trilex Pharmaceuticals, Inc.
 (formerly Ascalon Pharmaceuticals, Inc.) and the University of Kentucky
 Research Foundation dated May 30, 1996 (4)
- +10.22 License Agreement between the Registrant and Aventis SA (formerly Hoechst Marion Roussel, Inc.) effective as of December 31, 1996 (5)

</TABLE>

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<TABLE>

- <S> <C>
- 10.23 Employment Agreement between Registrant and Robert E. Farrell dated August 9, 1996 (5)
- 10.24 Financing Agreement between the Registrant and Ansan Pharmaceuticals, Inc. dated March 21, 1997 (6)
- 10.25 Agreement for Purchase and Sale of Assets between the Registrant and Pharmaceuticals Product Development, Inc. dated June 4, 1997 (6)
- +10.27 License Agreement between the Registrant and Bar-Ilan Research and Development Company Limited effective November 25, 1997 (7)
- 10.28 License Agreement between the Registrant and Ansan Pharmaceuticals, Inc. dated November 24, 1997 (7)
- 10.29 Stock Purchase Agreement between the Registrant and Ansan Pharmaceuticals, Inc. effective November 25, 1997 (7)
- +10.30 Sublicense Agreement between the Registrant and Novartis Pharma AG dated November 20, 1997 (7)
- 10.31 1998 Stock Option Plan, as amended (9)
- +10.32 License Agreement between the Registrant and Schering AG dated January 25, 2000. (10)
- 10.33 Employment Agreement between Registrant and Jan D. Wallace, M.D. dated February 17, 2000.
- 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 (11)
- 23.2 Consent of Ernst & Young LLP, Independent Auditors. $<\!\!/ \text{TABLE}\!\!>$

- + Confidential treatment has been granted with respect to portions of
- (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 Annual Report on Form 10-KSB for the year ended December 31, 1995.
- (3) Incorporated by reference from the Registrant's Quarterly Report on

Form 10-QSB for the period ended March 31, 1996.

- (4) Incorporated by reference from the Registrant's Registration Statement on Form SB-2 (File No. 333-13469).
- (5) Incorporated by reference from the Registrant's Annual Report on Form 10-KSB for the year ended December 31, 1996.
- (6) Incorporated by reference from the Registrant's Quarterly Report on Form 10-QSB for the period ended March 31, 1997.
- (7) Incorporated by reference from the Registrant's Registration Statement on Form S-3 (File No. 333-42367).
- (8) Incorporated by reference from the Registrant's Annual Report on Form 10-K for the year ended December 31, 1997.
- (9) Incorporated by reference from the Registrant's Definitive Proxy Statement filed on July 28, 2000.
- (10) Incorporated by reference from the Registrant's Annual Report on Form 10-K for the year ended December 31, 1999.
- (11) Incorporated by reference from the Registrant's Quarterly Report on Form 10-Q for the period ended September 30, 2000.
- (b) REPORTS ON FORM 8-K

On November 15, 2000, we filed a current report on Form 8-K to announce definitive purchase agreements for the sale of an aggregate of 1,200,000 shares of our common stock to institutional investors.

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TITAN PHARMACEUTICALS, INC. INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

<TABLE>
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| Consolidated Statements of Operations | F-4 |
| Consolidated Statement of Stockholders' Equity | F-5 |
| Consolidated Statements of Cash Flows | F-6 |
| Notes to Consolidated Financial Statements | F-7 |
| | |

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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, 2000 and 1999, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2000. 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, 2000 and 1999, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2000, in conformity with accounting principles generally accepted in the United States.

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TITAN PHARMACEUTICALS, INC. CONSOLIDATED BALANCE SHEETS

<TABLE>
<CAPTION>

| <caption></caption> | DECEMBER 31, | | |
|--|--------------|---------------|--|
| | 2000 | 1999 | |
| | | S OF DOLLARS) | |
| <\$> | <c></c> | <c></c> | |
| ASSETS | | | |
| Current assets: | | | |
| Cash and cash equivalents | \$ 20,300 | \$ 46,454 | |
| Marketable securities | 97,223 | 150 | |
| License fees and grants receivable | - 326 | 150 343 | |
| Prepaid expenses and other current assets | | 343 | |
| Total current assets | 117,849 | 46,947 | |
| Furniture and equipment, net | 593 | 415 | |
| | \$ 118,442 | \$ 47,362 | |
| | ======= | | |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | | |
| Current liabilities: | | | |
| Accounts payable | \$ 1,304 | \$ 849 | |
| Accrued clinical trials expenses | 432 | 437 | |
| Other accrued liabilities | 727 | 533 | |
| Total current liabilities | 2,463 | 1,819 | |
| Commitments | | | |
| Minority interest - Series B preferred stock of Ingenex, Inc. Stockholders' Equity | 1,241 | 1,241 | |
| 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, 2000 and 1999 Convertible Series D, 606,061 shares designated, none | - | - | |
| outstanding at December 31, 2000; 606,061 shares issued | | | |
| and outstanding at December 31, 1999 | _ | 5,000 | |
| Common stock, at amounts paid in, \$0.001 par value per share; | | 3,000 | |
| 50,000,000 shares authorized, 27,233,754 and 22,891,912 | | | |
| shares issued and outstanding at December 31, 2000 and 1999, | | | |
| respectively | 190,763 | 98,266 | |
| Additional paid-in capital | 8,744 | 6,955 | |
| Deferred compensation | (1, 254) | (501) | |
| Accumulated deficit | (84, 206) | (65, 418) | |
| Accumulated other comprehensive income | 691 | _ | |
| Total stockholders' equity | 114,738 | 44,302 | |
| | \$ 118,442 | \$ 47,362 | |
| | ======= | ======= | |
| | | | |

 | |See accompanying notes.

