

TITAN PHARMACEUTICALS INC

Form S-1/A

October 28, 2005

As filed with the Securities and Exchange Commission on October 28, 2005

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**AMENDMENT No. 1**  
**to**  
**Form S-1**

**REGISTRATION STATEMENT  
UNDER  
THE SECURITIES ACT OF 1933**



**Titan Pharmaceuticals, Inc.**

(Exact name of Registrant as specified in its charter)

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|   |   |  |
|---|---|--|
| <b>Delaware</b>   | <b>2836</b>   | <b>94-3171940</b>                          |
| (State or Other Jurisdiction of<br>Incorporation or Organization) | (Primary Standard Industrial<br>Classification Code Number) | (I.R.S. Employer Identification<br>Number) |



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

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(Address, including zip code, and telephone number,  
including area code, of Registrant's principal executive offices)



**Louis R. Bucalo**  
**Chief Executive Officer**  
**Titan Pharmaceuticals, Inc.**  
**400 Oyster Point Blvd., Ste. 505**  
**South San Francisco, California 94080**  
**(650) 244-4990**

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(Name, address, including zip code, and telephone number,  
including area code, of agent for service)



**Copies to:**





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**Approximate date of commencement of proposed sale to the public:** From time to time after this Registration Statement becomes effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If delivery of the prospectus is expected to be made pursuant to Rule 434, check the following box.

**CALCULATION OF REGISTRATION FEE**

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| Title of Each Class of Securities to be Registered | Amount to be Registered(1) | Proposed Maximum Offering Price Per Security | Proposed Maximum Aggregate Offering Price(2) | Amount of Registration Fee |
|--|----------------------------|--|--|----------------------------|
| Common Stock, par value \$.001 per share           | 21,819,923 \$              | 1.70 \$                                      | 37,093,869.1 \$                              | 4,365.95(3)                |

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(1) Pursuant to Rule 416 of the Securities Act of 1933, as amended, the shares of common stock offered hereby also include such presently indeterminate number of shares of our common stock as shall be issued by us to the selling shareholders as a result of stock splits, stock dividends or similar transactions.

(2) Estimated solely for the purpose of calculating the amount of the registration fee pursuant to Rule 457(c) under the Securities Act of 1933. For this purpose, we have used the closing price as reported on the American stock Exchange on October 12, 2005.

(3) Previously Paid.

**The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to Section 8(a) , may determine.**

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**INFORMATION CONTAINED HEREIN IS SUBJECT TO COMPLETION OR AMENDMENT. A REGISTRATION STATEMENT RELATING TO THESE SECURITIES HAS BEEN FILED WITH THE SECURITIES AND EXCHANGE COMMISSION. THESE SECURITIES MAY NOT BE SOLD UNTIL THE REGISTRATION STATEMENT BECOMES EFFECTIVE. THIS PROSPECTUS IS NOT AN OFFER TO SELL AND IS NOT A SOLICITATION OF AN OFFER TO BUY IN ANY STATE IN WHICH AN OFFER, SOLICITATION, OR SALE IS NOT PERMITTED.**

**SUBJECT TO COMPLETION, DATED October 28, 2005**



**PROSPECTUS**





**TITAN PHARMACEUTICALS, INC.**



21,819,923 Shares of Common Stock



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This prospectus relates to the offer and sale of up to 21,819,923 shares of common stock of Titan Pharmaceuticals, Inc. ( we, us, our or Titan ) by certain persons who are stockholders of Titan, including Cornell Capital Partners, LP ( Cornell Capital Partners ).

We are not selling any shares of common stock in this offering and therefore we will not receive any of the proceeds from this offering. We will, however, receive proceeds from the sale of common stock under the Standby Equity Distribution Agreement that we entered into as of September 28, 2005 with Cornell Capital Partners. All costs associated with this registration will be borne by us.

The shares of common stock are being offered for sale by the selling stockholders at prices established on the American Stock Exchange during the term of this offering. On October 12, 2005, the last reported sale price of our common stock was \$1.70 per share. Our common stock is presently listed on the American Stock Exchange under the symbol TTP.

Cornell Capital Partners is an underwriter within the meaning of the Securities Act of 1933 in connection with the sale of common stock it acquires pursuant to the Standby Equity Distribution Agreement. No other underwriter or person has been engaged to facilitate the sale of shares of common stock in this offering. This offering will terminate twenty-four months after the accompanying registration statement is declared effective by the Securities and Exchange Commission.

Cornell Capital Partners will pay us the lowest daily volume weighted average price of our common stock as quoted by Bloomberg, LP during the five consecutive trading day period immediately following the date we notify Cornell Capital Partners that we desire to make a draw-down under the Standby Equity Distribution Agreement. In addition, Cornell Capital Partners will retain 5% of each draw-down under the Standby Equity Distribution Agreement and we are required to pay Yorkville Advisors Management, LLC, the investment manager for Cornell Capital Partners, \$500 for each draw-down. We paid Cornell Capital Partners a one-time commitment fee equal to \$140,000 in the form of 75,407 shares of common stock and paid Yorkville Advisors Management a structuring fee of \$10,000, all of which are underwriting discounts payable or paid to Cornell Capital Partners.

Brokers or dealers effecting transactions in these shares should confirm that the shares are registered under the applicable state securities laws or that an exemption from registration is available.

**These securities are speculative and involve a high degree of risk. You should purchase securities only if you can afford a complete loss of your investment. See Risk Factors beginning on page 4.**





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**PROSPECTUS SUMMARY**

This summary highlights selected information appearing elsewhere in this prospectus. While this summary highlights what we consider to be the most important information about us, you should carefully read this prospectus and the registration statement of which this prospectus is a part in their entirety before investing in our common stock, especially the risks of investing in our common stock, which we discuss later in Risk Factors, and our financial statements and related notes beginning on page F-1. Unless the context requires otherwise, the words we, us and our refer to Titan Pharmaceuticals, Inc.

**About Titan Pharmaceuticals, Inc.**



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

Probuphine: for the treatment of opioid dependence and chronic pain

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

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

DITPA: for the treatment of congestive heart failure and hyperlipidemia

Gallium maltolate: for the treatment of cancer, bone related diseases and chronic bacterial infections

We were incorporated in Delaware in February 1992 and have funded our operations 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.

### **Summary of the Offering**



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This offering relates to the sale of common stock by selling stockholders consisting of (i) Cornell Capital Partners, which intends to sell up to 21,819,923 shares of common stock, 21,739,130 of which shares may be purchased by Cornell Capital Partners from Titan under the Standby Equity Distribution Agreement and 75,407 of which shares were issued to Cornell Capital Partners upon the signing of the Standby Equity Distribution Agreement as a commitment fee, and (ii) Monitor Capital, Inc., which intends to sell up to 5,386 shares of common stock that were issued to it as a placement agent fee.

Pursuant to the Standby Equity Distribution Agreement, we may, at our discretion, periodically issue and sell to Cornell Capital Partners shares of common stock for a total purchase price of up to \$35 million. The amount of each draw-down is subject to a maximum draw-down amount of \$2 million, and we may not submit any request for a draw-down within five trading days of a prior request. Cornell Capital Partners will pay us the lowest daily volume weighted average price of our common stock during the five consecutive trading day period immediately following the date we notify Cornell Capital Partners that we desire to access the Standby Equity Distribution Agreement. Cornell Capital Partners shall retain 5% of each draw-down it makes to us and we are required to pay Yorkville Advisors Management, LLC, the investment manager for Cornell Capital Partners, \$500 for each draw-down. We paid Cornell Capital Partners a one-time commitment fee equal to \$140,000 in the form of 75,407 shares of common stock and paid Yorkville Advisors Management a structuring fee of \$10,000, all of which are underwriting discounts payable or paid to Cornell Capital Partners. We understand that Cornell Capital Partners intends to sell any shares purchased under the Standby Equity Distribution Agreement at the then prevailing market price. Among other things, this prospectus relates to the shares of common stock to be issued under the Standby Equity Distribution

Agreement. There are substantial risks to investors as a result of the issuance of shares of common stock under the Standby Equity Distribution Agreement. These risks include dilution of stockholders, significant decline in our stock price and our inability to draw sufficient funds when needed.

There is an inverse relationship between our stock price and the number of shares to be issued under the Standby Equity Distribution Agreement in exchange for a cash payment of a particular size. That is, as our stock price declines, we would be required to issue a greater number of shares under the Standby Equity Distribution Agreement for a given draw-down. This inverse relationship is demonstrated by the following table, which shows the number of shares to be issued under the Standby Equity Distribution Agreement assuming that we draw-down the Standby Equity Distribution Agreement in full at \$1.61 per share (the closing price of our common stock on October 6, 2005) and at a 25%, 50% and 75% discount to that price.

|                          | Market Price:<br>\$1.61 | Market Price:<br>\$1.21 | Market Price:<br>\$0.81 | Market Price:<br>\$0.40 |
|--------------------------|-------------------------|-------------------------|-------------------------|-------------------------|
| No. of Shares (1):       | 21,739,130              | 28,925,620              | 43,209,877              | 87,500,000              |
| Total Outstanding (2):   | 54,212,558              | 61,399,048              | 75,683,305              | 119,973,428             |
| Percent Outstanding (3): | 66.9%                   | 89.1%                   | 133.1%                  | 269.5%                  |
| Net Cash to Access (4):  | \$ 33,115,000           | \$ 33,115,000           | \$ 33,115,000           | \$ 33,115,000           |

(1) Represents the number of shares of common stock which could be issued to Cornell Capital Partners under the Standby Equity Distribution Agreement at the prices set forth in the table.

(2) Represents the total number of shares of common stock outstanding after the issuance of the shares to Cornell Capital Partners under the Standby Equity Distribution Agreement, including the 75,407 shares issued to Cornell Capital Partners as a commitment fee and the 5,386 shares issued to Monitor Capital, Inc., as a placement agent fee.

(3) Represents the shares of common stock to be issued as a percentage of the total number shares outstanding as of October 6, 2005.

(4) Net cash equals the gross proceeds minus the 5% fee to be paid to Cornell Capital Partners, the \$10,000 fee paid to Yorkville Advisors Management and approximately \$125,000 in offering expenses.

We engaged Monitor Capital, Inc., a registered broker-dealer, to act as placement agent in connection with the Standby Equity Distribution Agreement. We paid Monitor Capital, Inc. a fee of \$10,000 in the form of 5,386 shares of our common stock as of September 28, 2005, under a Placement Agent Agreement.

Common Stock Offered 21,819,923 shares by the selling stockholders

Offering Price Market Price

Common Stock Outstanding Before the Offering 32,473,428 shares as of October 6, 2005

Use of Proceeds We will not receive any proceeds of the shares offered by the selling stockholders. Any proceeds we receive from the sale of common stock under the Standby Equity Distribution Agreement will be used

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for general working capital purposes. See Use of Proceeds.

Risk Factors

The securities offered hereby involve a high degree of risk. See Risk Factors beginning on page 4.

American Stock Exchange symbol TTP

## Selected Condensed Financial Information

The statements of operations data for the years ended December 31, 2002, 2003 and 2004 and the balance sheet data as of December 31, 2003 and 2004 are derived from our audited consolidated financial statements and footnotes thereto included in the section beginning on page F-1. The statements of operations data for the years ended December 31, 2000 and 2001 and the balance sheet data as of December 31, 2000, 2001 and 2002 have been derived from our audited consolidated financial statements not included in this prospectus. We have also included data for the six months ended June 30, 2004 and 2005 from our unaudited interim consolidated financial statements included in the section beginning on page F-1. This data should be read together with our consolidated financial statements and related footnotes thereto included in the section beginning on page F-1 and the information under Management's Discussion and Analysis of Financial Condition and Results of Operations.

|   | Six Months<br>Ended June 30,<br>(unaudited) |             | Year Ended December 31, |             |             |             |             |
|---|---|-------------|-------------------------|-------------|-------------|-------------|-------------|
|   | 2005  | 2004        | 2004                    | 2003        | 2002        | 2001        | 2000        |
| (in thousands, except per share data)                         |   |             |                         |             |             |             |             |
| <b>Statement of Operations Data:</b>                          |   |             |                         |             |             |             |             |
| Total revenue(1)  | \$ 27                                       | \$ 1        | \$ 31                   | \$ 89       | \$ 2,892    | \$ 4,572    | \$ 1,880    |
| Operating expenses:   |   |             |                         |             |             |             |             |
| Research and development                                      | 9,722                                       | 9,711       | 20,415                  | 22,258      | 29,819      | 23,339      | 16,744      |
| Acquired/in-process research and development(2)               |   |             | 759                     | 3,896       |             |             | 4,969       |
| General and administrative                                    | 2,600                                       | 2,486       | 5,237                   | 5,109       | 5,076       | 5,383       | 4,070       |
| Other income, net   | 257   | 260         | 376                     | 1,285       | 3,821       | 6,686       | 5,115       |
| Net loss  | \$ (12,038)                                 | \$ (11,936) | \$ (26,004)             | \$ (29,889) | \$ (28,182) | \$ (17,464) | \$ (18,788) |
| Basic and diluted net loss per share                          | \$ (0.37)                                   | \$ (0.39)   | \$ (0.83)               | \$ (1.07)   | \$ (1.02)   | \$ (0.63)   | \$ (0.73)   |
| Shares used in computing basic and diluted net loss per share | 32,350                                      | 30,558      | 31,381                  | 27,907      | 27,642      | 27,595      | 25,591      |

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

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

|   | As of June 30,<br>(unaudited) |           | As of December 31, |           |           |            |            |
|---|-------------------------------|-----------|--------------------|-----------|-----------|------------|------------|
|   | 2005                          | 2004      | 2004               | 2003      | 2002      | 2001       | 2000       |
| (in thousands)                                    |                               |           |                    |           |           |            |            |
| <b>Balance Sheet Data:</b>                        |                               |           |                    |           |           |            |            |
| Cash, cash equivalents, and marketable securities | \$ 24,279                     | \$ 48,469 | \$ 36,322          | \$ 46,555 | \$ 73,450 | \$ 105,051 | \$ 117,523 |
| Working capital                                   | 21,943                        | 47,103    | 33,760             | 44,578    | 70,702    | 100,193    | 115,386    |
| Total assets                                      | 26,505                        | 50,932    | 38,626             | 49,008    | 75,926    | 107,132    | 118,442    |
| Total stockholders equity                         | 21,834                        | 47,058    | 33,713             | 44,426    | 70,740    | 100,127    | 114,738    |



## RISK FACTORS

Any investment in our securities involves a high degree of risk. You should carefully consider the risks described below, which we believe are all the material risks to our business, together with the information contained elsewhere in this prospectus, before you make a decision to invest in our company.

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

From our inception through June 30, 2005, we had an accumulated deficit of approximately \$197.8 million. We will continue to incur losses for the foreseeable future as a result of the various costs associated with our research, development, financial, administrative, regulatory and management activities. We may never achieve or sustain profitability.

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

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

will be found to be ineffective or unsafe;

will not receive necessary regulatory clearances;

will be unable to get to market in a timely manner;

will not be capable of being produced in commercial quantities at reasonable costs;

will not be successfully marketed; or

will not be widely accepted by the physician community.

To date, we have experienced setbacks in some of our product development efforts. The results of a study evaluating the EKG profile of patients taking iloperidone, for example, found that iloperidone appeared to prolong the cardiac QTc interval, potentially a cause for concern. While iloperidone was shown to have a similar QTc profile to ziprasidone (Geodon), a product already approved by the FDA, these results significantly delayed the regulatory filings for that product and we cannot predict when, if ever, the development program for iloperidone will advance.

We previously announced study results with CeaVac that did not meet their primary endpoint, and, as a result, we have determined to discontinue our internal activities in the development of the monoclonal antibodies CeaVac, TriAb, and TriGem.

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

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

We may continue to experience unanticipated problems relating to product development, testing, regulatory compliance, manufacturing, marketing and competition, and our costs and expenses could exceed current estimates. We cannot predict whether we will successfully develop and commercialize any products.

**We must comply with extensive government regulations.**

Our research, development, preclinical and clinical trial activities and the manufacture and marketing of any products that we may successfully develop are subject to an extensive regulatory approval process by the FDA and other regulatory agencies in the U.S. and other countries. The process of obtaining required regulatory approvals for drugs, including conducting preclinical and clinical testing to determine safety and efficacy, is lengthy, expensive and uncertain. Even after such time and expenditures, we may not obtain necessary regulatory approvals for clinical testing or for the manufacturing or marketing of any products. We have limited experience in obtaining FDA approval. Regulatory approval may entail limitations on the indicated usage of a drug, which may reduce the drug's market potential. Even if regulatory clearance is obtained, post-market evaluation of the products, if required, could result in restrictions on a product's marketing or withdrawal of the product from the market, as well as possible civil and criminal sanctions. Our regulatory submissions may be delayed or we may cancel plans to make submissions for proposed products for a number of reasons, including:

unanticipated preclinical testing or clinical trial reports;

changes in regulations or the adoption of new regulations;

unanticipated enforcement of existing regulations;

unexpected technological developments; and

developments by our competitors.

Consequently, we cannot assure you that we will make our submissions promptly, or at all, or that our submissions will receive approval from the FDA. If our corporate partners and we are unable to obtain regulatory approval for our products, our business will be seriously harmed.

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

**We face risks associated with third parties conducting preclinical studies and clinical trials of our products as well as our dependence on third parties to manufacture any products that we may successfully develop.**

We depend on third-party laboratories and medical institutions to conduct preclinical studies and clinical trials for our products and other third-party organizations to perform data collection and analysis, all of which must maintain both good laboratory and good clinical practices. We will also depend upon third party manufacturers for the production of any products we may successfully develop to comply with current Good Manufacturing Practices of the FDA, which are similarly outside our direct control. If third party laboratories and medical institutions conducting studies of our products fail to maintain both good laboratory and clinical practices, the studies could be delayed or have to be repeated. Similarly, if the manufacturers of any products we develop in the future fail to comply with Good Manufacturing Practices of the FDA, we may be forced to cease manufacturing such product until we found another third party to manufacture the product.

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

In order to obtain the regulatory approvals that we need to commercialize any of our product candidates, we must demonstrate that each product candidate is safe and effective for use in humans for each target indication. The results of preclinical and Phase I and Phase II clinical studies are not necessarily indicative of whether a product will demonstrate safety and efficacy in large patient populations. Although two of our product candidates have reached Phase III human clinical trials, results from the studies have not supported a regulatory filing. Several other product candidates are currently advancing into Phase II human clinical trials. We may not be able to demonstrate that any

of our product candidates will be safe or effective in advanced trials that involve larger numbers of patients. Clinical trials are subject to oversight by institutional review boards and the FDA and:

must be conducted in conformance with the FDA's good laboratory practice regulations;

must meet requirements for institutional review board oversight;

must meet requirements for informed consent;

must meet requirements for good clinical practices;

are subject to continuing FDA oversight; and

may require large numbers of test subjects.

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

unanticipated, negative or ambiguous results;

undesirable side effects which delay or extend the trials;

our inability to locate, recruit and qualify a sufficient number of patients for our trials;

regulatory delays or other regulatory actions;

difficulties in manufacturing sufficient quantities of the particular product candidate or any other components needed for our preclinical testing or clinical trials;

change in the focus of our development efforts; and

reevaluation of our clinical development strategy.

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

**We face risks associated with clinical trial liability claims in the event that the use or misuse of our product candidates results in personal injury or death.**

We face an inherent risk of clinical trial liability claims in the event that the use or misuse of our product candidates results in personal injury or death. Our clinical liability insurance coverage may not be sufficient to cover claims that may be made against us. Any claims against us, regardless of their merit, could severely harm our financial condition, strain our management and other resources or destroy the prospects for commercialization of the product which is the subject of any such claim.

**We may be unable to protect our patents and proprietary rights.**

Our future success will depend to a significant extent on our ability to:

obtain and keep patent protection for our products and technologies on an international basis;

enforce our patents to prevent others from using our inventions;

maintain and prevent others from using our trade secrets; and

operate and commercialize products without infringing on the patents or proprietary rights of others.

We cannot assure you that our patent rights will afford any competitive advantages, and these rights may be challenged or circumvented by third parties. Further, patents may not be issued on any of our pending patent applications in the U.S. or abroad. Because of the extensive time

required for development, testing and regulatory review of a potential product, it is possible that before a potential product can be commercialized, any related patent

may expire or remain in existence for only a short period following commercialization, reducing or eliminating any advantage of the patent. If we sue others for infringing our patents, a court may determine that such patents are invalid or unenforceable. Even if the validity of our patent rights is upheld by a court, a court may not prevent the alleged infringement of our patent rights on the grounds that such activity is not covered by our patent claims.

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

pay substantial damages;

stop using our technologies and methods;

stop certain research and development efforts;

develop non-infringing products or methods; and

obtain one or more licenses from third parties.

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

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

We also rely in our business on trade secrets, know-how and other proprietary information. We seek to protect this information, in part, through the use of confidentiality agreements with employees, consultants, advisors and others. Nonetheless, we cannot assure you that those agreements will provide adequate protection for our trade secrets, know-how or other proprietary information and prevent their unauthorized use or disclosure. To the extent that consultants, key employees or other third parties apply technological information independently developed by them or by others to our proposed products, disputes may arise as to the proprietary rights to such information, which may not be resolved in our favor. Most of our consultants are employed by, or have consulting agreements with, third parties and any inventions discovered by such



individuals generally will not become our property. There is a risk that other parties may breach confidentiality agreements or that our trade secrets may become known or independently discovered by competitors.

**We face intense competition.**

Competition in the pharmaceutical and biotechnology industries is intense. We face, and will continue to face, competition from numerous companies that currently market, or are developing, products for the treatment of the diseases and disorders we have targeted. Many of these entities have significantly greater research and development capabilities, experience in obtaining regulatory approvals and manufacturing, marketing, financial and managerial resources than we have. We also compete with universities and other research institutions in the development of products, technologies and processes, as well as the recruitment of highly qualified personnel. Our competitors may succeed in developing technologies or products that are more effective than the ones we have under development or that render our proposed products or technologies noncompetitive or obsolete. In addition, our competitors may achieve product commercialization or patent protection earlier than we will.

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

As a company with limited resources, we rely significantly on the resources of third parties to conduct research and development and complete the regulatory approval process on our behalf. For example, our ability to ultimately

derive revenues from iloperidone is almost entirely dependent upon Novartis and Vanda Pharmaceuticals conducting the Phase III trials and completing the regulatory approval process and implementing the marketing program necessary to commercialize iloperidone if the product is approved by the FDA. We are similarly dependent upon Schering, our collaborator for the development and commercialization of Spheramine. Beyond our contractual rights, we cannot control the amount or timing of resources that any existing or future corporate partner devotes to product development and commercialization efforts for our product candidates. In addition, we also receive substantial government funding for our cancer immunotherapeutic programs. We cannot assure you that we will continue to receive such governmental funding. If such funds are no longer available, some of our current and future development efforts may be delayed or terminated. We depend on our ability to maintain existing collaborative relationships, to develop new collaborative relationships with third parties and to acquire or in-license additional products and technologies for the development of new product candidates. We cannot assure you that we will be able to maintain or develop new collaborative relationships, or that any such third-party products or technology will be available on acceptable terms, if at all.

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

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

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

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

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

**Healthcare reform and restrictions on reimbursements may limit our financial returns.**

Our ability or the ability of our collaborators to commercialize drug products, if any, may depend in part on the extent to which government health administration authorities, private health insurers and other organizations will reimburse consumers for the cost of these products. These third parties are increasingly challenging both the need for and the price of new drug products. Significant uncertainty exists as to the reimbursement status of newly approved therapeutics. Adequate third party reimbursement may not be available for our own or our collaborator's drug products to enable us or them to maintain price levels sufficient to realize an appropriate return on their and our investments in research and product development.

**We may not be able to retain our key management and scientific personnel.**

As a company with a limited number of personnel, we are highly dependent on the services of Dr. Louis R. Bucalo, our Chairman, President and Chief Executive Officer, as well as the other principal members of our management and scientific staff. The loss of one or more of such individuals could substantially impair ongoing research and

development programs and could hinder our ability to obtain corporate partners. Our success depends in large part upon our ability to attract and retain highly qualified personnel. We compete in our hiring efforts with other pharmaceutical and biotechnology companies, as well as universities and nonprofit research organizations, and we may have to pay higher salaries to attract and retain personnel.

**We will need additional financing.**

At June 30, 2005, we had approximately \$24.3 million of cash, cash equivalents, and marketable securities that we believe will enable us to fund our operations into the second quarter of 2006 and although the agreement with Cornell Capital Partners provides us with up to \$35,000,000 of financing, it is likely that we will need to seek additional financing to continue our product development activities, and will be required to obtain substantial funding to commercialize any products other than iloperidone or Spheramine that we may successfully develop. Other than the Standby Equity Distribution Agreement with Cornell Capital Partners, we do not have any funding commitments or arrangements. If we are unable to generate adequate revenues, enter into a corporate collaboration, complete a debt or equity offering, or otherwise obtain sufficient financing when and if needed, we may be required to reduce, defer or discontinue one or more of our product development programs.

**Future sales of our common stock in the public market could decrease our stock price.**

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

**Our stock price has been and will likely continue to be volatile.**

Our stock price has experienced substantial fluctuations and could continue to fluctuate significantly due to a number of factors, including:

variations in our anticipated or actual operating results;

sales of substantial amounts of our common stock;

announcements about us or about our competitors, including introductions of new products;

litigation and other developments relating to our patents or other proprietary rights or those of our competitors;

conditions in the pharmaceutical or biotechnology industries;

governmental regulation and legislation; and

change in securities analysts' estimates of our performance, or our failure to meet analysts' expectations.

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

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

**Cornell Capital Partners may sell shares of our common stock after we deliver a draw-down notice during the pricing period, which could cause our stock price to decline.**

Cornell Capital Partners is deemed to beneficially own the shares of common stock corresponding to a particular draw-down on the date that we deliver a draw-down notice to Cornell Capital Partners, which is prior to the date the

stock is delivered to Cornell Capital Partners. Cornell Capital Partners may sell such shares any time after we deliver a draw-down notice. Accordingly, Cornell Capital Partners may sell such shares during the pricing period. Such sales may cause our stock price to decline and if so would result in a lower volume weighted average price during the pricing period, which would result in us having to issue a larger number of shares of common stock to Cornell Capital Partners in respect of the draw-down.

**Sales of our shares of common stock under the Standby Equity Distribution Agreement could result in significant dilution to the existing shareholders**

The issuance of shares of our common stock under the Standby Equity Distribution Agreement will dilute our existing stockholders and the issuance or even potential issuance of such shares could have a negative effect on the market price of our common stock. As a result, our net income per share could decrease in future periods, and the market price of our common stock could decline. In addition, the lower our stock price, the more shares of common stock we will have to issue under the Standby Equity Distribution Agreement to draw-down the full amount. If our stock price is lower, then our existing stockholders would experience greater dilution.

**Sales of our stock under the Standby Equity Distribution Agreement could encourage short sales by third parties which could contribute to the future decline of our stock price**

In many circumstances, the provisions of a Standby Equity Distribution Agreement have the potential to cause significant downward pressure on the price of our common stock. This is especially true if the shares being placed into the market exceed the market's ability to buy the increased stock. Such an event could place further downward pressure on the price of our common stock. We may request numerous draw-downs pursuant to the terms of the Standby Equity Distribution Agreement. Even if we use the Standby Equity Distribution Agreement to invest in assets that are materially beneficial to us, the opportunity exists for short sellers and others to contribute to the future decline of our stock price. If there are significant short sales of stock, the price decline that would result from this activity in turn may cause long holders of the stock to sell their shares thereby contributing to sales of stock in the market. If there is an imbalance on the sell side of the market for our common stock, the price will decline.

**We may not be able to make a draw-down under the equity distribution agreement if Cornell Capital Partners holds more than 9.9% of our common stock.**

Pursuant to our agreement with Cornell Capital Partners, in the event Cornell Capital Partners holds more than 9.9% of our then-outstanding common stock, we will be unable to make a draw-down under the Standby Equity Distribution Agreement. A possibility exists that Cornell Capital Partners may own more than 9.9% of our outstanding common stock at a time when we would otherwise plan to make a draw-down under the Standby Equity Distribution Agreement. In that event, if we are unable to obtain additional external funding, we could be forced to curtail or cease our operations.

**We will not be able to make a draw-down under the equity distribution agreement if we would be required to issue more than 6,475,287 shares of our common stock unless we obtain stockholder approval for such issuance.**

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Because we are listed on the American Stock Exchange, we will not be able to issue more than 6,475,287 shares of our common stock in the aggregate to Cornell pursuant to the Standby Equity Distribution Agreement unless we obtain stockholder approval prior to the issuance of such greater number of shares. If we want to make a draw-down under the Standby Equity Distribution Agreement but have already issued the maximum number of shares and are unable to obtain stockholder approval for such issuance in a timely fashion, we will be forced to seek an alternate financing source. In the event that we are unable to obtain financing from an alternate source, we could be forced to cease operations.

**SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This prospectus, including the sections titled Prospectus Summary, Risk Factors, Management's Discussion and Analysis of Financial Condition and Results of Operations and Business, contains forward-looking statements. Forward-looking statements convey our current expectations or forecasts of future events. All statements contained in this prospectus other than statements of historical fact are forward-looking statements. Forward-looking statements include statements regarding our future financial position, business strategy, budgets, projected costs, plans and objectives of management for future operations. The words may, continue, estimate, intend, plan, will, believe, project, expect, anticipate and similar expressions may identify forward-looking statements, but the absence of these words does not necessarily mean that a statement is not forward-looking. These forward-looking statements include, among other things, statements about:

the progress, timing and completion of research, development and clinical trials for our drug candidates;

the time and costs involved in obtaining regulatory approvals of our drug candidates and any limitations imposed by regulatory authorities;

our ability to establish, maintain and enforce collaborative arrangements and other agreements to develop and commercialize drug candidates;

our ability to establish and protect intellectual property rights in our drug candidates without infringing on the intellectual property rights of others, including the costs involved in filing and prosecuting patent applications and enforcing or defending patent claims and potential drug candidates;

our ability to hire and retain the employees necessary to staff our development programs;

our use of the net proceeds from the sale of common stock under the Standby Equity Distribution Agreement;  
and

our estimates of future performance.

Any or all of our forward-looking statements in this prospectus may turn out to be inaccurate. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. They may be affected by inaccurate assumptions we might make or by known or unknown risks and uncertainties, including the risks, uncertainties and assumptions described in Risk Factors. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this prospectus may not occur as contemplated, and



actual results could differ materially from those anticipated or implied by the forward-looking statements.