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TITAN PHARMACEUTICALS, INC. CONSOLIDATED STATEMENTS OF OPERATIONS

<TABLE>
<CAPTION>

| | YEAR | ENDED DECEM | BER 31, |
|------------------|----------------|-------------|---------------|
| | 2000 | 1999 | 1998 |
| | (IN THOUSANDS, | EXCEPT PER | SHARE AMOUNT) |
| <\$> | <c></c> | <c></c> | <c></c> |
| Revenue: | | | |
| Contract revenue | \$ 1,194 | \$ 30 | \$ |
| License revenue | 415 | 50 | |
| Grant revenue | 271 | 257 | |
| | | | |
| Total revenue | 1,880 | 337 | |

Operating expenses:

| Research and development | 16,744 | 9,429 | 7,813 |
|--|--------------|-------------|--------------|
| Acquired in-process research and development | 4,969 | 136 | |
| General and administrative | • | 2,794 | , |
| Total operating expenses | 25, 783 | 12,359 | 11,521 |
| Loss from operations | (23, 903) | (12,022) | (11,521) |
| Other income (expense): | | | |
| Interest income | 5,156 | 75 <i>6</i> | 848 |
| Other (expense) income | (41) | (30) | 59 |
| Other income, net | 5,115 | 726 | 907 |
| Net loss | \$ (18, 788) | \$ (11,296) | \$ (10, 614) |
| | | | |
| Basic and diluted net loss per share | \$ (0.73) | \$ (0.70) | \$ (0.81) |
| | | | |
| Weighted average shares used in computing | | | |
| basic and diluted net loss per share | 25,591 | 16,112 | 13,109 |
| | | | |
| | | | |

</TABLE>

See accompanying notes.

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TITAN PHARMACEUTICALS, INC. CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (IN THOUSANDS)

<TABLE> <CAPTION>

| <caption></caption> | i | PREFER | RRED STOCK | | COMMON STOCK | | | ITIONAL | | | |
|---|---------|---------|----------------|-------|----------------|---------------------------|--|-----------------------|----------------|--------------------------|--|
| | SHARES | | HARES AMOUNT | | SHARES | IARES AMOUNT | | PAID-IN NT CAPITAL | | DEFERRED COMPENSATION | |
| <pre><s> BALANCES AT DECEMBER 31, 1997 Issuance of common stock upon</s></pre> | <c></c> | 828 | <c> \$</c> | 5,000 | <c> 13,053</c> | <c> \$ 49,623</c> | <c:< th=""><th> > 6,521</th><th><c> \$</c></th><th>(458)</th></c:<> | > 6,521 | <c> \$</c> | (458) | |
| exercise of stock options Release of guaranteed security | | | | | 71 | 213 | | | | | |
| value Increase in paid-in capital from issuance of common stock by | | | | | | 2,455 | | | | | |
| Theracell, Inc. Amortization of deferred compensation Net loss | | | | | | | | 3 | | 171 | |
| Balances at December 31, 1998 Issuance of common stock in a private placement, net of | | 828 | | 5,000 | 13,124 | 52, 291 | | 6,524 | | (287) | |
| issuance costs of \$403 Issuance of common stock to minority stockholders pursuant | | | | | 2,255 | 5,797 | | | | | |
| to the Theracell Merger Issuance of common stock upon exercise of options and | | | | | 33 | 136 | | | | | |
| warrants Issuance of common stock upon exercise of Class A Warrants, | | | | | 396 | 650 | | | | | |
| net of issuance costs of \$3,254 Deferred compensation related to | | | | | 7,084 | 39, 392 | | | | | |
| stock options Amortization of deferred compensation Net loss | | | | | | | | 431 | | (431) 217 | |
| Balances at December 31, 1999 Comprehensive loss: Net loss Unrealized gain on marketable securities | | 828 | | 5,000 | 22,892 | 98,266 | | 6,955 | | (501) | |
| Comprehensive loss Issuance of common stock in a private placement in March 2000, net of issuance costs | | | | | | | | | | | |
| of \$2,591 Issuance of common stock upon | | | | | 1,200 | 38,809 | | | | | |

| exercise of options and warrants | | | 1,181 | 4,252 | | |
|---|-------|---------|--------|-----------|----------|------------|
| Conversion of Series D preferred | | | | | | |
| stock to common stock | (606) | (5,000) | 667 | 5,000 | | |
| Issuance of common stock to acquire | | | | | | |
| a technology, net | | | 94 | 3,522 | | |
| Issuance of common stock in a private placement in November 2000, | | | | | | |
| net of issuance costs of \$2,886 | | | 1,200 | 40,914 | | |
| Compensation related to stock | | | | | | |
| options | | | | | 1,789 | (1, 324) |
| Amortization of deferred | | | | | | |
| compensation | | | | | | 571 |
| | | | | | | |
| BALANCES AT DECEMBER 31, 2000 | 222 | \$ | 27,234 | \$190,763 | \$ 8,744 | \$ (1,254) |
| | | | | | | |
| | | | | | | |