## USE OF PROCEEDS

This prospectus relates to shares of our common stock that may be offered and sold from time to time by certain selling stockholders. There will be no proceeds to us from the sale of shares of common stock in this offering. We will, however, receive the proceeds from the sale of shares of common stock to Cornell Capital Partners under the Standby Equity Distribution Agreement. The purchase price of the shares purchased under the Standby Equity Distribution Agreement will be equal to the lowest daily volume weighted average price of our common stock during the five consecutive trading day period immediately following the date we notify Cornell Capital Partners that we desire to make a draw-down under the Standby Equity Distribution Agreement. We will pay a fee equal to 5% of each draw-down to Cornell Capital Partners and \$500 for each draw-down to Yorkville Advisors Management as an additional fee.

Pursuant to the Standby Equity Distribution Agreement, the amount of each draw-down is subject to a maximum amount of \$2 million, and we may not submit any request for a draw-down within five trading days of a prior request, or request more than \$35 million over 24 months from the date of this prospectus. We may not request draw-downs if the shares to be issued in connection with such draw-downs would result in Cornell Capital Partners owning more than 9.9% of our outstanding common stock.

For illustrative purposes only, we have set forth below our intended use of proceeds assuming receipt of the maximum amount of net proceeds available under the Standby Equity Distribution Agreement. The table assumes estimated offering expenses of \$125,000, plus the 5% fee payable to Cornell Capital Partners under the Standby Equity Distribution Agreement and the \$10,000 fee paid to Yorkville Advisors Management. The figures below are estimates only, and may be changed due to various factors, including the timing of the receipt of the proceeds.

|  |    |            |
|--|----|------------|
| <b>Gross Proceeds</b>  | \$ | 35,000,000 |
| <b>Net Proceeds</b>  | \$ | 33,115,000 |
| Number of shares issued under the Standby Equity Distribution Agreement at an assumed offering price of \$1.61 |    | 21,739,130 |
| <b>Use of Proceeds:</b>  |    |            |
| General Working Capital  | \$ | 33,115,000 |

The Standby Equity Distribution Agreement limits our use of proceeds to general corporate purposes. However, we cannot use the net proceeds from this offering for the payment (or loan to any such person for the payment) of any judgment, or other liability, incurred by any executive officer, officer, director or employee of ours, except for any liability owed to such person for services rendered, or if any judgment or other liability is incurred by such person originating from services rendered to us, or we have indemnified such person from liability.

## STANDBY EQUITY DISTRIBUTION AGREEMENT

### Overview

On September 28, 2005, we entered into a Standby Equity Distribution Agreement with Cornell Capital Partners. Pursuant to the Standby Equity Distribution Agreement, we may, at our discretion, periodically sell to Cornell Capital Partners shares of common stock for a total purchase price of up to \$35 million. For each share of common stock purchased under the Standby Equity Distribution Agreement, Cornell Capital Partners will pay us the lowest daily volume weighted average price of our common stock during the five consecutive trading day period

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immediately following the date we notify Cornell Capital Partners that we desire to access the Standby Equity Distribution Agreement. The number of shares purchased by Cornell Capital Partners for each draw-down is determined by dividing the amount of each draw-down by the purchase price for the shares of common stock. Further, Cornell Capital Partners will retain 5% of each draw-down under the Standby Equity Distribution Agreement and we will pay \$500 for each draw-down to Yorkville Advisors Management as an additional fee. Cornell Capital Partners is a private limited partnership whose business operations are conducted through its general partner, Yorkville Advisors Management, LLC. The sale of the shares under the Standby Equity Distribution Agreement is conditioned upon us registering the shares of common stock with the Securities and Exchange

Commission. We will bear the costs associated with this registration. There are no other significant closing conditions to draws under the equity line, except as specified below.

### Standby Equity Distribution Agreement Explained

Pursuant to the Standby Equity Distribution Agreement, we may periodically sell shares of common stock to Cornell Capital Partners to raise capital to fund our working capital needs. The periodic sale of shares is known as a draw-down. We may request a draw-down every five trading days. A closing will be held six trading days after such written notice at which time we will deliver shares of common stock and Cornell Capital Partners will pay the draw-down amount. We may request draw-downs under the Standby Equity Distribution Agreement once the underlying shares are registered with the SEC. Thereafter, we may continue to request draw-downs until Cornell Capital Partners has advanced us a total amount of \$35 million or 24 months after the date of this prospectus, whichever occurs first.

The amount of each draw-down is subject to a maximum amount of \$2 million, and we may not submit a request for a draw-down within five trading days of a prior request. The amount available under the Standby Equity Distribution Agreement is not dependent on the price or volume of our common stock. We may not request draw-downs if the shares to be issued in connection with such draw-downs would result in Cornell Capital Partners owning more than 9.9% of our outstanding common stock. If Cornell Capital Partners owns more than 9.9% of our outstanding common stock at a time when we would otherwise plan to take a draw-down under the Standby Equity Distribution Agreement, we would not be able to make such draw-down.

We do not have any agreements with Cornell Capital Partners regarding the holding or distribution of such stock.

We cannot predict the actual number of shares of common stock that will be issued pursuant to the Standby Equity Distribution Agreement in part because the purchase price of the shares will fluctuate based on prevailing market conditions and we have not determined the total amount of draw-downs we intend to make. Nonetheless, we can estimate the number of shares of our common stock that will be issued using certain assumptions. Assuming we issued the number of shares of common stock being registered in the accompanying registration statement at the closing price on October 6, 2005 (\$1.61 per share) we would issue 21,739,130 shares of common stock to Cornell Capital Partners for gross proceeds of \$35,000,000. We previously paid a commitment fee of 75,407 shares of our common stock to Cornell Capital Partners and a placement agent fee of 5,386 shares of common stock to Monitor Capital, Inc. Assuming the price at which we drew-down the Standby Equity Line of Credit was \$1.61, we would have issued 66.9% of our outstanding common stock as of October 6, 2005.

There is an inverse relationship between our stock price and the number of shares to be issued under the Standby Equity Distribution Agreement. That is, as our stock price declines, we would be required to issue a greater number of shares under the Standby Equity Distribution Agreement for a given draw-down. This inverse relationship is demonstrated by the following tables, which show the net cash to be received by us and the number of shares to be issued under the Standby Equity Distribution Agreement at a price of \$1.61 per share (the closing price on October 6, 2005) and 25%, 50% and 75% discounts that price.

|                          | Market Price:<br>\$1.61 | Market Price:<br>\$1.21 | Market Price:<br>\$0.81 | Market Price:<br>\$0.40 |
|--------------------------|-------------------------|-------------------------|-------------------------|-------------------------|
| No. of Shares (1):       | 21,739,130              | 28,925,620              | 43,209,877              | 87,500,000              |
| Total Outstanding (2):   | 54,212,558              | 61,399,048              | 75,683,305              | 119,973,428             |
| Percent Outstanding (3): | 66.9%                   | 89.1%                   | 133.1%                  | 269.5%                  |

|                         |    |            |    |            |    |            |    |            |
|-------------------------|----|------------|----|------------|----|------------|----|------------|
| Net Cash to Access (4): | \$ | 33,115,000 | \$ | 33,115,000 | \$ | 33,115,000 | \$ | 33,115,000 |
|-------------------------|----|------------|----|------------|----|------------|----|------------|

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(1) Represents the number of shares of common stock which could be issued to Cornell Capital Partners under the Standby Equity Distribution Agreement at the prices set forth in the table.

(2) Represents the total number of shares of common stock outstanding after the issuance of the shares to Cornell Capital Partners under the Standby Equity Distribution Agreement, including the 75,407 shares issued to Cornell Capital Partners as a commitment fee and the 5,386 shares issued to Monitor Capital, Inc., as a placement agent fee.

- (3) Represents the shares of common stock to be issued as a percentage of the total number shares outstanding as of October 6, 2005.
- (4) Net cash equals the gross proceeds minus the 5% fee to be paid to Cornell Capital Partners, the \$10,000 fee paid to Yorkville Advisors Management and approximately \$125,000 in offering expenses.

Proceeds used under the Standby Equity Distribution Agreement will be used in the manner set forth in the "Use of Proceeds" section of this prospectus. We cannot predict the total amount of proceeds to be raised in this transaction because we have not determined the total amount of the draw-downs we intend to make. Cornell Capital Partners has the ability to permanently terminate its obligation to purchase shares of common stock from us under the Standby Equity Distribution Agreement if there shall occur any stop order or suspension of the effectiveness of the registration statement for an aggregate of 50 trading days other than due to acts by Cornell Capital Partners or if we fail materially to comply with certain terms of the Standby Equity Distribution Agreement, which failure remains uncured for 30 days after notice from Cornell Capital Partners.

All fees and expenses under the Standby Equity Distribution Agreement will be borne by us. We expect to incur expenses of approximately \$125,000 in connection with this registration, consisting primarily of professional fees.

We paid Cornell Capital Partners a one-time commitment fee equal to \$140,000 in the form of 75,407 shares of common stock and paid Yorkville Advisors Management a structuring fee of \$10,000, all of which are underwriting discounts payable or paid to Cornell Capital Partners.

We engaged Monitor Capital, Inc., a registered broker-dealer, to act as placement agent in connection with the Standby Equity Distribution Agreement. We paid Monitor Capital, Inc. a fee of \$10,000 in the form of 5,386 shares of our common stock as of September 28, 2005, under a Placement Agent Agreement.

### SELLING STOCKHOLDERS

The following table presents information regarding the selling stockholders. The selling stockholders assisted in or provided financing to us.

| Selling Stockholder          | Shares Beneficially Owned Before Offering | Percentage of Outstanding Shares Beneficially Owned Before Offering (1) | Shares to be Acquired under the Standby Equity Distribution Agreement | Percentage of Outstanding Shares Beneficially Owned Assuming Acquisition of All Shares Acquired Under Standby Equity Distribution Agreement (1) | Shares to be Sold in the Offering | Percentage of Outstanding Shares Beneficially Owned After the Offering (1) |
|------------------------------|---|---|---|---|-----------------------------------|--|
| Cornell Capital Partners, LP | 75,407                                    | *   | 21,739,130  | 40.23%  | 21,814,537                        |  |
| Monitor Capital, Inc.        | 5,386                                     | *   |   | *   | 5,386                             |  |

\* Less than 1%.

(1) Applicable percentage of ownership is based on 32,473,428 shares of common stock outstanding as of October 6, 2005, together with securities exercisable for or convertible into shares of common stock within 60 days of October 6, 2005, for each stockholder. Beneficial ownership is determined in accordance with Rule 13d-3(d) promulgated by the SEC under the Securities Exchange Act of 1934, as amended. Each person or group identified possesses sole voting and investment power with respect to the shares. Shares not outstanding but deemed beneficially owned by virtue of the right of a person to acquire them within 60 days are treated as outstanding only for purposes of determining the number of and percent owned by such person.

### Shares Acquired In Financing Transactions

The following information contains a description of each selling stockholder's relationship to us, and how each selling stockholder acquired the shares to be sold in this offering is detailed below. Neither of the selling stockholders have held a position or office, or had any other material relationship, with us, except as follows:

#### Cornell Capital Partners

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Cornell Capital Partners is the investor under the Standby Equity Distribution Agreement and a holder of shares of our common stock. Yorkville Advisors Management, LLC, the general partner of Cornell Capital Partners controls and makes all investment decisions for Cornell Capital Partners. Mark Angelo, the managing member of Yorkville Advisors Management, makes the investment decisions on behalf of and controls Yorkville Advisors Management. All the shares being registered for Cornell Capital Partners under this registration statement have been issued or are issuable to Cornell Capital Partners pursuant to the Standby Equity Distribution Agreement which we entered into on September 28, 2005. Pursuant to the Standby Equity Distribution Agreement, we may, at our discretion, periodically sell to Cornell Capital Partners shares of common stock for a total purchase price of up to \$35 million. For each share of common stock purchased under the Standby Equity Distribution Agreement, Cornell Capital Partners will pay us the lowest daily volume weighted average price of our common stock during the five consecutive trading day period immediately following the date we notify Cornell Capital Partners that we desire to access the Standby

Equity Distribution Agreement. Further, Cornell Capital Partners will retain 5% of each draw-down under the Standby Equity Distribution Agreement and we will pay \$500 for each draw-down to Yorkville Advisors Management as an additional fee. We paid Cornell Capital Partners a one-time commitment fee equal to \$140,000 in the form of 75,407 shares of common stock and paid Yorkville Advisors Management a structuring fee of \$10,000 in connection with the Standby Equity Distribution Agreement.

### **Monitor Capital, Inc.**

We engaged Monitor Capital, Inc., a registered broker-dealer, to act as placement agent in connection with the Standby Equity Distribution Agreement. We paid Monitor Capital, Inc. a fee of \$10,000 in the form of 5,386 shares of common stock on September 28, 2005, under a Placement Agent Agreement. Each of Hsiao-wen Kao, Monitor Capital, Inc.'s President and Chief Executive Officer, and John Dickerson, Monitor Capital, Inc.'s majority stockholder, individually, make investment decisions for Monitor Capital, Inc.



**PLAN OF DISTRIBUTION**

The selling stockholders have advised us that the sale or distribution of our common stock owned by the selling stockholders may be effected directly to purchasers by the selling stockholders as principals or through one or more underwriters, brokers, dealers or agents from time to time in one or more transactions (which may involve crosses or block transactions) (i) on the American Stock Exchange or in any other market on which the price of our shares of common stock are quoted or (ii) in transactions otherwise than on the American Stock Exchange or in any other market on which the price of our shares of common stock are quoted. Any of such transactions may be effected at market prices prevailing at the time of sale, at prices related to such prevailing market prices, at varying prices determined at the time of sale or at negotiated or fixed prices, in each case as determined by the selling stockholders or by agreement between the selling stockholders and underwriters, brokers, dealers or agents, or purchasers. If the selling stockholders effect such transactions by selling their shares of common stock to or through underwriters, brokers, dealers or agents, such underwriters, brokers, dealers or agents may receive compensation in the form of discounts, concessions or commissions from the selling stockholders or commissions from purchasers of common stock for whom they may act as agent (which discounts, concessions or commissions as to particular underwriters, brokers, dealers or agents may be in excess of those customary in the types of transactions involved).

Cornell Capital Partners is an underwriter within the meaning of the Securities Act of 1933 in connection with the sale of common stock under the Standby Equity Distribution Agreement. Cornell Capital Partners will pay us the lowest daily volume weighted average price of our common stock during the five consecutive trading day period immediately following the date we notify Cornell Capital Partners that we desire to access the Standby Equity Distribution Agreement. In addition, Cornell Capital Partners will retain 5% of each draw-down under the Standby Equity Distribution Agreement and we are required to pay Yorkville Advisors Management, LLC, the investment manager for Cornell Capital Partners, a \$500 for each draw-down. We paid Cornell Capital Partners a one-time commitment fee equal to \$140,000 in the form of 75,407 shares of common stock and paid Yorkville Advisors Management a structuring fee of \$10,000, all of which are underwriting discounts payable or paid to Cornell Capital Partners.

The following table shows the discount that Cornell Capital Partners will receive in connection with our draw-down in full of the Standby Equity Distribution Agreement, assuming a market price of \$1.61 (the closing price of the common stock on October 6, 2005) and the issuance of 21,739,130 shares of our common stock.

|   | Per share |      | Total |            |
|---|-----------|------|-------|------------|
| Market price  | \$        | 1.61 | \$    | 35,000,000 |
| Discount (5% and \$10,000 fee to Yorkville Advisors Management) (1) | \$        | 1.53 | \$    | 1,760,000  |
| Proceeds before expenses  | \$        | 1.52 | \$    | 33,240,000 |

(1) Does not include the \$500 per draw-down fee to be paid to Yorkville Advisors Management.

In addition, we engaged Monitor Capital, Inc., a registered broker-dealer, to act as placement agent in connection with the Standby Equity Distribution Agreement. We paid Monitor Capital, Inc. a fee of \$10,000 in the form of 5,386 shares of our common stock on September 28, 2005 pursuant to a Placement Agent Agreement.

Cornell Capital Partners was formed in February 2000 as a Delaware limited partnership. Cornell Capital Partners is a domestic hedge fund in the business of investing in and financing public companies. Cornell Capital Partners does not intend to make a market in our stock or to otherwise engage in stabilizing or other transactions intended to help support the stock price. Prospective investors should take these factors into

consideration before purchasing our common stock.

Under the securities laws of certain states, the shares of common stock may be sold in such states only through registered or licensed brokers or dealers. The selling stockholders are advised to ensure that any underwriters, brokers, dealers or agents effecting transactions on behalf of the selling stockholders are registered to sell securities in all fifty states. In addition, in certain states the shares of common stock may not be sold unless the shares have been registered or qualified for sale in such state or an exemption from registration or qualification is available and is complied with.

We will pay all the expenses incident to the registration, offering and sale of the shares of common stock to the public hereunder other than commissions, fees and discounts of underwriters, brokers, dealers and agents. If any of these other expenses exists, we expect the selling stockholders to pay these expenses. We have agreed to indemnify Cornell Capital Partners and its controlling persons against certain liabilities. We estimate that the expenses of the offering to be borne by us will be approximately \$125,000.

The selling stockholders are subject to applicable provisions of the Securities Exchange Act of 1934, as amended, and its regulations, including Regulation M. Under Regulation M, the selling stockholders or their agents may not bid for, purchase, or attempt to induce any person to bid for or purchase, shares of our common stock while such selling stockholders are distributing shares covered by this prospectus. Pursuant to the requirements of Item 512 of Regulation S-K and as stated in Part II of this Registration Statement, we must file a post-effective amendment to the accompanying Registration Statement once informed of a material change from the information set forth with respect to the Plan of Distribution.

Pursuant to our agreement with Cornell Capital Partners, in the event Cornell Capital Partners holds more than 9.9% of our then-outstanding common stock, we will be unable to make a draw-down under the Standby Equity Distribution Agreement. A possibility exists that Cornell Capital Partners may own more than 9.9% of our outstanding common stock at a time when we would otherwise plan to make a draw-down under the Standby Equity Distribution Agreement

**MANAGEMENT'S DISCUSSION AND ANALYSIS OF  
FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

**Overview**

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

Probuphine: for the treatment of opioid dependence and chronic pain

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

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

DITPA: for the treatment of congestive heart failure and hyperlipidemia

Gallium maltolate: for the treatment of cancer, bone related diseases and chronic bacterial infections

We were incorporated in Delaware in February 1992 and have funded our operations 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.

**Results of Operations**

**Three and Six Months Ended June 30, 2005 Compared to Three and Six Months Ended June 30, 2004**

Our net loss for the three months ended June 30, 2005 was approximately \$5.7 million, or \$0.18 per share, compared to approximately \$5.6 million, or \$0.17 per share, for the comparable period in 2004. For the six months ended June 30, 2005, our net loss was approximately \$12.0

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million, or \$0.37 per share, compared to approximately \$11.9 million, or \$0.39 per share, for the comparable period in 2004.

We had revenues from licensing agreements of approximately \$13,000 during the three month periods ended June 30, 2005 and no revenue during the comparable three month period of 2004. During the six months ended June 30, 2005 and 2004, we had revenues of approximately \$27,000 and \$1,000, respectively.

Research and development expenses for the three months ended June 30, 2005 were approximately \$4.5 million, compared to approximately \$4.6 million for the comparable period in 2004, a decrease of \$0.1 million, or 2%. Research and development expenses for the six months ended June 30, 2005 were approximately \$9.7 million, compared to approximately \$9.7 million for the comparable period in 2004. External research and development expenses include direct expenses such as clinical research organization charges, investigator and review board fees, patient expense reimbursements, pre-clinical activities and contract manufacturing expenses. In the second quarter 2005, our external research and development expenses relating to our core product development programs were approximately: \$1.2 million related to Probuphine, \$1.4 million related to DITPA, and \$568,000 related to gallium maltolate. Other research and development expenses include internal operating costs such as clinical research and development personnel-related expenses, clinical trials related travel expenses, and allocation of facility and corporate costs. As a result of the risks and uncertainties inherently associated with pharmaceutical research and development activities described elsewhere in this report, we are unable to estimate the specific timing and future costs of our clinical development programs or the timing of material cash inflows, if any, from our product candidates.

General and administrative expenses for the three months ended June 30, 2005 were approximately \$1.3 million, compared to approximately \$1.1 million for the comparable period in 2004, an increase of \$0.2 million, or 18%. General and administrative expenses for the six months ended June 30, 2005 were approximately \$2.6 million, compared to approximately \$2.5 million for the comparable period in 2004, an increase of \$0.1 million, or 4%. The increase in general and administrative expenses during the three months ended June 30, 2005 was primarily related to an increase in personnel related costs and other general and administrative costs, including professional fees.

Net other income for the three months ended June 30, 2005 was approximately \$106,000, compared to net other income of approximately \$161,000 in the comparable period in 2004. Net other income for the six months ended June 30, 2005 was approximately \$257,000, compared to net other income of approximately \$260,000 in the comparable period in 2004. The decrease, primarily in interest income, was a result of lower balances of cash and marketable securities.

#### **Year Ended December 31, 2004 Compared to Year Ended December 31, 2003**

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

Research and development expenses for 2004 were \$20.4 million compared to \$22.3 million for 2003, a decrease of \$1.9 million. The decrease in research and development was primarily associated with the pending completion of a Phase II clinical study and the reduction of internal resources to our immunotherapy products in 2004. Of our 2004 research and development expenses, approximately 44%, or \$9.0 million, were attributable to external R&D expenses. External R&D expenses include direct expenses such as clinical research organization charges, investigator and review board fees, patient expense reimbursements, pre-clinical activities and contract manufacturing expenses. In 2004, approximately \$3.9 million of external R&D expenses were related to Pivanex, \$1.4 million to Probuphine, \$1.3 million to gallium maltolate, \$1.2 million to DITPA, \$0.2 million to Spheramine, and the remainder to other projects.

Remaining R&D expenses were attributable to internal operating costs, which include clinical research and development personnel salaries and employment related expenses, clinical trials related travel expenses, and allocation of facility and corporate costs. In 2004, we recorded a \$759,000 acquired research and development expense in connection with the acquisition of minority shares of ProNeura, Inc. The entire purchase price of the shares was charged to acquired research and development on the acquisition date in accordance with generally accepted accounting principles. As a result of the risks and uncertainties inherently associated with pharmaceutical research and development activities described elsewhere in this report, we are unable to estimate the specific timing and future costs of our clinical development programs or the timing of material cash inflows, if any, from our product candidates.



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

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

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

#### **Year Ended December 31, 2003 Compared to Year Ended December 31, 2002**

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

Research and development expenses for 2003 were \$22.3 million compared to \$29.8 million for 2002, a decrease of \$7.5 million. The decrease in research and development was primarily associated with the completion of a randomized, placebo-controlled Phase III clinical study in 2002. Of our 2003 research and development expenses, approximately 52%, or \$11.7 million, were attributable to external R&D expenses. External R&D expenses include direct expenses such as clinical research organization charges, investigator and review board fees, patient expense reimbursements, pre-clinical activities and contract manufacturing expenses. In 2003, approximately \$5.2 million of external R&D expenses were related to Pivanex, \$1.2 million to Probuphine, \$1.3 million to gallium maltolate, \$0.6 million to Spheramine, and the remainder to other projects. Remaining R&D expenses were attributable to internal operating costs, which include clinical research and development personnel salaries and employment related expenses, clinical trials related travel expenses, and allocation of facility and corporate costs. In 2003, we recorded a \$3.9 million acquired research and development expense in connection with the acquisition of DITPA, a novel product for the potential treatment of congestive heart failure. The entire purchase price was charged to acquired research and development on the acquisition date in accordance with generally accepted accounting principles.

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

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

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

#### **Liquidity And Capital Resources**

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



grants. At June 30, 2005, we had \$24.3 million of cash, cash equivalents, and marketable securities compared to \$36.3 million at December 31, 2004.

Our operating activities used \$12.0 million during the six months ended June 30, 2005. This consisted primarily of the net loss for the period of \$12.0 million offset in part by non-cash charges of \$0.2 million related to depreciation and amortization expenses and \$0.2 million related to changes in prepaid expenses, receivables, other assets, accounts payable and other accrued liabilities. Uses of cash in operating activities were primarily to fund product development programs and administrative expenses. We have entered into various agreements with research institutions, universities, and other entities for the performance of research and development activities and for the acquisition of licenses related to those activities. Certain of the licenses require us to pay royalties on future product sales, if any. In addition, in order to maintain license and other rights while products are under development, we must comply with customary licensee obligations, including the payment of patent related costs, annual minimum license fees, meeting project-funding milestones and diligent efforts in product development. The aggregate commitments we have under these agreements, including minimum license payments, for the next 12 months is approximately \$0.3 million.

Net cash provided by investing activities of \$11.7 million during the six months ended June 30, 2005 consisted of sales and maturities of marketable securities of \$16.9 million, partially offset by purchases of marketable securities of \$4.9 million and capital expenditures of \$0.2 million.

Net cash provided by financing activities during the six months ended June 30, 2005 was \$82,000, which consisted primarily of net proceeds from the exercise of stock options.

On September 30, 2005, we reduced our workforce by 10 employees in order to reduce our operating expenses. We expect to save approximately \$300,000 per quarter in payroll expenses due to the reduction.

On September 28, 2005, we entered into a Standby Equity Distribution Agreement with Cornell Capital Partners. Under the agreement, we can require Cornell to purchase up to \$35,000,000 of our common stock over a two year period following the effective date of a registration statement covering the shares of the common stock to be sold to Cornell Capital Partners. We can make draw-downs under the agreement in \$2,000,000 increments. At the closing of each draw-down (which will take place six days after our notification to Cornell Capital Partners) we will issue to Cornell Capital Partners a number of shares of our common stock equal to the amount of the draw-down divided by the lowest daily volume weighted average price of our common stock during the five trading days following the draw-down notice to Cornell Capital Partners. At each closing, we will pay 5% of the amount of the draw-down to Cornell Capital Partners and \$500 to Yorkville Associates Management, the investment advisor to Cornell Capital Partners. We are not obligated to make any draw-downs under the agreement, and will not pay any additional fees to Cornell Capital Partners if we do not do so.

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

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 into the second quarter of 2006.

Although the agreement with Cornell Capital Partners provides us with up to \$35,000,000 of financing and the workforce reduction described above will save us approximately \$300,000 per quarter, we continue to seek alternative financing sources and in the future we will need to seek additional financing to continue our product development activities, and will be required to obtain substantial funding to commercialize any products other than iloperidone or Spheramine that we may successfully develop. In the future, if we are unable to complete a debt or equity offering, or otherwise obtain sufficient financing when and if needed, we may be required to reduce, defer or discontinue one or more of our product development programs.

### Critical Accounting Policies and Estimates

The preparation of our financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in our financial statements and accompanying notes. Actual results could differ materially from those estimates. We believe the following accounting policies and estimates for the year ended December 31, 2004, to be critical:

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

### Contractual Obligations and Commitments

The following table sets forth the aggregate contractual cash obligations as of June 30, 2005 (in thousands):

| Contractual obligations                 | Total    | Payments Due by Period |           |           |          |
|---|----------|------------------------|-----------|-----------|----------|
|   |          | < 1 year               | 1-3 years | 3-5 years | 5 years+ |
| Operating leases                        | \$ 3,206 | \$ 805                 | \$ 1,235  | \$ 1,166  | \$       |
| Sponsored research & license agreements | \$ 1,326 | \$ 332                 | \$ 438    | \$ 370    | \$ 186   |
| Total contractual cash obligations      | \$ 4,532 | \$ 1,137               | \$ 1,673  | \$ 1,536  | \$ 186   |



**BUSINESS**

**Overview**

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

Probuphine: for the treatment of opioid dependence and chronic pain

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

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

DITPA: for the treatment of congestive heart failure and hyperlipidemia

Gallium maltolate: for the treatment of cancer, bone related diseases and chronic bacterial infections

We are directly developing our product candidates and also utilizing strategic partnerships. These partnerships help fund product development and enable us to retain significant economic interest in our products. In June 2004, we announced that Vanda Pharmaceuticals, Inc. (Vanda) had acquired from Novartis Pharma AG (Novartis) the worldwide rights to develop and commercialize iloperidone, our proprietary antipsychotic agent in Phase III clinical development for the treatment of schizophrenia and related psychotic disorders. Vanda will now pursue advancement of the iloperidone Phase III development program. All of our rights and economic interests in iloperidone, including royalties on sales of iloperidone, remain essentially unchanged under the agreement. Spheramine development is primarily funded by our corporate partner for Spheramine, Schering AG, Germany (Schering) under an agreement in which Schering received exclusive, worldwide development, manufacturing and commercialization rights, and, in addition to clinical and manufacturing development funding and milestone payments, Schering will pay us a royalty on future product sales.

We were incorporated in Delaware in February 1992 and have funded our operations 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.

**Financial Information about Industry Segments**

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

**Product Development Programs**



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

| <b>Product</b>    | <b>Potential Indication(s)</b>                                | <b>Phase of Development</b> | <b>Marketing Rights</b>     |
|-------------------|---|-----------------------------|-----------------------------|
| Probuphine        | Opioid dependence   | Initiating Phase III        | Titan                       |
| Probuphine        | Chronic pain  | Initiating Phase II         | Titan                       |
| Iloperidone       | Schizophrenia, psychosis                                      | Phase III                   | Vanda Pharmaceuticals, Inc. |
| Spheramine        | Parkinson's disease   | Phase IIb                   | Schering AG                 |
| DITPA             | Congestive heart failure, hyperlipidemia                      | Phase II                    | Titan                       |
| Gallium maltolate | Cancer, bone related disease and chronic bacterial infections | Phase I                     | Titan                       |

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

***Probuphine***



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We are developing Probuphine for the treatment of opioid dependence and chronic pain. Probuphine is the first product to utilize our novel, proprietary ProNeura long-term drug delivery technology (See ProNeura Continuous Drug Delivery Technology below). Probuphine is designed to provide six months of steady state therapeutic levels of buprenorphine, an approved agent for the treatment of opioid dependence and pain.

In June 2002, we presented data at the International Conference on Pain and Chemical Dependency in New York demonstrating that Probuphine continuously delivered buprenorphine for one year in preclinical studies. In June 2004, we announced final results from a pilot clinical study that evaluated the safety, pharmacokinetics and preliminary efficacy of Probuphine in the treatment of opioid-dependent patients. The results were presented at the Annual Meeting of The International Society of Addiction Medicine in Helsinki, and demonstrated that all 12 patients switched from daily sublingual buprenorphine therapy to Probuphine, had maintenance of therapeutic benefit for a period of six months following a single treatment of Probuphine. Treatment with Probuphine was well tolerated in this pilot study, with no significant adverse events.