 | | | | | |, -----

<TABLE>

| <caption></caption> | | | | |
|--|--------------|---------------|---------------------|--|
| | | ACCUMULATED | | |
| | | OTHER | TOTAL | |
| | ACCUMULATED | COMPREHENSIVE | STOCKHOLDERS' | |
| | DEFICIT | INCOME | EQUITY | |
| | | | | |
| <s></s> | <c></c> | <c></c> | <c></c> | |
| BALANCES AT DECEMBER 31, 1997 | \$ (43,508) | \$ | <i>\$</i> 17,178 | |
| Issuance of common stock upon | | | 012 | |
| exercise of stock options | | | 213 | |
| Release of guaranteed security value | | | 2,455 | |
| Increase in paid-in capital from | | | 2,433 | |
| issuance of common stock by | | | | |
| Theracell, Inc. | | | 3 | |
| Amortization of deferred | | | | |
| compensation | | | 171 | |
| Net loss | (10,614) | | (10,614) | |
| | | | | |
| Balances at December 31, 1998 | (54, 122) | | 9,406 | |
| Issuance of common stock in a | | | | |
| private placement, net of | | | 5 707 | |
| issuance costs of \$403 Issuance of common stock to | | | 5,797 | |
| minority stockholders pursuant | | | | |
| to the Theracell Merger | | | 136 | |
| Issuance of common stock upon | | | 150 | |
| exercise of options and | | | | |
| warrants | | | 650 | |
| Issuance of common stock upon | | | | |
| exercise of Class A Warrants, | | | | |
| net of issuance costs of \$3,254 | | | 39,392 | |
| Deferred compensation related to | | | | |
| stock options | | | | |
| Amortization of deferred | | | 017 | |
| compensation | (11 206) | | 217 | |
| Net loss | (11, 296) | | (11,296) | |
| Balances at December 31, 1999 | (65, 418) | | 44,302 | |
| Comprehensive loss: | (00) 120) | | , | |
| Net loss | (18, 788) | | (18, 788) | |
| Unrealized gain on marketable | | | | |
| securities | | 691 | 691 | |
| | | | | |
| Comprehensive loss | | | (18,097) | |
| Issuance of common stock in a | | | | |
| private placement in March | | | | |
| 2000, net of issuance costs of \$2,591 | | | 38,809 | |
| • • | | | 38,809 | |
| Issuance of common stock upon exercise of options and | | | | |
| warrants | | | 4,252 | |
| Conversion of Series D preferred | | | -, - | |
| stock to common stock | | | | |
| Issuance of common stock to acquire | | | | |
| a technology, net | | | 3,522 | |
| Issuance of common stock in a | | | | |
| private placement in November 2000 |), | | | |
| net of issuance costs of \$2,886 | | | 40,914 | |
| Compensation related to stock | | | 465 | |
| options Amortization of deferred | | | 465 | |
| Amortization of deferred compensation | | | 571 | |
| Compensacion | | | J/1 | |
| BALANCES AT DECEMBER 31, 2000 | \$ (84, 206) | \$ 691 | \$114,738 | |
| | ======= | ====== | 7114,730 ======= | |
| | | | | |

 | | | || | | | | |
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TITAN PHARMACEUTICALS, INC. CONSOLIDATED STATEMENTS OF CASH FLOWS

<TABLE> <CAPTION>

</TABLE>

| <caption></caption> | YEARS ENDED DECEMBER 31, | | |
|--|--------------------------|---------------------|-------------------|
| | 2000 | | |
| | | HOUSANDS OF D | |
| <\$> | <c> (1N 1.</c> | +COSANDS OF D C> | ОШАКЗ) <c></c> |
| CASH FLOWS FROM OPERATING ACTIVITIES: | | | |
| Net loss | \$ (18,788) | \$ (11,296) | \$ (10,614) |
| Adjustments to reconcile net loss to net cash | | | |
| provided by (used in) operating activities: | | | |
| Depreciation and amortization | 196 | | |
| Acquired in-process research and development | 4,969 | | |
| Payment of guaranteed security value | 1.026 | | (3,044) |
| Non-cash compensation related to stock options Issuance of common stock to acquire | 1,036 | 217 | 171 |
| minority interest of Theracell, Inc. | | 136 | |
| Other | | 13 | 13 |
| Changes in operating assets and liabilities: | | | |
| Receivables, prepaid expenses and other current assets | 167 | (337) | 298 |
| Accounts payable | (931) | | (405) |
| Accrued clinical trials and other liabilities | 188 | | 309 |
| Net cash used in operating activities | (13, 163) | (10,855) | (13, 150) |
| CLAU TLAUG TRAU TITTIATIVA LATIVITATIA | | | |
| CASH FLOWS FROM INVESTING ACTIVITIES: | (274) | (105) | (200) |
| Purchases of furniture and equipment, net Purchases of marketable securities | (374) (167, 355) | (185) | (298) |
| Proceeds from sales of marketable securities | 70,823 | | 500 |
| | | | |
| Net cash provided by (used in) investing activities | (96, 906) | (185) | 202 |
| CASH FLOWS FROM FINANCING ACTIVITIES: | | | |
| Issuance of common stock, net | | 45,839 | 216 |
| | | | |
| Net cash provided by financing activities | 83,915 | 45,839 | 216 |
| | | | |
| NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS | (26, 154) | 34,799 | (12, 732) |
| Cash and cash equivalents at beginning of year | 46,454 | 11,655 | 24,387 |
| CASH AND CASH EQUIVALENTS AT END OF YEAR | | 46,454 | 11,655 |
| Marketable securities at end of year | 97,223 | | |
| CACH CACH BOUTURE BUMG AND MADVEMADE GEGUDTMER | | | |
| CASH, CASH EQUIVALENTS AND MARKETABLE SECURITIES AT END OF YEAR | \$ 117,523 | \$ 46,454 | \$ 11,655 |
| AT END OF TEAR | | | |
| | | | |
| SCHEDULE OF NON-CASH TRANSACTION: | | | |
| Issuance of common stock to acquire a technology, net | \$ 3,522 | \$ | <i>\$</i> |
| | | | |
| / | | | |

See accompanying notes.

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TITAN PHARMACEUTICALS, INC. NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

THE COMPANY AND ITS SUBSIDIARIES

We are a biopharmaceutical company developing proprietary therapeutics for the treatment of central nervous system disorders, cancer, and other serious and life threatening diseases. We conduct a portion of our operations through our two subsidiaries: Ingenex, Inc. and ProNeura, Inc. Another majority owned subsidiary, Theracell, Inc., engaged in the development of cell-based therapies for site-specific delivery to the central nervous system for treatment of various neurologic disorders, was merged with and into Titan in March 1999 (the Theracell Merger). Pursuant to the Theracell Merger, we issued 33,418 shares of our common stock to the minority stockholders of Theracell and recorded an

in-process research and development expense of \$136,000, which equals the value of the common stock issued. In the third quarter of 2000 and in connection with the acquisition of worldwide rights to gallium maltolate, a novel and proprietary agent for the potential treatment of cancer and other conditions, including HIV infection, we acquired GeoMed, Inc., a privately held California corporation (See Note 8). We operate in one business segment, the development of biopharmaceutical products.

INGENEX, INC.