We are currently in the process of finalizing a clinical development plan with regulatory authorities in various countries to commence Phase III clinical testing potentially leading to product approval. We expect to initiate

clinical testing in the treatment of opioid dependence in the near future. We also plan to initiate Phase II clinical testing of Probuphine in chronic pain in late 2005.

*Iloperidone*



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Iloperidone is our novel, proprietary product in development for the treatment of schizophrenia and related psychotic disorders. Iloperidone has been evaluated in an extensive Phase III program comprising over 3,500 patients at more than 200 sites in 24 countries, administered and funded by Novartis Pharma AG. In three completed efficacy studies, iloperidone statistically significantly reduced the symptoms of schizophrenia compared to placebo. Iloperidone has also been investigated in three 12-month safety studies, which confirm safety and tolerability. Additionally, Novartis has completed a study in elderly patients with good results. Although iloperidone was considered safe in the above efficacy studies, it has shown a dose dependent increase in the QTc interval.

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

In June 2004, we announced that Vanda Pharmaceuticals, Inc. acquired from Novartis Pharma AG the worldwide rights to develop and commercialize iloperidone. Vanda was founded by Dr. Argeris N. Karabelas, former CEO of Novartis Pharmaceuticals, and Dr. Mihael Polymeropoulos, former Vice President of Pharmacogenetics at Novartis Pharmaceuticals. Under its agreement with Novartis, Vanda is now pursuing advancement of the iloperidone Phase III development program and is expected to initiate further Phase III clinical testing of iloperidone by the end of 2005. All of our rights and economic interests in iloperidone, including royalties on sales of iloperidone, remain essentially unchanged under the agreement.

### *Spheramine*



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

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

Spheramine is currently being studied in a multicenter, randomized, blinded, controlled clinical trial in Parkinson's disease. This Phase IIB clinical study will enroll 68 patients with advanced Parkinson's disease (Hoehn and Yahr Stages III and IV) to further evaluate the efficacy, safety, and tolerability of Spheramine. Fifty one patients have been treated to date and we expect initial efficacy results by early 2007.



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

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

***DITPA***



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

We plan to initially develop DITPA as a potential treatment for CHF associated with low serum thyroid hormone (T<sub>3</sub>). CHF is a syndrome of progressive decrease in cardiac function and inability of the heart to pump sufficient blood for proper function of the lungs, kidneys, and other vital organs and tissues. Symptoms include decreasing activity capacity, shortness of breath, and peripheral and pulmonary edema. There are a total of approximately nine million people in the U.S. and Europe with CHF. In the U.S., approximately 25% of patients have moderate or severe symptoms (NYHA Class III or IV), and CHF is the most common hospital discharge diagnosis in the U.S. for patients over 65. Currently, only approximately 50% of patients diagnosed with CHF survive for five years, and only 50% of patients with NYHA Class IV CHF survive one year. New treatments for CHF are greatly needed to improve symptoms, enhance cardiac function, and avoid dangerous and progressive complications of congestive heart failure.

Researchers have demonstrated that approximately 30% of patients with advanced (NYHA Class III and IV) CHF have abnormally low levels of T<sub>3</sub>, the active form of thyroid hormone needed by heart cells, and that low levels of T<sub>3</sub> are a strong independent predictor of increased mortality in CHF patients.

The important role of thyroid hormone in maintaining heart and blood vessel function, and the association of low T<sub>3</sub> and increased mortality in CHF suggest a potential role for DITPA as a thyroid hormone replacement therapy in CHF. Currently available thyroid hormone medications are generally not suitable for chronic use in CHF, because they are primarily T<sub>4</sub> preparations, or have too short a half-life, and have the potential to increase heart rate, which is an unwanted side effect in CHF patients.

In December 2004, we initiated a randomized, double blind, placebo controlled Phase IIb clinical study with DITPA in NYHA Class III and Class IV CHF patients with low thyroid hormone (T<sub>3</sub>) levels. The study will evaluate clinical and laboratory parameters related to severity of CHF, including change in global clinical status, echocardiographic parameters, B-type Natriuretic Peptide (BNP) levels, exercise testing and quality of life measurements in addition to safety. Enrollment in this study is progressing.

Additionally, we believe that scientific evidence concerning thyroid hormone and cardiovascular function suggest potential utility of DITPA in the settings of hyperlipidemia, diastolic dysfunction, left ventricular dysfunction post myocardial infarction and cardiopulmonary bypass surgery. During the fourth quarter of 2005, we are planning to initiate a Phase II clinical study in hyperlipidemia patients whose lipid levels are not sufficiently controlled by statins alone.

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

***Gallium Maltolate***



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Gallium maltolate is our novel oral agent for the potential treatment of bone disease, chronic bacterial infections, and cancer. Gallium is a semi-metallic element with distinct mechanisms of action with potential for the treatment of certain cancers, bone disease and chronic bacterial infections. Gallium acts upon bone by enhancing the formation of osteoblasts and inhibiting osteoclasts, thereby increasing bone deposition and reducing bone turnover. Gallium also inhibits ribonucleotide reductase, a key enzyme essential for DNA replication in cancer cells. Additionally, gallium deprives bacteria of iron required for growth and renders resistant bacteria in biofilms susceptible to treatment.

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

Prior independent studies using intravenously administered gallium nitrate have demonstrated preliminary evidence of clinical activity in several cancers, including multiple myeloma, lymphoma, bladder cancer and prostate cancer. An intravenous formulation of gallium nitrate, received FDA approval in 1991 for the treatment of hypercalcemia of malignancy.

In the first quarter of 2005, we completed a dose ranging Phase I clinical study of gallium maltolate in cancer patients. Significant blood levels of gallium were achieved, and a maximum tolerated dose level was not reached in this study. We are currently completing development of an optimal formulation of gallium maltolate with increased bioavailability, and subsequent clinical trials are planned to use this new formulation of gallium maltolate.

### ***ProNeura Continuous Drug Delivery Technology***



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Our ProNeura continuous drug delivery system consists of a small, solid rod made from a mixture of ethylene-vinyl acetate (EVA) and a drug substance. The resulting product is a solid matrix that is placed subcutaneously, normally in the upper arm in a simple 15-minute office procedure, and is removed in a similar manner at the end of the treatment period. The drug substance is released slowly, at continuous levels, through the process of diffusion. This results in a constant rate of release similar to intravenous administration. We believe that such long-term, linear release characteristics are desirable by avoiding peak and trough level dosing that poses problems for many CNS and other therapeutic agents.

In addition to Probuphine, which is our first product in clinical testing to utilize our proprietary ProNeura long term drug delivery technology, we are developing our ProNeura sustained drug delivery technology for other potential treatment applications including chronic pain, Parkinson's disease, alcoholism, and others, in which conventional treatment is limited by variability in blood drug levels and poor patient compliance. ProNeura technology was developed to address the need for a simple, practical method to achieve continuous long-term drug delivery, and potentially can provide controlled drug release on an outpatient basis over extended periods up to 6 - 12 months.

### **Sponsored Research and License Agreements**





We are a party to several agreements with research institutions, companies, universities and other entities for the performance of research and development activities and for the acquisition of licenses relating to such activities.

*Iloperidone*

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

In November 1997, we granted a worldwide sublicense, except Japan, to Novartis under which Novartis will continue, at its expense, all further development of iloperidone. In April 2001, that sublicense was extended to include Japan. Novartis will make our milestone payments to Aventis during the life of the Novartis agreement, and will also pay to Aventis and Titan a royalty on future net sales of the product. The results of a QTc study evaluating the EKG profile of patients taking iloperidone announced in July 2002 found that iloperidone has a similar profile to ziprasidone (Geodon), an approved product. These results have significantly delayed the regulatory filings for this product.

In June 2004, we announced that Vanda Pharmaceuticals, Inc. acquired from Novartis Pharma AG the worldwide rights to develop and commercialize iloperidone, our proprietary antipsychotic agent in Phase III clinical development for the treatment of schizophrenia and related psychotic disorders. Under its agreement with Novartis, Vanda will pursue advancement of the iloperidone Phase III development program. All of our rights and economic interests in iloperidone, including royalties on sales of iloperidone, remain essentially unchanged under the agreement.

***ProNeura Long-term Drug Delivery System***



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In October 1995, we acquired from the Massachusetts Institute of Technology (MIT) an exclusive worldwide license to certain U.S. and foreign patents relating to the long-term drug delivery system. The exclusive nature of the MIT license is subject to certain conditions regarding timely performance of product development activities. We must also satisfy certain other usual terms and conditions set forth in the MIT license in order to retain our license rights, including payments of royalties based on sale of products and processes incorporating the licensed technology, as well as a percentage of income derived from sublicenses of the licensed technology.

### *Spheramine and Other Cell Therapy Products*



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

In January 2000, we entered into a sublicense agreement with Schering granting Schering exclusive worldwide commercialization rights to Spheramine. Under the agreement, we will collaborate with Schering on manufacturing and clinical development of cell therapy for the treatment of Parkinson's disease. We will receive funding for development activities, as well as potential reimbursement of certain prior research and development expenses. Schering will fully fund, and manage in collaboration with us, all future pilot and pivotal clinical studies, and manufacturing and development activities. Schering will pay us a royalty on net sales of Spheramine. Schering may terminate this sublicense for any reason by providing us 90 days notice in advance.

***DITPA***





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In October 2003, through the acquisition of Developmental Therapeutics, Inc. (DTI), we acquired an exclusive worldwide license to an issued U.S. patent and pending international patent applications covering DITPA. Under this license agreement, we made an initial stock payment of 1,187,500 shares of our common stock and a cash payment of \$171,250 to The University of Arizona, the licensor of the technology, and will also make an additional payment of 712,500 shares of our common stock upon the achievement of positive pivotal study results or certain

other substantial milestones within five years. A cash payment of \$102,750 or, alternatively, an additional payment of 37,500 shares of our common stock, will also be made to the licensor of the technology upon achievement of such study results or such other substantial milestones within five years. Also under this agreement, we are required to make royalty payments to the licensor based on net sales of products and processes incorporating the licensed technology, subject to minimum annual amounts commencing in the first year following the commercial sale of the product, as well as a percentage of any income derived from any sublicense of the licensed technology. In addition, we are required to make milestone payments to the licensor upon the achievement of certain clinical or regulatory milestones.

*Gallium Complexes*



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In August 2000, through the acquisition of GeoMed, Inc., we acquired an exclusive worldwide license to make, use and sell products developed under the patent rights to the compositions and application of gallium complexes. Under this license agreement, we are required to make an annual license payment to Dr. Lawrence Bernstein, technology inventor, of \$50,000, as well as royalty payments based on future net sales of products and processes incorporating the licensed technology. We must also pay all costs and expenses incurred in patent prosecution and maintenance.

In February 2004, we executed an agreement giving us an exclusive worldwide license to patent rights held by The Ohio State University covering the methods of treating arthritis using gallium compounds. Under this agreement, we are required to pay a license issuance fee and certain minimum annual royalty payments. In addition, we are required to pay royalties based on net sales of products and processes incorporating the licensed technology.

In July 2005, we executed an agreement giving us an exclusive worldwide license to patent rights held by the University of Iowa Research Foundation covering the methods of treating biofilm formation, pseudomonas aeruginosa growth, human deficiency virus, and intracellular pathogens and pathogens causing chronic pulmonary infection using gallium maltolate. Under this agreement, we are required to pay a license issuance fee and certain minimum annual royalty payments. In addition, we are required to pay royalties based on net sales of products and processes incorporating the licensed technology.

### **Patents and Proprietary Rights**



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

## **Iloperidone**





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We hold a license from Aventis under one issued U.S. patent and certain foreign patents relating to iloperidone and its methods of use. Our license is exclusive for use in the treatment of psychiatric disorders, psychotic disorders and analgesia. Unless its term is extended, the U.S. patent that covers certain aspects of our iloperidone product and its use will expire in 2011. Prosecution of various divisional and continuation applications and their foreign counterparts continues satisfactorily, although it is uncertain whether additional patents will be granted.

### *ProNeura Long-term Drug Delivery System*



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We are the exclusive licensee under the MIT license to three U.S. patents, expiring in 2007, 2009 and 2014, and certain European patents relating to a long-term drug delivery system, expiring in 2008 and 2010. Additional patent applications have been filed which incorporate the use of specific compounds with the ProNeura technology.

### *Spheramine and Other Cell Therapy Products*



## Edgar Filing: TITAN PHARMACEUTICALS INC - Form S-1/A

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

satisfactorily, although it is uncertain whether additional patents will be granted. Patents have issued that cover certain aspects of our Spheramine product and its use, including four U.S. patents that will expire in 2010, 2014, 2015, and 2017, one European patent, which has been unbundled as 15 European national patents, all of which will expire in 2011, and one Australian and one Canadian patent, both of which will expire in 2011. Patents have issued relating to aspects of our gene transfer technology, including two U.S. patents that will expire in 2016, two Australian patents that will expire in 2017, one South African patent that will expire in 2017, one Taiwanese patent that will expire in 2017, and one Philippine patent that will expire in 2019. These dates do not include possible term extensions.

We are the owners of certain U.S. and foreign patents and patent applications relating to our CCM technology. Prosecution of patent applications relating to these technologies continues satisfactorily, as does prosecution of their foreign counterparts, although it is uncertain whether additional patents will be granted. Three foreign patents have issued that cover certain aspects of the use of our Spheramine product and other CCM technology, including one Australian and one New Zealand patent, both of which will expire in 2018, one New Zealand patent that will expire in 2020, and one South African patent that will expire in 2020. These dates do not include possible term extensions.

*DITPA*



## Edgar Filing: TITAN PHARMACEUTICALS INC - Form S-1/A

Through our wholly-owned subsidiary, Developmental Therapeutics, Inc., we hold an exclusive license from the University of Arizona to two U.S. patents, both expiring in 2021, one pending U.S. patent, and related foreign patent applications relating to the use of 3,5-diiodothyropropionic acid (DITPA) for the treatment of heart failure and elevated cholesterol. In April 2005, we filed a U.S. patent application related to stimulating the metabolic rate in overweight patients and or for lowering triglycerides.

### *Gallium Complexes*





## Edgar Filing: TITAN PHARMACEUTICALS INC - Form S-1/A

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

### **Competition**



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The pharmaceutical and biotechnology industries are characterized by rapidly evolving technology and intense competition. Many companies of all sizes, including major pharmaceutical companies and specialized biotechnology companies, are engaged in the development and commercialization of therapeutic agents designed for the treatment of the same diseases and disorders that we target. Many of our competitors have substantially greater financial and other resources, larger research and development staffs and more experience in the regulatory approval process. Moreover, potential competitors have or may have patents or other rights that conflict with patents covering our technologies.

### *Probuphine*



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With regard to Probuphine, we are aware that Reckitt Benckiser, Inc. received FDA approval in 2002 for a sublingual buprenorphine product (combined with naloxone) for the treatment of opioid dependence. This product, to be administered daily, might compete with our six-month implantable product for drug abuse. The FDA previously approved Orphan Drug designation, expiring in October 2009, for Reckitt Benckiser's sublingual buprenorphine for the treatment of opioid dependence. Other forms of buprenorphine are also in development by other companies, including intramuscular injections and intranasally delivered buprenorphine, which also might compete with our product for drug abuse.