Ingenex is engaged in the development of gene-based therapeutics for the treatment of cancer. In September 1994, Ingenex issued shares of its Series B convertible preferred stock to a third party for \$1.2 million, net of issuance costs. In June 1997, Ingenex sold a research technology and certain fixed assets for \$8.7 million in cash and the assumption of certain capital lease liabilities and recognized a gain of \$8.4 million. At December 31, 2000, we owned 81% of Ingenex, assuming the conversion of all preferred stock to common stock.

PRONEURA, INC.

ProNeura is engaged in the development of cost effective, long-term treatment solutions to neurologic and psychiatric disorders through an implantable drug delivery system. At December 31, 2000, we owned 79% of ProNeura.

BASTS OF PRESENTATION

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. The consolidated financial statements are reformatted to present dollars in thousands. Certain prior year balances have been reclassified to conform to the current year presentation.

Through December 31, 1999, we were considered to be a developmental stage company. In January 2000, we entered into a collaborative agreement with Schering AG (see Note 7), under which we recorded research revenue. As a result of this agreement, and with the potential of other collaborative partnership agreements in the future, we are no longer considered to be in the developmental stage.

USE OF ESTIMATES

The preparation of financial statements in conformity with accounting principles generally accepted

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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.

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 and commonly used valuation methodologies. We do not use derivative financial instruments in our investment portfolio.

All highly liquid investments with insignificant interest rate risk with original maturities of three months or less are considered to be cash equivalents. Our marketable securities, consisting primarily of high-grade debt securities, are classified as available-for-sale at time of purchase and carried at fair value. Amortization of premiums and discounts, and realized gains and losses are included as interest income. Unrealized gains and losses are included as accumulated other comprehensive income, a separate component of stockholders' equity. Cost of securities sold is based on specific identification method.

FURNITURE AND EQUIPMENT

Furniture 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.

REVENUE RECOGNITION

Revenue under collaborative agreements is recorded when earned as defined under the terms of the respective agreements and collectibility is reasonably assured. Payments for our research and development effort under contractual arrangements are recognized as revenue ratably over the period in which the related work is performed. Nonrefundable license fees, under which we

have no future performance obligations, are recognized upon receipt. Government grants, which support our research effort in specific projects, generally provide for reimbursement of approved costs as defined in the grant documents, and revenue is recognized when subsidized project costs are incurred.

SPONSORED RESEARCH AND DEVELOPMENT COSTS

Research and development expenses under sponsored research arrangements are recorded when related services are performed, generally ratably over the period of the service agreements. License fees are expensed when paid, if we have no alternative future use of the technology.

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 reflects the impact of other dilutive equity instruments, primarily preferred stock, options and warrants. For the years ended December 31, 2000, 1999 and 1998, we reported net losses and, therefore, other dilutive securities were excluded from the calculation as they would have been anti-dilutive. Had we been in a net income position, shares used in calculating diluted earnings per share for 2000, 1999 and 1998 would have included the effect of an additional 3,915,734, 4,293,859 and 12,387,331 shares, respectively, related to our convertible preferred stock, options and warrants, prior to the application of treasury stock method.

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COMPREHENSIVE INCOME (LOSS)

Comprehensive income (loss) is comprised of net income (loss) and other comprehensive income (loss). The only component of other comprehensive income (loss) is unrealized gains and losses on our marketable securities. Comprehensive loss for the year ended December 31, 2000 was \$18.1 million. Comprehensive loss was the same as our net loss for the years ended December 31, 1999 and 1998. Comprehensive loss has been disclosed in the Statement of Stockholders' Equity for all periods presented.

RECENT ACCOUNTING PRONOUNCEMENT

In June 1998, the Financial Accounting Standards Board issued SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities" (SFAS 133), which establishes accounting and reporting standards for derivative instruments, including certain derivative instruments embedded in other contracts, and for hedging activities. In June 1999, the FASB issued SFAS No. 137, "Accounting for Derivative Instruments and Hedging Activities — Deferral of the Effective Date of FASB Statement No. 133." We are required to adopt SFAS 133 effective January 1, 2001. Because we do not hold any derivative instruments and do not engage in hedging activities, management does not believe the adoption of SFAS 133 will have an impact on our financial position or results of operations.

2. AVAILABLE-FOR-SALE SECURITIES

The following is a summary of our available-for-sale securities at December 31, 2000 (in thousands):

<TABLE>

| | | AMORTIZED COST | UNREALIZED GAINS | UNREALIZED LOSSES | ESTIMATED FAIR VALUE |
|--|---------|-------------------|---------------------|----------------------|-------------------------|
| <\$> | <c></c> | | <c></c> | <c></c> | <c></c> |
| AVAILABLE-FOR-SALE SECURITIES: | | | | | |
| Money market funds | | \$17,835 | \$ | \$ | \$17,835 |
| Securities of the U.S. government and its agencies | | 52,280 | 393 | | 52,673 |
| Corporate notes and bonds | | 42,289 | 296 | | 42,585 |
| Commercial paper | | 3, 957 | 2 | _ _ _ | 3,959 |
| | | \$116,361 | \$691 | \$ | ,, |
| CLASSIFIED AS: | | | | | |
| Cash equivalents | | | | | \$19,829 |
| Marketable Securities | | | | | 97, 223 |
| | | | | | \$117,052 |
| | | | | | |

</TABLE>

The amortized cost and estimated fair value of available-for-sale securities at December 31, 2000, by contractual maturity, are summarized below (in thousands):

<TABLE>

| | | ORTIZED COST | ESTIMATED F VALUE | 'AIR |
|-------------------|---------|-----------------|----------------------|------|
| <\$> | <c></c> | | <c></c> | |
| Due within 1 year | | \$30,116 | \$30,1 | 48 |

| Due between 1 - 3 years | 86,245 | 86,904 |
|-------------------------|-----------|-----------|
| | | |
| | \$116,361 | \$117,052 |

</TABLE>

Gross realized gains and losses on sales of marketable securities were immaterial for the year ended December 31, 2000.