### *Iloperidone*



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With respect to iloperidone, several products categorized as atypical antipsychotics are already on the market. These products include Risperdal sold by Janssen Pharmaceuticals, Zyprexa sold by Eli Lilly, Clozaril sold by



Novartis, Seroquel sold by AstraZeneca, Geodon sold by Pfizer, and Abilify sold by Bristol-Myers Squibb. Competition among these companies is already intense and iloperidone will face significant competition. The success of iloperidone will depend on how it can be differentiated from products already on the market on the basis of efficacy, side-effect profile, cost, availability of formulations and dose requirements, among other things.

**Spheramine**



## Edgar Filing: TITAN PHARMACEUTICALS INC - Form S-1/A

With regard to Spheramine, we are aware of several new treatments for Parkinson's disease that are in pre-clinical and clinical development. In addition, several public and private companies, including StemCells, Inc., are actively pursuing alternative cell transplant technologies. Deep brain stimulation, also known as subthalamic stimulation is also a competing therapy for patients with advanced Parkinson's disease. The FDA has approved a stimulator device (Activa) manufactured by Medtronic, Inc., which is marketed in the U.S.

*DITPA*



## Edgar Filing: TITAN PHARMACEUTICALS INC - Form S-1/A

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

### *Gallium Complexes*



## Edgar Filing: TITAN PHARMACEUTICALS INC - Form S-1/A

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

### **Manufacturing**





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

**Government Regulation**



## Edgar Filing: TITAN PHARMACEUTICALS INC - Form S-1/A

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

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

Human clinical trials on drugs are typically conducted in three sequential phases, although the phases may overlap. Phase I trials typically consist of testing the product in a small number of healthy volunteers or patients, primarily for safety in one or more doses. During Phase II, in addition to safety, dose selection and efficacy of the

product is evaluated in up to several hundred patients and sometimes more. Phase III trials typically involve additional testing for safety and confirmation of efficacy in an expanded patient population at multiple test sites. The FDA may order the temporary or permanent discontinuation of a clinical trial at any time.

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

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

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

#### **Foreign Regulatory Issues**



Sales of pharmaceutical products outside the United States are subject to foreign regulatory requirements that vary widely from country to country. Whether or not FDA approval has been obtained, approval of a product by a comparable regulatory authority of a foreign country must generally be obtained prior to the commencement of marketing in that country. Although the time and data 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.

#### **Legal Proceedings**

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

#### **Employees**

At September 30, 2005 we had 55 full-time employees, after the previously noted workforce reduction. 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.

## MANAGEMENT

## Executive Officers, Significant Employees and Directors

Set forth below are the name, age and position and a brief account of the business experience of each of our executive officers and directors as of October 6, 2005.

| Name                             | Age | Office   |
|----------------------------------|-----|--|
| Louis R. Bucalo, M.D.            | 46  | Chairman, President and Chief Executive Officer                |
| Sunil Bhonsle                    | 55  | Executive Vice President, Chief Operating Officer and Director |
| Richard C. Allen, Ph.D.          | 62  | Executive Vice President, Cell Therapy                         |
| Robert E. Farrell, J.D.          | 55  | Executive Vice President and Chief Financial Officer           |
| Victor J. Bauer, Ph.D.           | 70  | Director   |
| Eurelio M. Cavalier(1)(3)(4)     | 72  | Director   |
| Hubert E. Huckel, M.D.(1)(2)(3)  | 73  | Director   |
| M. David MacFarlane, Ph.D.(2)(4) | 65  | Director   |
| Ley S. Smith(1)(2)(4)            | 70  | Director   |
| Konrad M. Weis, Ph.D.(1)(3)      | 76  | Director   |
| Joachim Friedrich Kapp           | 63  | Director   |

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

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

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

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

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

**Victor J. Bauer, Ph.D.**, has served on our Board of Directors since November 1997. Dr. Bauer serves as the Executive Vice President of Concordia Pharmaceuticals, Inc., a biopharmaceutical company he co-founded in January 2004. From February 1997 through March 2003, Dr. Bauer was employed by Titan, most recently as our Executive Director of Corporate Development. From April 1996 until its merger into Titan, Dr. Bauer also served as a director and Chairman of Theracell. From December 1992 until February 1997, Dr. Bauer was a self-employed consultant to companies in the pharmaceutical and biotechnology industries. Prior to that time, Dr. Bauer was with Hoechst-Roussel Pharmaceuticals Inc., where he served as President from 1988 through 1992.

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

**Hubert E. Huckel, M.D.**, has served on our Board of Directors since October 1995. Dr. Huckel serves as the Executive Chairman of the Board of Concordia Pharmaceuticals, Inc., a biopharmaceutical company he co-founded in January 2004. He served in various positions with The Hoechst Group from 1964 until his retirement in December 1992. At the time of his retirement, Dr. Huckel was Chairman of the Board of Hoechst-Roussel Pharmaceuticals, Inc., Chairman and President of Hoechst-Roussel Agri-Vet Company and a member of the



Executive Committee of Hoechst Celanese Corporation. He currently serves on the Board of Directors of Thermogenesis, Corp. and Amarin Pharmaceuticals, plc and is a member of their compensation committees.

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

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

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

**Jochim Friedrich Kapp, M.D., Ph.D.** has served on our Board of Directors since August 2005. Mr. Kapp has worked in various capacities for Schering AG since 1991, most recently as the President of the Global Business Unit on Specialized Therapeutics. Prior to joining Schering AG, Dr. Kapp worked in various capacities with Warner Lambert and its subsidiaries. Dr. Kapp holds an M.D. and a Ph.D. from the University of Essex.

#### **Executive Compensation**



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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, 2004 (collectively, the named executive officers) for services during the fiscal years ended December 31, 2004, 2003 and 2002:

### **Summary Compensation Table**

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

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

**Stock Options**



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

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

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

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

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

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

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

### Equity Compensation Plan Information

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

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

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

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

#### Executive Employment Agreements

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

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

#### Director Compensation

Non-employee directors are entitled to receive a fee for each meeting attended and all directors are entitled to receive stock options pursuant to our stockholder-approved stock option plans, including an initial grant of 10,000 options upon becoming a director, a biennial grant of 20,000 options thereafter, and an annual grant of 5,000 options for each committee on which they serve. During 2004, each director was granted an annual option to purchase 5,000 shares of our common stock at an exercise price of \$2.37, which was equal to the fair market value of our common stock at date of grant, with respect to each committee of the Board on which each director served. In addition to having their out-of-pocket expenses reimbursed, non-employee directors received \$2,500 for each Board of Directors meeting attended in 2004. Directors are



not precluded from serving us in any other capacity and receiving compensation therefore.

**Compensation Committee Interlocks And Insider Participation**

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

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

## SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth, as of October 6, 2005, certain information concerning the beneficial ownership of our common stock by (i) each stockholder known by us to own beneficially five percent or more of our outstanding common stock; (ii) each director; (iii) each executive officer; and (iv) all of our executive officers and directors as a group, and their percentage ownership and voting power.

| Name and Address of Beneficial Owner(1)  | Shares<br>Beneficially<br>Owned(2) | Percent of Shares<br>Beneficially<br>Owned |
|--|------------------------------------|--|
| Louis R. Bucalo, M.D.  | 2,146,029(3)                       | 6.6%                                       |
| Richard C. Allen, Ph.D.  | 604,449(4)                         | 1.9%                                       |
| Victor J. Bauer, Ph.D.   | 261,268(5)                         | *  |
| Sunil Bhonsle  | 928,299(6)                         | 2.9%                                       |
| Eurelio M. Cavalier  | 145,624(7)                         | *  |
| Robert E. Farrell, J.D.  | 364,832(8)                         | 1.1%                                       |
| Hubert Huckel, M.D.  | 178,967(9)                         | *  |
| Dr. Joachim-Friedrich Kapp   |                                    | *  |
| M. David MacFarlane, Ph.D.   | 49,374(10)                         | *  |
| Ley S. Smith   | 123,124(11)                        | *  |
| Konrad M. Weis, Ph.D.  | 170,698(12)                        | *  |
| Kevin Douglas and The Douglas Family Trust<br>1101 Fifth Avenue, Suite 360<br>San Rafael, CA 94901 | 1,674,100(13)                      | 5.2%                                       |
| All executive officers and directors as a group (10) persons                                       | 4,971,821                          | 15.3%                                      |

\* 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.

(3) Includes 1,649,543 shares issuable upon exercise of outstanding options.

(4) Consists of 516,161 shares issuable upon exercise of outstanding options.

- (5) Includes 252,624 shares issuable upon exercise of outstanding options.
  
- (6) Includes (i) 747,905 shares issuable upon exercise of outstanding options and (ii) 100,000 shares owned by the Bhonsle Family Trust which were sold pursuant to a variable forward sale on June 4, 2001, of which Mr. Bhonsle retains voting power.
  
- (7) Includes 115,624 shares issuable upon exercise of outstanding options.
  
- (8) Includes 317,052 shares issuable upon exercise of outstanding options.
  
- (9) Includes (i) 138,624 shares issuable upon exercise of outstanding options, (ii) 200 shares held by Dr. Huckel's son, and (iii) 3,643 shares held by his wife.
  
- (10) Includes 39,374 shares issuable upon exercise of outstanding options.
  
- (11) Includes 113,124 shares issuable upon exercise of outstanding options.
  
- (12) Includes 135,124 shares issuable upon exercise of outstanding options.
  
- (13) Derived from a Schedule 13G/A filed by Kevin Douglas and The Douglas Family Trust on February 14, 2005.

**MARKET FOR OUR COMMON STOCK, DIVIDENDS AND  
RELATED STOCKHOLDER INFORMATION**

**Market For Our Common Stock**

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.

|  | <b>High</b> | <b>Low</b> |
|--|-------------|------------|
| <b>Fiscal Year Ended December 31, 2003:</b>  |             |            |
| First Quarter                                | \$ 1.81     | \$ 1.36    |
| Second Quarter                               | \$ 3.09     | \$ 1.44    |
| Third Quarter                                | \$ 2.80     | \$ 1.91    |
| Fourth Quarter                               | \$ 4.00     | \$ 2.42    |
| <b>Fiscal Year Ended December 31, 2004:</b>  |             |            |
| First Quarter                                | \$ 5.89     | \$ 2.80    |
| Second Quarter                               | \$ 5.15     | \$ 2.43    |
| Third Quarter                                | \$ 2.84     | \$ 1.80    |
| Fourth Quarter                               | \$ 3.39     | \$ 1.94    |
| <b>Fiscal Year Ending December 31, 2005:</b> |             |            |
| First Quarter                                | \$ 3.08     | \$ 2.22    |
| Second Quarter                               | \$ 2.47     | \$ 1.83    |
| Third Quarter                                | \$ 2.27     | \$ 1.77    |
| Fourth Quarter through October 12, 2005      | \$ 1.83     | \$ 1.60    |

**Approximate Number of Equity Security Holders**

The number of record holders of our common stock as of October 6, 2005 was approximately 157. Based on the last ADP search, we believe there are in excess of 10,000 beneficial holders of our common stock.

**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.

## SELECTED CONDENSED FINANCIAL INFORMATION

The statements of operations data for the years ended December 31, 2002, 2003 and 2004 and the balance sheet data as of December 31, 2003 and 2004 are derived from our audited consolidated financial statements and footnotes thereto included in the section beginning on page F-1. The statements of operations data for the years ended December 31, 2000 and 2001 and the balance sheet data as of December 31, 2000, 2001 and 2002 have been derived from our audited consolidated financial statements not included in this prospectus. We have also included data for the six months ended June 30, 2004 and 2005 from our unaudited interim consolidated financial statements included in the section beginning on page F-1. This data should be read together with our consolidated financial statements and related footnotes thereto included in the section beginning on page F-1 and the information under Management's Discussion and Analysis of Financial Condition and Results of Operations.

|   | Six Months<br>Ended June 30,<br>(unaudited) |             | Year Ended December 31, |             |             |             |             |
|---|---|-------------|-------------------------|-------------|-------------|-------------|-------------|
|   | 2005  | 2004        | 2004                    | 2003        | 2002        | 2001        | 2000        |
| (in thousands, except per share data)                         |   |             |                         |             |             |             |             |
| <b>Statement of Operations Data:</b>                          |   |             |                         |             |             |             |             |
| Total revenue(1)  | \$ 27                                       | \$ 1        | \$ 31                   | \$ 89       | \$ 2,892    | \$ 4,572    | \$ 1,880    |
| Operating expenses:   |   |             |                         |             |             |             |             |
| Research and development                                      | 9,722                                       | 9,711       | 20,415                  | 22,258      | 29,819      | 23,339      | 16,744      |
| Acquired/in-process research and development(2)               |   |             | 759                     | 3,896       |             |             | 4,969       |
| General and administrative                                    | 2,600                                       | 2,486       | 5,237                   | 5,109       | 5,076       | 5,383       | 4,070       |
| Other income, net   | 257   | 260         | 376                     | 1,285       | 3,821       | 6,686       | 5,115       |
| Net loss  | \$ (12,038)                                 | \$ (11,936) | \$ (26,004)             | \$ (29,889) | \$ (28,182) | \$ (17,464) | \$ (18,788) |
| Basic and diluted net loss per share                          | \$ (0.37)                                   | \$ (0.39)   | \$ (0.83)               | \$ (1.07)   | \$ (1.02)   | \$ (0.63)   | \$ (0.73)   |
| Shares used in computing basic and diluted net loss per share | 32,350                                      | 30,558      | 31,381                  | 27,907      | 27,642      | 27,595      | 25,591      |

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

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

|   | As of June 30,<br>(unaudited) |           | As of December 31, |           |           |            |            |
|---|-------------------------------|-----------|--------------------|-----------|-----------|------------|------------|
|   | 2005                          | 2004      | 2004               | 2003      | 2002      | 2001       | 2000       |
| (in thousands)                                    |                               |           |                    |           |           |            |            |
| <b>Balance Sheet Data:</b>                        |                               |           |                    |           |           |            |            |
| Cash, cash equivalents, and marketable securities | \$ 24,279                     | \$ 48,469 | \$ 36,322          | \$ 46,555 | \$ 73,450 | \$ 105,051 | \$ 117,523 |
| Working capital                                   | 21,943                        | 47,103    | 33,760             | 44,578    | 70,702    | 100,193    | 115,386    |

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|                           |        |        |        |        |        |         |         |
|---------------------------|--------|--------|--------|--------|--------|---------|---------|
| Total assets              | 26,505 | 50,932 | 38,626 | 49,008 | 75,926 | 107,132 | 118,442 |
| Total stockholders equity | 21,834 | 47,058 | 33,713 | 44,426 | 70,740 | 100,127 | 114,738 |

## SUPPLEMENTARY FINANCIAL INFORMATION

The supplementary financial information presented below summarizes certain financial data which has been derived from and should be read in conjunction with our consolidated financial statements and footnotes thereto included in the section beginning on page F-1.

|                                      | First<br>Quarter | Second<br>Quarter<br>(in thousands, except per share amount) | Third<br>Quarter | Fourth<br>Quarter |
|--------------------------------------|------------------|--|------------------|-------------------|
| <b>2005 (through June 30, 2005)</b>  |                  |  |                  |                   |
| Total revenue                        | \$ 14            | \$ 13  | n/a              | n/a               |
| Net loss                             | \$ (6,296)       | \$ (5,742)   | n/a              | n/a               |
| Basic and diluted net loss per share | \$ (0.19)        | \$ (0.18)  | n/a              | n/a               |
| <b>2004</b>                          |                  |  |                  |                   |
| Total revenue                        | \$ 1             |  |                  | \$ 30             |
| Net loss                             | \$ (6,381)       | \$ (5,555)   | \$ (6,270)       | \$ (7,798)        |
| Basic and diluted net loss per share | \$ (0.22)        | \$ (0.17)  | \$ (0.20)        | \$ (0.24)         |
| <b>2003</b>                          |                  |  |                  |                   |
| Total revenue                        | \$ 26            | \$ 2   |                  | \$ 61             |
| Net loss                             | \$ (6,530)       | \$ (6,681)   | \$ (6,169)       | \$ (10,509)       |
| Basic and diluted net loss per share | \$ (0.24)        | \$ (0.24)  | \$ (0.22)        | \$ (0.37)         |

## DESCRIPTION OF CAPITAL STOCK

## General

The following description of our securities does not purport to be complete and is subject in all respects to applicable Delaware law and to the provisions of our Amended and Restated Certificate of Incorporation and By-laws.