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3. FURNITURE AND EQUIPMENT

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

<TABLE>

| | 2000 | 1999 |
|--------------------------------|---------|---------|
| | | |
| <\$> | <c></c> | <c></c> |
| At cost: | | |
| Furniture and office equipment | \$191 | \$96 |
| Leasehold improvements | 213 | 103 |
| Laboratory equipment | 354 | 324 |
| Computer equipment | 250 | 111 |
| | 1,008 | 634 |
| Less accumulated depreciation | • • | (219) |
| Furniture and equipment, net | | \$415 |
| | | |

</TABLE>

Depreciation expense was \$196,000, \$174,000 and \$122,000 for the years ended December 31, 2000, 1999 and 1998, respectively.

4. SPONSORED RESEARCH AND LICENSE AGREEMENTS

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. Expenses under these agreements totaled \$1.5 million, \$1.3 million and \$1.6 million in the years ended December 31, 2000, 1999 and 1998, respectively.

At December 31, 2000, the annual aggregate commitments we have under these agreements, including minimum license payments, are as follows (in thousands):

| <table> <s></s></table> | <c></c> |
|-------------------------|---------|
| 2001 | \$735 |
| 2002 | 304 |
| 2003 | 304 |
| 2004 | 304 |
| 2005 | 304 |
| | \$1,951 |

</TABLE>

After 2005, we must make annual payments aggregating \$304,000 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 January 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. Pursuant to the license, we paid a fee of \$9.5 million consisting of: (i) \$4 million in cash, and (ii) \$5.5 million through the issuance of 594,595 shares of common stock to Aventis. We were obligated to pay Aventis the difference between \$5.5 million and the net proceeds received by Aventis upon sale of such shares. In February 1998, Aventis sold the shares for net proceeds of \$2.5 million. Accordingly, we paid to Aventis \$3 million in cash and the remaining balance of \$2.5 million was transferred to stockholders' equity. We are required to make

commercialization of the product, the license agreement provides that we will pay royalties based on net sales.

6. ZOMARIL (TM) (ILOPERIDONE) SUBLICENSE TO NOVARTIS PHARMA AG

In November 1997, we entered into an agreement with Novartis Pharma AG, pursuant to which we granted Novartis a sublicense for the worldwide (with the exception of Japan) development, manufacturing and marketing of Zomaril (TM) (iloperidone). Pursuant to the sublicense, Novartis paid us \$20 million consisting of a fee of \$15 million and \$5 million for the purchase of 606,061 shares of Series D convertible preferred stock. In addition, approximately \$2.4 million in cash was paid by Novartis as reimbursement of research and development costs incurred by us. The Novartis sublicense provides for future payments by Novartis contingent upon the achievement of regulatory milestones as well as a royalty on net sales, if any, of the product. Novartis has assumed the responsibility for all clinical development, registration, manufacturing and marketing of Zomaril (TM).

7. LICENSING AND COLLABORATIVE AGREEMENT WITH SCHERING AG

In January 2000, we entered into a licensing and collaborative agreement with Schering AG, under which we will collaborate with Schering on manufacturing and clinical development of our cell therapy product, Spheramine(R), 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, 2000, we recognized \$1.0 million of contract revenue under this agreement. 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 certain payments upon the achievement of specific milestones. Schering also retains the right to make an equity investment in Titan, up to a specified amount, upon initiation of pivotal clinical studies. The potential economic value of the agreement to us, including development funding and equity investment, but not including funding of clinical trials and product royalties, is approximately \$26 million.

8. ACQUISITION OF A NOVEL AND PROPRIETARY AGENT

In July 2000, we announced the acquisition of worldwide, royalty-bearing, exclusive license to a novel and proprietary agent, gallium maltolate, for the potential treatment of cancer and other conditions, including HIV infection. We obtained these rights through the acquisition of GeoMed, Inc., a privately held California corporation. 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 net sales of products and processes incorporating the licensed technology. We completed the acquisition in August 2000 by assuming \$1.4 million of GeoMed's liabilities and issuing an aggregate of 93,590 shares of Titan common stock valued at approximately \$3.6 million using the fair market value of our common stock at the date of the agreement in accordance with generally accepted accounting principles. The entire purchase price of approximately \$5.0 million was charged to acquired in-process research and development as the acquired technology was in an early stage of development that, as of the acquisition date, technological feasibility had not been reached and no alternative use existed.

9. LEASE COMMITMENTS

We lease facilities under operating leases that expire at various dates through October 2003. Rent expense was \$411,000, \$331,000 and \$328,000, for years ended December 31, 2000, 1999 and 1998, respectively.

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The following is a schedule of future minimum lease payments at December 31, 2000 (in thousands):

<TABLE>

| <s></s> | <c></c> |
|---------|---------|
| 2001 | \$446 |
| 2002 | 257 |
| 2003 | 78 |
| | |
| | \$781 |
| | ======= |

</TABLE>

10. STOCKHOLDERS' EQUITY

PREFERRED STOCK

In connection with the merger of our Trilex Pharmaceuticals, Inc. subsidiary (Trilex) in October 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 common stock, on a one-to-one basis, only if certain development milestones are achieved within certain timeframes. Upon achievement of the milestones, we would be required to value the technology against the then fair market value of our common stock issuable upon conversion.

Holders of Series C Preferred are entitled to receive dividends, when, as and if declared by the board of directors ratably with any declaration or payment of any dividend on our common stock or other junior securities. The Series C Preferred has a liquidation preference equal to \$0.01 per share. No value was assigned to the Series C Preferred in the accompanying financial statements.

In November 1997, we issued to Novartis 606,061 shares of Series D convertible preferred stock (the Series D Preferred) pursuant to an agreement by which we granted certain technology rights to Novartis (see Note 6). The Series D Preferred were issued pursuant to a stock purchase agreement that provides for conversion of such shares into our common stock at the option of Novartis at any time after January 29, 1999. The conversion price equaled the market price during a specified period within the first two fiscal quarters of 1999 and was subject to a floor of \$7.50 and a ceiling of \$9.00. In March 2000, upon satisfying the conditions for conversion and at the request of Novartis, all outstanding Series D Preferred shares were converted into 666,667 shares of our common stock.