## Common Stock

We are authorized to issue 75,000,000 shares of common stock, of which 32,473,428 were issued and outstanding at October 6, 2005. Holders of Common Stock have the right to cast one vote for each share held of record on all matters submitted to a vote of holders of common stock, including the election of directors. There is no right to cumulate votes for the election of directors. Stockholders holding a majority of the voting power of the capital stock issued and outstanding and entitled to vote, represented in person or by proxy, are necessary to constitute a quorum at any meeting of our stockholders, and the vote by the holders of a majority of such outstanding shares is required to effect certain fundamental corporate changes such as liquidation, merger or amendment of our Certificate of Incorporation.

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Holders of common stock are entitled to receive dividends pro rata based on the number of shares held, when, as and if declared by the Board of Directors, from funds legally available therefor, subject to the rights of holders of any outstanding preferred stock. In the event of our liquidation, dissolution or winding up, all our assets remaining after the payment of all debts and other liabilities, subject to the rights of the holders of any outstanding preferred stock, shall be distributed, pro rata, among the holders of the common stock. Holders of common stock are not entitled to preemptive or subscription or conversion rights, and there are no redemption or sinking fund provisions applicable to the common stock.



### **Preferred Stock**

We are authorized to issue 5,000,000 shares of preferred stock, of which 222,400 have been designated Series C Preferred Stock, all of which shares of Series C Preferred Stock were issued and outstanding at October 6, 2005. No other classes of preferred stock were issued and outstanding as of October 6, 2005. Pursuant to our Certificate of Incorporation, our Board of Directors may divide the authorized but unissued shares of preferred stock into any number of series, fix the designation and number of shares of each such series, and determine the relative rights, preferences and limitations of any series of preferred stock.

In connection with the merger of our Trilex Pharmaceuticals, Inc. subsidiary in 1997, we issued 222,400 shares of Series C convertible preferred stock to certain members of the Trilex management team and to certain consultants of Trilex. The Series C Preferred would have automatically converted into shares of our common stock on a one-to-one basis if certain development milestones were achieved by October 6, 2004. Those milestones were not achieved by October 6, 2004. Therefore, we have the right to redeem all, but not less than all, of the outstanding shares of Series C Preferred Stock at a redemption price equal to the aggregate par value of the shares plus accrued and unpaid dividends, if any. Holders of Series C Preferred are not entitled to vote but are entitled to receive dividends, when, as and if declared by the Board of Directors ratably with any declaration or payment of any dividend on our common stock or other junior securities. The Series C Preferred has a liquidation preference equal to \$0.01 per share. No value was assigned to the Series C Preferred in our financial statements. There were no accrued and unpaid dividends outstanding as of October 6, 2005.

### **Anti-Takeover Provisions**

Our Amended and Restated Certificate of Incorporation provides that our Board of Directors may divide the authorized shares of preferred stock into any number of series, fix the designation and number of shares of each such series, and determine the relative rights, preferences and limitations of any series of preferred stock. In addition, the Board of Directors is authorized, without any action on the part of our stockholders, to amend our by-laws. Our Board of Directors may use their ability to designate classes of preferred stock or amend our by-laws to deter or delay certain transactions involving an actual or potential change in control of us, including transactions that our stockholders deem beneficial to them.

### **TRANSFER AGENT AND REGISTRAR**

The Transfer Agent and Registrar for shares of our common stock is Continental Stock Transfer & Trust Company, New York, New York.

## LEGAL MATTERS

The validity of the securities offered hereby have been passed upon for us by Loeb & Loeb LLP, New York, New York.

## EXPERTS

The financial statements as of and for the year ended December 31, 2004 and management's assessment of the effectiveness of internal control over financial reporting as of December 31, 2004 have been audited by Odenberg, Ullakko, Muranishi & Co. LLP, an independent registered public accounting firm, as stated in their reports appearing herein.

The consolidated financial statements of Titan Pharmaceuticals, Inc. at December 31, 2003, and for each of the two years in the period ended December 31, 2003, appearing in this Prospectus and Registration Statement have been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their report thereon appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

## WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act of 1933 with respect to the common stock offered hereby. This prospectus, which constitutes a part of the registration statement, does not contain all of the information in the registration statement and the exhibits of the registration statement. For further information with respect to us and the share being offered under this prospectus, we refer you to the registration statement, including the exhibits and schedules thereto.

You may read and copy the registration statement of which this prospectus is a part at the SEC's Public Reference Room, which is located at 100 F Street, N.E., Washington, D.C. 20549. You can request copies of the registration statement by writing to the SEC and paying a fee for the copying cost. Please call the SEC at 1-800-SEC-0330 for more information about the operation of the SEC's Public Reference Room. In addition, the SEC maintains an Internet web site, which is located at [www.sec.gov](http://www.sec.gov), which contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC. You may access the registration statement of which this prospectus is a part at the SEC's Internet web site. We are subject to the information reporting requirements of the Securities Exchange Act of 1934, and we will file reports, proxy statements and other information with the SEC.

We maintain an Internet web site at [www.titanpharm.com](http://www.titanpharm.com). We have not incorporated by reference into this prospectus the information on our web site, and you should not consider it to be a part of this prospectus.



**TITAN PHARMACEUTICALS, INC.  
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

**For the Three and Six Months Ended June 30, 2005**

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**For the Fiscal Year Ended December 31, 2004**

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**Part I. Financial Information****Item 1. Condensed Financial Statements (unaudited)****TITAN PHARMACEUTICALS, INC.****CONDENSED CONSOLIDATED BALANCE SHEETS****(in thousands)**

|   | <b>June 30,<br/>2005<br/>(unaudited)</b> | <b>December 31,<br/>2004<br/>(Note A)</b> |
|---|--|---|
| <b>Assets</b>   |  |   |
| Current assets  |  |   |
| Cash and cash equivalents                                     | \$ 5,270                                 | \$ 5,463                                  |
| Marketable securities   | 19,009                                   | 30,859                                    |
| Prepaid expenses, other receivables and current assets        | 1,094                                    | 1,110                                     |
| Total current assets  | 25,373                                   | 37,432                                    |
| Property and equipment, net                                   | 982                                      | 1,044                                     |
| Investment in other companies                                 | 150                                      | 150                                       |
| Total assets  | \$ 26,505                                | \$ 38,626                                 |
| <b>Liabilities and Stockholders Equity</b>                    |  |   |
| Current liabilities   |  |   |
| Accounts payable  | \$ 590                                   | \$ 689                                    |
| Accrued clinical trials expenses                              | 1,095                                    | 1,445                                     |
| Other accrued liabilities                                     | 1,745                                    | 1,538                                     |
| Total current liabilities                                     | 3,430                                    | 3,672                                     |
| Minority interest - Series B preferred stock of Ingenex, Inc. | 1,241                                    | 1,241                                     |
| Stockholders equity   |  |   |
| Common stock, at amounts paid-in                              | 210,346                                  | 210,264                                   |
| Additional paid-in capital                                    | 9,287                                    | 9,327                                     |
| Deferred compensation   | (51)                                     | (82)                                      |
| Accumulated deficit   | (197,783)                                | (185,745)                                 |
| Accumulated other comprehensive income                        | 35                                       | (51)                                      |
| Total stockholders equity                                     | 21,834                                   | 33,713                                    |
| Total liabilities and stockholders equity                     | \$ 26,505                                | \$ 38,626                                 |

Note A: The balance sheet has been derived from the audited financial statements at that date but does not include all of the information and footnotes required by generally accepted accounting principles in the United States for complete financial statement presentation.

See Notes to Condensed Consolidated Financial Statements

## TITAN PHARMACEUTICALS, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(unaudited)

(in thousands, except per share amount)

|  | Three Months Ended June 30, |            | Six Months Ended June 30, |             |
|--|-----------------------------|------------|---------------------------|-------------|
|  | 2005                        | 2004       | 2005                      | 2004        |
| License revenue  | \$ 13                       | \$         | \$ 27                     | \$ 1        |
| Total revenue  | 13                          |            | 27                        | 1           |
| Operating expenses:  |                             |            |                           |             |
| Research and development   | 4,523                       | 4,598      | 9,722                     | 9,711       |
| General and administrative   | 1,338                       | 1,118      | 2,600                     | 2,486       |
| Total operating expenses   | 5,861                       | 5,716      | 12,322                    | 12,197      |
| Loss from operations   | (5,848)                     | (5,716)    | (12,295)                  | (12,196)    |
| Other income (expense):  |                             |            |                           |             |
| Interest income, net   | 138                         | 178        | 288                       | 337         |
| Other expense  | (32)                        | (17)       | (31)                      | (77)        |
| Other income (expense), net  | 106                         | 161        | 257                       | 260         |
| Net loss   | \$ (5,742)                  | \$ (5,555) | \$ (12,038)               | \$ (11,936) |
| Basic and diluted net loss per share   | \$ (0.18)                   | \$ (0.17)  | \$ (0.37)                 | \$ (0.39)   |
| Weighted average shares used in computing basic and diluted net loss per share | 32,361                      | 32,108     | 32,350                    | 30,558      |

See Notes to Condensed Consolidated Financial Statements

## TITAN PHARMACEUTICALS, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

(in thousands)

|   | Six Months Ended June 30, |                  |
|---|---------------------------|------------------|
|   | 2005                      | 2004             |
| <b>Cash flows from operating activities:</b>  |                           |                  |
| Net loss  | \$ (12,038)               | \$ (11,936)      |
| Adjustments to reconcile net loss to net cash provided by (used in) operating activities: |                           |                  |
| Depreciation and amortization   | 255                       | 207              |
| Non-cash compensation related to stock options  | (9)                       | 187              |
| Write-down of securities available-for-sale   |                           | 50               |
| Changes in operating assets and liabilities:  |                           |                  |
| Prepaid expenses, receivables and other assets  | 16                        | 97               |
| Accounts payable and other accrued liabilities  | (242)                     | (708)            |
| Net cash used in operating activities   | (12,018)                  | (12,103)         |
| <b>Cash flows from investing activities:</b>  |                           |                  |
| Purchases of furniture and equipment, net   | (193)                     | (314)            |
| Purchases of marketable securities  | (4,940)                   | (18,494)         |
| Proceeds from maturities of marketable securities   | 16,876                    | 14,800           |
| Net cash provided by (used for) investing activities                                      | 11,743                    | (4,008)          |
| <b>Cash flows from financing activities:</b>  |                           |                  |
| Issuance of common stock, net   | 82                        | 14,502           |
| Net cash provided by financing activities   | 82                        | 14,502           |
| <b>Net decrease in cash and cash equivalents</b>  | <b>(193)</b>              | <b>(1,609)</b>   |
| Cash and cash equivalents at beginning of period  | 5,463                     | 6,832            |
| Cash and cash equivalents at end of period  | 5,270                     | 5,223            |
| Marketable securities at end of period  | 19,009                    | 43,246           |
| <b>Cash, cash equivalents and marketable securities at end of period</b>                  | <b>\$ 24,279</b>          | <b>\$ 48,469</b> |

See Notes to Condensed Consolidated Financial Statements

**TITAN PHARMACEUTICALS, INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**(unaudited)**

**1. Organization and Summary of Significant Accounting Policies**

*The Company*





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We are a biopharmaceutical company developing proprietary therapeutics for the treatment of central nervous system (CNS) disorders, cardiovascular disease, bone disease and other disorders. Our product development programs focus primarily on large pharmaceutical markets with significant unmet medical needs and commercial potential. We are directly developing our product candidates and also utilizing strategic partnerships to help fund product development and enable us to retain significant economic interest in our products. We operate in one business segment, the development of pharmaceutical products.

### *Basis of Presentation*



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The accompanying unaudited condensed consolidated financial statements include the accounts of Titan and its subsidiaries after elimination of all significant intercompany accounts and transactions. Certain prior period balances have been reclassified to conform to the current period presentation. These financial statements have been prepared in accordance with generally accepted accounting principles in the United States for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for a complete financial statement presentation. In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation have been included. Operating results for the three and six month periods ended June 30, 2005 are not necessarily indicative of the results that may be expected for the year ending December 31, 2005.

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and footnotes thereto included in the Titan Pharmaceuticals, Inc. annual report on Form 10-K/A for the year ended December 31, 2004.

### ***Revenue Recognition***



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

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

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

which represent the culmination of the earnings process. Amounts received in advance are recorded as deferred revenue until the technology is transferred, costs are incurred, or milestone is reached.

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

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

*Operating Subsidiary*





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We conduct some of our operations through our subsidiary, Ingenex, Inc. At June 30, 2005, we owned 81% of Ingenex (assuming the conversion of all preferred stock to common stock).

### *Recent Accounting Pronouncements*



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On April 14, 2005, the Securities and Exchange Commission ( SEC ) adopted a new rule that amends the compliance dates for Financial Accounting Standards Board's Statement of Financial Accounting Standards No. 123 (revised 2004), *Share-Based Payment* (SFAS 123R). Under the new rule, the Company is required to adopt SFAS 123R in the first quarter of fiscal 2006, beginning January 1, 2006. The Company has not yet determined the method of adoption or the effect of adopting SFAS 123R, and it has not determined whether the adoption will result in amounts that are similar to the current pro forma disclosures under Statement of Financial Accounting Standards No. 123 (or SFAS 123), *Accounting for Stock-Based Compensation*. The adoption of SFAS 123R could materially impact our results of operations.

### 2. Stock Option Plans

Until December 31, 2005, when we will be required to follow SFAS 123R, we have elected to continue to follow Accounting Principles Board Opinion No. 25 (or APB 25), *Accounting for Stock Issued to Employees*, rather than the alternative method of accounting prescribed by SFAS 123, *Accounting for Stock-Based Compensation*. Under APB 25, no compensation expense is recognized when the exercise price of our employee stock options equals the market price of the underlying stock on the date of grant. The following table illustrates the effect on our net loss and net loss per share if Titan had applied the provisions of SFAS 123 to estimate and recognize compensation expense for our stock-based employee compensation.

|  | Three months ended June 30,             |            | Six months ended June 30, |             |
|--|---|------------|---------------------------|-------------|
|  | 2005                                    | 2004       | 2005                      | 2004        |
|  | (in thousands, except per share amount) |            |                           |             |
| Net loss, as reported  | \$ (5,742)                              | \$ (5,555) | \$ (12,038)               | \$ (11,936) |
| Add: Stock-based employee compensation expense included in reported net loss   | 29                                      | 71         | 25                        | 134         |
| Deduct: Estimated stock-based employee compensation expense determined in accordance with SFAS 123 for all stock option grants | (304)                                   | (385)      | (544)                     | (607)       |
| Pro forma net loss   | \$ (6,017)                              | \$ (5,869) | \$ (12,525)               | \$ (12,409) |
| Basic and diluted net loss per share, as reported  | \$ (0.18)                               | \$ (0.17)  | \$ (0.37)                 | \$ (0.39)   |
| Pro forma basic and diluted net loss per share   | \$ (0.19)                               | \$ (0.18)  | \$ (0.39)                 | \$ (0.41)   |

The fair value of options was estimated at the date of grant using a Black-Scholes option pricing model with the following assumptions for the three-month periods ended June 30, 2005 and 2004: weighted-average volatility factor of 0.70 and 0.70, respectively; no expected dividend payments; weighted-average risk-free interest rates in effect of 4.0% and 3.8%, respectively; and a weighted-average expected life of 3.5 and 4.5 years, respectively. For purposes of disclosure, the estimated fair value of options is amortized to expense over the options' vesting period.

### **3. Net Loss Per Share**

We calculate net loss per share using the weighted average common shares outstanding for the periods presented. For the periods ended June 30, 2005 and 2004, the effect of an additional 7,059,866 and 6,479,890 shares, respectively, related to our authorized and issued convertible preferred stock and options, were not included in the computation of diluted earnings per share because they are anti-dilutive.

### **4. Comprehensive Loss**

Comprehensive loss is comprised of net loss and other comprehensive income or loss. The only component of other comprehensive income or loss is unrealized gains and losses on our marketable securities. Comprehensive losses for the three and six months ended June 30, 2005 were \$5.7 million and \$12.0 million, respectively, and for the three and six months ended June 30, 2004 were \$5.8 million and \$12.1 million, respectively.

### **5. Stockholders Equity**

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

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**



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





## Edgar Filing: TITAN PHARMACEUTICALS INC - Form S-1/A

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

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

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

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

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

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

/s/ Odenberg Ullakko Muranishi & Co. LLP

San Francisco, California  
February 15, 2005

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**



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



## Edgar Filing: TITAN PHARMACEUTICALS INC - Form S-1/A

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

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

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

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

/s/ Odenberg Ullakko Muranishi & Co. LLP

San Francisco, California  
February 15, 2005

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





## Edgar Filing: TITAN PHARMACEUTICALS INC - Form S-1/A

The Board of Directors and Stockholders  
Titan Pharmaceuticals, Inc.

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

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

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

Palo Alto, California  
February 20, 2004



**TITAN PHARMACEUTICALS, INC.  
CONSOLIDATED BALANCE SHEETS**

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



**TITAN PHARMACEUTICALS, INC.**  
**CONSOLIDATED STATEMENT OF OPERATIONS**

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

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**TITAN PHARMACEUTICALS, INC**

**CONSOLIDATED STATEMENT OF STOCKHOLDERS EQUITY**

(in thousands)

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

See accompanying notes.

**TITAN PHARMACEUTICALS, INC.**  
**CONSOLIDATED STATEMENT OF CASH FLOWS**

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

See accompanying notes.

**TITAN PHARMACEUTICALS, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**1. Organization and Summary of Significant Accounting Policies**



*The Company and its Subsidiaries*

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

*Basis of Presentation and Consolidation*

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

*Reclassifications*

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

*Use of Estimates*

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

*Stock Option Plans*

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

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

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

*Cash, Cash Equivalents and Marketable Securities*





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

All investments with original maturities of three months or less are considered to be cash equivalents. Our marketable securities, consisting primarily of high-grade debt securities including money market funds, U.S. government and corporate notes and bonds, and commercial paper, are classified as available-for-sale at time of purchase and carried at fair value. If the fair value of a security is below its amortized cost for six consecutive months or if its decline is due to a significant adverse event, the impairment is considered to be other-than-temporary.

Other-than-temporary declines in fair value of our marketable securities are charged against interest income. We recognized expenses of approximately \$102,000 in 2004, \$40,000 in 2003, and \$9,000 in 2002 as a result of charges related to other-than-temporary declines in the fair values of certain of our marketable securities. Amortization of premiums and discounts, and realized gains and losses are included in interest income. Unrealized gains and losses are included as accumulated other comprehensive income, a separate component of stockholders' equity. The cost of securities sold is based on use of the specific identification method.

### *Property and Equipment*



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

### *Investment in Other Companies*



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

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

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

***Revenue Recognition***



## Edgar Filing: TITAN PHARMACEUTICALS INC - Form S-1/A

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

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

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

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

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



*Research and Development Costs*



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

### *Net Loss Per Share*



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

### *Comprehensive Income*



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

### *Recent Accounting Pronouncements*





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

**2. Cash, Cash Equivalents and Marketable Securities**



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

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

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

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

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

### 3. Property and Equipment

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

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

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

**4. Research and License Agreements**



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

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

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

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

### 5. Agreement with Aventis SA





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

### **6. Iloperidone Sublicense to Novartis Pharma AG**



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

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

**7. Licensing and Collaborative Agreement with Schering AG**



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

### **8. DITPA Acquisition**





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

### **9. Commitments and Contingencies**



*Lease Commitments*



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

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

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

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*Legal Proceedings*



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

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

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

### **10. Guarantees and Indemnifications**





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

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

### **11. Stockholders' Equity**



*Preferred Stock*



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

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

*Common Stock*





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

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

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

### *Shares Reserved for Future Issuance*



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

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

### 12. Stock Option Plans



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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

### 13. Minority Interest





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

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

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

**14. Related Party Transactions**



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

**15. Income Taxes**



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

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

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

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

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

**16. Quarterly Financial Data (Unaudited)**



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

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21,819,923 Shares

Common Stock

TITAN PHARMACEUTICALS, INC.

Prospectus

, 2005

**You should rely only on the information contained in this prospectus. We have not authorized anyone to provide you with information different from that contained in this prospectus or any prospectus supplement. This prospectus is not an offer of these securities in any jurisdiction where an offer and sale is not permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of our common stock.**

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**PART II****INFORMATION NOT REQUIRED IN PROSPECTUS****Item 13. Other Expenses of Issuance and Distribution**

The following table sets forth the costs and expenses, other than underwriting discounts and commissions, to be paid by the Registrant in connection with the issuance and distribution of the common stock being registered. All amounts other than the SEC registration fee are estimates.

|                                 |           |                   |
|---------------------------------|-----------|-------------------|
| SEC Registration Fee            | \$        | 4,365.95          |
| Printing and Engraving Expenses |           | 10,000.00         |
| Legal Fees and Expenses         |           | 85,000.00         |
| Accounting Fees and Expenses    |           | 20,000.00         |
| Miscellaneous                   |           | 5,634.05          |
| <b>Total</b>                    | <b>\$</b> | <b>125,000.00</b> |

**Item 14. Indemnification of Directors and Officers**

Section 145 of the Delaware General Corporation Law authorizes a court to award, or a corporation's board of directors to grant, indemnity to directors and officers in terms sufficiently broad to permit such indemnification under certain circumstances for liabilities (including reimbursement for expenses incurred) arising under the Securities Act of 1933, as amended (the "Securities Act").

The Amended and Restated Certificate of Incorporation and By-Laws of the Registrant provide that the registrant shall indemnify any person to the full extent permitted by the Delaware General Corporation Law (the "DGCL"). Section 145 of the DGCL, relating to indemnification, is hereby incorporated herein by reference.

In accordance with Section 102(a)(7) of the DGCL, the Certificate of Incorporation of the registrant eliminates the personal liability of directors to the registrant or its stockholders for monetary damages for breach of fiduciary duty as a director with certain limited exceptions set forth in Section 102(a)(7).

The registrant also enters into indemnification agreements with each of its officers and directors, the form of which is incorporated by reference as Exhibit 10.6 and reference is hereby made to such form.

In addition, the registrant currently maintains an officers and directors liability insurance policy which insures, subject to the exclusions and limitations of the policy, officers and directors of the Registrant against certain liabilities which might be incurred by them solely in such capacities.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers or persons controlling the registrant, pursuant to the foregoing provisions, the Registrant has been informed that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act of 1933 and is, therefore, unenforceable.

**Item 15. Recent Sales of Unregistered Securities**

On September 28, 2005, the Registrant issued 75,407 shares of its common stock to Cornell Capital Partners, L.P. ( Cornell ) as a commitment fee in connection with the execution of a Standby Equity Distribution Agreement (the

Agreement ) with Cornell. The Registrant also issued 5,386 shares of its common stock to Monitor Capital, Inc., which acted as placement agent in connection with the Agreement, and paid a \$10,000 structuring fee to Yorkville Advisors Management, LLC, the investment manager for Cornell. The Registrant relied on the exemption from registration contained in Section 4(2) of the Securities Act of 1933, as amended, and the regulations promulgated thereunder, because the shares of the Registrant's common stock were issued to sophisticated entities in a private transaction.

On October 5, 2004, the Registrant issued 149,599 shares of its common stock to two individuals in connection with the acquisition of 101,700 shares of the outstanding common stock of Proneura, Inc. from such two individuals. No fees were paid to any third party in connection with the issuance of the shares. The Registrant relied on the exemption from registration contained in Section 4(2) of the Securities Act of 1933, as amended, and the regulations promulgated thereunder, because the shares of the Registrant's common stock were issued to sophisticated individuals in a private transaction.

On October 15, 2003, the Registrant issued 1,187,500 shares of its common stock to seven individuals in connection with the acquisition of 100% of the outstanding shares of common stock of Developmental Therapeutics, Inc. No fees were paid to any third party in connection with the issuance of the shares. The Registrant relied on the exemption from registration contained in Section 4(2) of the Securities Act of 1933, as amended, and the regulations promulgated thereunder, because the shares of the Registrant's common stock were issued to sophisticated individuals in a private transaction.

## Item 16. Exhibits and Financial Statement Schedules

### Exhibits

- 3.1 Restated Certificate of Incorporation of the Registrant(1)
- 3.2 Form of Amendment to Restated Certificate of Incorporation of the Registrant(1)
- 3.3 By-laws of the Registrant(1)
- 4.7 Certificate of Designation of Series C Preferred Stock(6)
- 4.8 Registration Rights Agreement between the Registrant and Cornell Capital Partners LP, dated September 28, 2005. (14)
- 5.1 Opinion of Loeb & Loeb LLP
- 10.1\* 1993 Stock Option Plan(1)
- 10.2\* 1995 Stock Option Plan, as amended(2)
- 10.3\* Employment Agreement between the Registrant and Louis Bucalo dated February 1, 1993, amended as of February 3, 1994(1).
- 10.4\* Employment Agreement between Registrant and Richard Allen dated July 28, 1995(1)
- 10.5\* Employment Agreement between Registrant and Sunil Bhonsle, dated August 6, 1995(1)

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- 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)

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- 10.15 Exclusive License Agreement between Ingenex, Inc. and the Board of Trustees of the University of Illinois, dated July 1, 1994(1)
- 10.16 License Agreement between Ingenex, Inc. and the Massachusetts Institute of Technology, dated September 11,1992(1)
- 10.17 License Agreement between Ingenex, Inc. and Baylor College of Medicine, dated October 21, 1992(1)
- 10.18 Lease for Registrant s facilities, amended as of October 1, 2004.(13)
- 10.20 License Agreement between Trilex Pharmaceuticals, Inc. (formerly Ascalon Pharmaceuticals, Inc.) and the University of Kentucky Research Foundation dated May 30, 1996(3)
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- 21 List of Subsidiaries (13)
- 23.1 Consent of Odenberg Ullakko Muranishi & Co. LLP, Independent Registered Public Accounting Firm.
- 23.2 Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm.
- 23.3 Consent of Loeb & Loeb LLP (included in Exhibit 5.1)

24.1 Power of Attorney (Previously filed)

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

\* Represents a management contract or compensatory plan.

II-3

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- (1) Incorporated by reference from the Registrant's Registration Statement on Form SB-2 (File No. 33-99386).
- (2) Incorporated by reference from the Registrant's Definitive Proxy Statement filed on September 3, 1996.
- (3) Incorporated by reference from the Registrant's Registration Statement on Form SB-2 (File No. 333-13469) filed on October 4, 1996, amended on November 25, 1996.
- (4) Incorporated by reference from the Registrant's Annual Report on Form 10-KSB for the year ended December 31, 1996.
- (5) Incorporated by reference from the Registrant's Registration Statement on Form S-3 (File No. 333-42367) filed on December 16, 1997.
- (6) Incorporated by reference from the Registrant's Annual Report on Form 10-K for the year ended December 31, 1997.
- (7) Incorporated by reference from the Registrant's Definitive Proxy Statement filed on July 28, 2000.
- (8) Incorporated by reference from the Registrant's Annual Report on Form 10-K for the year ended December 31, 1999.
- (9) Incorporated by reference from the Registrant's Quarterly Report on Form 10-Q for the period ended September 30, 2000.
- (10) Incorporated by reference from the Registrant's Annual Report on Form 10-K for the year ended December 31, 2001.
- (11) Incorporated by reference from the Registrant's Annual Report on Form 10-K for the year ended December 31, 2002.
- (12) Incorporated by reference from the Registrant's Annual Report on Form 10-K for the year ended December 31, 2003.
- (13) Incorporated by reference from the Registrant's Annual Report on Form 10-K for the year ended December 31, 2004.
- (14) Incorporated by reference from the Registrant's Current Report on Form 8-K dated September 28, 2005.

**Item 17. Undertakings**

The undersigned registrant hereby undertakes:

- (1) To file, during any period in which offers or sales are being made pursuant to this Registration Statement, a post-effective amendment to this registration statement:
  - (i) to include any prospectus required by Section 10(a)(3) of the Securities Act of 1933.
  - (ii) to reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the Calculation

of Registration Fee table in the effective registration statement.

(iii) to include any material information with respect to the plan of distribution not previously disclosed in this Registration Statement or any material change to such information in this Registration Statement.

- (2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new Registration Statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
- (3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.
- (4) The undersigned Registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the Registrant's annual report pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
- (5) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions described in Item 15 above, or otherwise, the Registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

**SIGNATURES**

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Pursuant to the requirements of the Securities Act of 1933 the Registrant has duly caused this amendment to the Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of South San Francisco, California on this 28<sup>th</sup> day of October, 2005.

TITAN PHARMACEUTICALS, INC.

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

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

| Signature   | Title   | Date             |
|---|---|------------------|
| /s/ LOUIS R. BUCALO<br>Louis R. Bucalo, M.D.                          | Chairman, President and Chief Executive Officer (principal executive officer)                     | October 28, 2005 |
| *<br>Victor J. Bauer, Ph.D.   | Director  | October 28, 2005 |
| *<br>Sunil Bhonsle  | Executive Vice President, Chief Operating Officer and Director                                    | October 28, 2005 |
| Eurelio M. Cavalier   | Director  | October 28, 2005 |
| *<br>Hubert E. Huckel, M.D.   | Director  | October 28, 2005 |
| *<br>M. David MacFarlane, Ph.D.                                       | Director  | October 28, 2005 |
| *<br>Ley S. Smith   | Director  | October 28, 2005 |
| *<br>Konrad M. Weis, Ph.D.  | Director  | October 28, 2005 |
| Joachim Friedrich Kapp  | Director  | October 28, 2005 |
| /s/ ROBERT E. FARRELL<br>Robert E. Farrell, J.D.                      | Executive Vice President and Chief Financial Officer (principal financial and accounting officer) | October 28, 2005 |
| *By<br>/s/ ROBERT E. FARRELL<br>Robert E. Farrell<br>Attorney-in-Fact |   |                  |



**EXHIBIT INDEX**

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