COMMON STOCK

In January 1999, we completed a private placement of 2,254,545 shares of our common stock for net proceeds of \$5.8 million, after deducting fees and commissions and other expenses of the offering.

In March 2000, we completed a private placement of 1.2 million shares of our common stock for net proceeds of \$38.8\$ million, after deducting fees and commissions and other expenses of the offering.

In November 2000, we completed a private placement of 1.2 million shares of our common stock for net proceeds of \$40.9\$ million, after deducting fees and commissions and other expenses of the offering.

WARRANTS

During 1996 in connection with the initial public offering (IPO), repayment of a bridge financing and a private placement, we issued 7,091,000 Class A Warrants, each of which was exercisable for one share of common stock at an adjusted exercise price of \$6.02 at any time up to January 2001. The warrants were subject to redemption on 30 days written notice if the closing bid price of our common stock averaged in excess of \$9.10 per share for 30 consecutive trading days ending within 15 days of the date of notice of redemption.

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In October 1999, upon satisfying the conditions for warrant redemption, we called for the redemption on November 19, 1999 (the Redemption Date) of our outstanding Class A Warrants for cash at the redemption price of \$0.05 per warrant. Rather than surrendering the warrants for redemption, warrant holders had the option to purchase our common stock at a price of \$6.02 per share before the Redemption Date. The warrant call resulted in 7,083,711 of our then outstanding Class A Warrants being exercised with net proceeds totaled \$39.4 million, after deducting advisory fee and other related expenses.

UNIT PURCHASE OPTIONS

In connection with our IPO, the underwriter was granted an option to acquire 320,000 units at a price of \$6.50 per unit, and in connection with a private placement, the placement agent was granted an option to purchase an additional 321,065 units, as adjusted, at an adjusted exercise price of \$9.97 per unit. Each unit consists of one share of common stock and one Class A warrant. In 1999, 247,573 units were exercised, primarily on a cashless basis, resulting in the issuance of 124,449 shares of our common stock. In 2000, all remaining units were exercised, resulting in net proceeds of \$2.3 million and the issuance of 689.160 shares of our common stock.

SHARES RESERVED FOR FUTURE ISSUANCE

As of December 31, 2000, shares of common stock reserved by us for future issuance consisted of the following (shares in thousands):

<TABLE>

| <\$> | <c></c> |
|--|---------|
| Warrants related to certain private financing transactions in 1995 | 27 |
| Stock options | 4,824 |
| Preferred stock | 222 |
| | |
| | 5,073 |
| | |

</TABLE>

11. STOCK OPTION PLANS

Under our amended 1998 Stock Option Plan and predecessor option plans, a total of 4.4 million shares of our common stock were reserved and authorized for issuance. The option plans provide for the grant of incentive stock options to employees, and non-qualified stock options to employees, directors and

consultants. 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 incentive stock options, non-qualified stock options and options granted to 10% stockholders, shall be at least 100%, 85% and 110%, respectively, of the fair market value of the stock on the date of grant.

Our 1998 Option Plan provides for the automatic grant of non-qualified stock 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 bi-annual (i.e. every two years) grant of an option to purchase 15,000 shares of common stock on the day immediately following the date of each annual stockholders meeting, as long as such director is a member of the Board of Directors. In addition, each Eligible Director will receive

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an automatic annual grant of an option to purchase 5,000 shares of common stock on the day immediately following the date of each annual stockholders meeting for each committee of the Board on which they serve.

In November 1999 and in connection with the warrant call, we granted 813,000 non-qualified stock options outside of our stock option plans to our executive officers, at an exercise price of \$12.75, vesting equally over 36 months from the date of grant.

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

<TABLE>

| <caption></caption> | | SHARES AVAILABLE FOR GRANT | OP OUTS | BER OF TIONS TANDING | WEIGH AVER EXERCISE | AGE |
|------------------------------|---------|----------------------------------|------------|----------------------------|---------------------------|---------|
| <\$> | <c></c> | | <c></c> | | <c></c> | |
| Balance at December 31, 1997 | | 123 | | 1,817 | | \$6.88 |
| Increase in shares reserved | | 1,000 | | _ | | - |
| Options granted | | (1, 102) | | 1,102 | | \$6.82 |
| Options exercised | | - | | (71) | | \$3.00 |
| Options cancelled | | 847 | | (924) | | \$10.10 |
| Balance at December 31, 1998 | | 868 | | 1,924 | - | \$5.45 |
| Increase in shares reserved | | 226 | | _ | | _ |
| Options granted | | (784) | | 1,597 | | \$8.12 |
| Options exercised | | _ | | (147) | | \$3.32 |
| Options cancelled | | 67 | | (70) | | \$4.84 |
| Balance at December 31, 1999 | | 377 | | 3,304 | - | \$6.82 |
| Increase in shares reserved | | 1,500 | | _ | | _ |
| Options granted | | (748) | | 748 | | \$36.20 |
| Options exercised | | - | | (353) | | \$4.31 |
| Options cancelled | | 28 | | (33) | | \$19.17 |
| Balance at December 31, 2000 | | 1,157 | | 3,666 | | \$12.95 |
| / | === | | | | = | |

</TABLE>

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 2000, 1999 and 1998, 1,626, 3,165 and 77,222 Substitute Options, respectively, were cancelled and are included as shares expired during the year.

In June 1998, we adopted an Option Exchange Program whereby certain employee stock options that were previously granted at exercise prices greater than \$10.75 per share were exchanged for new options with an exercise price of \$7.50 per share. Notwithstanding the original vesting schedule, all exchanged options vested as of the exchange date are considered vested under the new options and the unvested portion will vest ratably over 24 months and have a term of approximately eight years. A total of 820,135 options with a weighted-average exercise price of \$10.91 were exchanged and reflected as grants and cancellations in the above summary table.

Options for 2,057,648 and 1,167,265 shares were exercisable at December 31, 1999 and 1998, respectively. The options outstanding at December 31, 2000 have been segregated into three ranges for additional disclosure as follows (option shares in thousands):

<TABLE> <CAPTION>

OPTIONS OUTSTANDING OPTIONS EXERCISABLE

| | | | WEIGHTED AVERAGE | | | WEIGHTED |
|---------|------------------------|-------------|---------------------|------------------|-------------|----------------|
| | | NUMBER | REMAINING | WEIGHTED AVERAGE | NUMBER | AVERAGE |
| RAI | NGE OF EXERCISE PRICES | OUTSTANDING | LIFE (YEARS) | EXERCISE PRICE | EXERCISABLE | EXERCISE PRICE |
| <s></s> | | <c></c> | <c></c> | <c></c> | <c></c> | <c></c> |
| | \$0.08 - \$5.69 | 1,153 | 6.41 | \$2.87 | 1,105 | \$2.80 |
| | \$7.13 - \$12.69 | 1,778 | 7.95 | \$9.87 | 1,253 | \$8.71 |
| | \$12.75 - \$46.50 | 735 | 9.42 | \$36.21 | 50 | \$35.72 |
| | | | | | | |
| | | 3,666 | 7.76 | \$12.95 | 2,408 | \$6.56 |
| | | | | | ======= | |
| | | | | | | |

</TABLE>

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 follow APB 25 in accounting for our stock options because the alternative fair value method of accounting prescribed by SFAS 123 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 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 has been determined as if we had accounted for our employee stock options granted subsequent to 1994 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 2000, 1999 and 1998: weighted-average volatility factor of 0.9, 0.8 and 0.7, respectively; no expected dividend payments; weighted-average risk-free interest rates in effect of 5.0%, 6.0% and 5.5%, respectively; and a weighted-average expected life of 3.69, 2.52 and 2.86, respectively.

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, 2000, 1999 and 1998 was \$23.56, \$4.83 and \$1.87, respectively.

For purposes of SFAS 123 disclosures, the estimated fair value of the options is amortized to expense over the options' vesting period. Our pro forma information is as follows (in thousands, except per share amount):

<TABLE> <CAPTION>

| | DECEMBER 31 | | |
|--|--------------|--------------|--------------|
| | 2000 | 1999 | 99 1998 |
| | | | |
| <\$> | <c></c> | <c></c> | <c></c> |
| Net loss as reported | \$ (18,788) | \$ (11, 296) | \$(10,614) |
| Basic and diluted net loss per share as reported | \$ (0.73) | \$ (0.70) | \$(0.81) |
| Pro forma net loss | \$ (27, 569) | \$ (13, 487) | \$ (11, 355) |
| Pro forma basic and diluted net loss per share | \$(1.08) | \$(0.84) | \$(0.87) |

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The consolidated pro forma net loss calculated above includes the estimated fair value of the options granted by our subsidiaries in 2000, 1999 and 1998, calculated on substantially equivalent assumptions.

12. 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.

13. INCOME TAXES

As of December 31, 2000, we had net operating loss carryforwards for federal income tax purposes of approximately \$79.0 million which expire in the years 2006 through 2020, and federal research and development tax credits of approximately \$1.5 million which expire in the years 2007 through 2020. We also had net operating loss carryforwards for state income tax purposes of approximately \$22.0 million which expire in the years 2001 through 2020.

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

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

<TABLE> <CAPTION>

DECEMBER 31, 1999 2000 <5> <C> <C> Deferred tax assets: Net operating loss carryforwards..... \$28,200 \$21,000 Research credit carryforwards..... 2,000 1,400 2,300 Capitalized research and development..... 2,900 Other, net..... 2,000 800 35,100 25,500 Total deferred tax assets..... Deferred tax liabilities: Unrealized gain on investments..... (200) (25.500) Valuation allowance..... (34,900)Net deferred tax assets..... \$-

</TABLE>

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 \$6.7 million and \$4.3 million during 1999 and 1998, respectively. The valuation allowance at December 31, 2000 includes \$2.8 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.

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14. QUARTERLY FINANCIAL DATA (UNAUDITED)

<TABLE>

| <caption></caption> | | | | |
|---------------------------------------|---------------|-------------|---------------|-------------|
| | FIRST | SECOND | THIRD | FOURTH |
| | QUARTER | QUARTER | QUARTER | QUARTER |
| | | | | |
| | • | • | PER SHARE AMO | • |
| <\$> | <c> <0</c> | C> < | ·C> | <c></c> |
| 2000 | | | | |
| Total revenue | <i>\$335</i> | \$281 | \$695 | \$569 |
| Net loss | \$ (3, 648) | \$ (2, 423) | \$(8,711) | \$ (4,006) |
| Basic and diluted net loss per share | \$(0.15) | \$(0.09) | \$(0.34) | \$(0.15) |
| Cash, cash equivalents and marketable | | | | |
| securities | \$83,865 | \$82,515 | \$79,797 | \$117,523 |
| 1999 | | | | |
| Total revenue | \$47 | <i>\$</i> - | \$52 | \$238 |
| Net loss | \$ (2,820) | \$ (3, 106) | \$ (2, 445) | \$ (2, 925) |
| Basic and diluted net loss per share | \$(0.19) | \$(0.20) | \$(0.16) | \$(0.15) |
| Cash, cash equivalents and marketable | | | | |
| securities | | | | |

 \$14,792 | \$11,813 | \$9,147 | \$46,454 |

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 30, 2001

r: /s/ Louis R. Bucalo

Louis R. Bucalo, M.D.,

Chairman, President and Chief Executive Officer

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

| <table> <caption> SIGNATURE</caption></table> | TITLE | DATE |
|---|---|----------------|
| <\$> | <c> <</c> | C> |
| /s/ Louis R. Bucalo | Chairman, President and Chief Executive Officer (principal executive officer) | March 30, 2001 |
| Louis R. Bucalo, M.D. | (| |
| /s/ Ernst-Gunter Afting | Director | March 30, 2001 |
| Ernst-Gunter Afting, M.D., Ph.D. | | |
| /s/ Victor J. Bauer | Director | March 30, 2001 |
| Victor J. Bauer, Ph.D. | | |
| /s/ Eurelio M. Cavalier | Director | March 30, 2001 |
| Eurelio M. Cavalier | | |
| /s/ Michael K. Hsu | Director | March 30, 2001 |
| Michael K. Hsu | | |
| /s/ Hubert E. Huckel | Director | March 30, 2001 |
| Hubert E. Huckel, M.D. | | |
| /s/ Ley S. Smith | Director | March 30, 2001 |
| Ley S. Smith | | |
| /s/ Konrad M. Weis | Director | March 30, 2001 |
| Konrad M. Weis, Ph.D. | | |
| /s/ Robert E. Farrell | Executive Vice President and Chief Financial Officer (principal financial and accounting officer) | March 30, 2001 |
| Robert E. Farrell | | |

 officer (principal financial and accounting officer) | |February 17, 2000

Jan D. Wallace, M.D. 1663 Bush Street San Francisco, CA 94109

Dear Jan:

It is with great pleasure that I would like to offer you the position of Executive Vice President, Clinical Development and Regulatory Affairs, at Titan Pharmaceuticals, Inc. In this position, you will be responsible for strategic planning and implementation of all of the Company's Phase I, II and III clinical trials, as well as regulatory strategy and submissions to various regulatory agencies worldwide in support of clinical testing and regulatory approval of the Company's products. As operational head of clinical development and regulatory affairs for the Company, you will supervise all personnel in these areas, and your position will report to the President and CEO. This letter will confirm the terms of your employment with Titan, such employment to begin on March 13, 2000. If the terms discussed below are acceptable, please sign this letter where indicated and return it to me, retaining a copy for your records. As used herein, the term "Company" refers to Titan Pharmaceuticals, Inc.

1. COMPENSATION

- (a) SALARY. You will be paid a monthly salary of \$24,166.67 less applicable withholdings (\$290,000.00 annually) with a performance bonus of 0-20% based upon company and individual performance. All reasonable business expenses will be reimbursed so long as they are incurred in the ordinary course of business. You will be entitled to annual increases in your salary in accordance with Company policies at such time. If any profit sharing plan is implemented for employees, you will be appropriately included in such plan.
- (b) STOCK OPTIONS. You will receive stock options to acquire 230,000 shares of Titan's Common Stock under the 1998 Stock Option Plan, subject to approval by the Board of Directors. All options granted will vest monthly, commencing on your first date of employment over a four (4) year period, at a rate of twenty-five percent (25%) per year, subject to a requirement of at least 12 months of employment for vesting any options. The option price will be the closing price per share on your employment date. In the event of sale of transfer of substantially all of the assets of Titan, your options will automatically

accelerate immediately prior to such event such that 100% of the option shares will be exercisable.

- (c) HEALTH BENEFITS. Health insurance coverage for you and your family will be provided under the Company's group health plan. You will be entitled to all health and medical benefits as are provided to other employees. In addition, you will be entitled to participate in the Company's 401(k) plan and all other sponsored employee benefit plans as they are adopted by Titan.
- (d) VACATION, HOLIDAYS AND SICK LEAVE. You will receive three (3) weeks of paid vacation per year. Sick leave and holidays will be provided in accordance with the Company's established policies.

- TERMINATION. You or the Company may terminate the employment 2. relationship at any time, for any reason, with or without good cause. However, if the Company terminates your employment without good cause, the Company will continue to pay your monthly salary on a regular bi-monthly basis for six (6) months from the date of termination, less all applicable withholdings, provided, however, that the employment salary received during this six-month period shall be subject to offset any other employment salary received during this period. For purposes of this Agreement, "good cause" means gross misconduct, wrongful acts or omissions that may materially adversely affect the Company's business, neglect of duties, breach of any material terms or conditions of the Agreement or the Company's Proprietary Information Agreement, death, or any disability that renders you incapable of diligently performing all of your essential duties and obligations to the Company for any period of three (3) consecutive months or four (4) months in any twelve (12) month period.
- 3. NON-COMPETE AND OUTSIDE ACTIVITIES. You agree that, while serving as an employee of the Company, you will not engage in any activity which is competitive with the Company and you will give sole and only loyalty to the Company. It is understood that buying and selling of securities of any public company does not constitute a violation of this agreement.
- 4. PROPRIETARY INFORMATION AND INVENTIONS AGREEMENT. Your acceptance of this offer is contingent upon the execution of the Company's Proprietary Information and Inventions Agreement, copies of which are enclosed for your review and execution.
- 5. ARBITRATION. Any controversy between the parties hereto involving the construction or application of terms, covenants or conditions of this Agreement, or any claims arising out of or relating to this Agreement or

the breach thereof or with your employment of with the Company or any termination of that employment, except with respect to prejudgment remedies, will be submitted to and settled by final and binding arbitration in San Francisco, California, in accordance with the Model Employment Dispute Resolution Rules of the American Arbitration Association (the "Rules") then in effect, any arbitrator shall be selected pursuant to such Rules and judgment upon the award rendered by the arbitrators may be entered in any court having jurisdiction thereof.

To accept this offer, please sign in the space below, indicating your acceptance and agreement to the terms contained herein and return a signed copy to my attention by February 25, 2000. No amendment or modification of the terms of this letter will be valid unless made in writing and signed by you and an authorized officer of the Company.

Jan, on a personal note, I have enjoyed meeting you and look forward to working with you at Titan.

Sincerely,

| /s/ JAN D. WALLACE |
|----------------------|
| Jan D. Wallace, M.D. |
| February 25, 2000 |
| Date |

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 and No. 333-86001 (pertaining to the 1993 Stock Option Plan, the 1995 Stock Option Plan, and the 1998 Stock Option Plan, as amended and restated), and Forms S-3 No. 333-33710, No. 333-51250 and No. 333-53538 of Titan Pharmaceuticals, Inc. of our report dated February 20, 2001, 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, 2000.

/s/ Ernst & Young LLP

Palo Alto, California March 30, 2001