

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

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**FORM 8-K**

**CURRENT REPORT**

**PURSUANT TO SECTION 13 OR 15(d) OF  
THE SECURITIES EXCHANGE ACT OF 1934**

Date of Report (date of earliest event reported): **March 14, 2005**

**Titan Pharmaceuticals, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of incorporation)

**0-27436**  
(Commission File Number)

**94-3171940**  
(I.R.S. Employer Identification No.)

**400 Oyster Point Blvd., Suite 505, South San Francisco, CA**  
(Address of principal executive offices)

**94080**  
(Zip Code)

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
  - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
  - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
  - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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**Item 2.02. Results of Operations and Financial Condition**

On March 14, 2005, Titan Pharmaceuticals, Inc. (the "Company") issued a press release containing its financial results for the year ended December 31, 2004 (the "Release"). A copy of the Release is furnished herewith as Exhibit 99.1 and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, except as shall be expressly set forth by specific reference in such filing.

**Item 8.01 Other Events**

On March 14, 2005, the Company issued the Release, which contained updated information with regard to its Spheramine program. A copy of the Release is furnished herewith as Exhibit 99.1

**Item 9.01. Financial Statements and Exhibits**

(c) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release of Titan Pharmaceuticals, Inc. dated March 14, 2005.

SIGNATURES

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

TITAN PHARMACEUTICALS, INC.

By: /s/ Robert E. Farrell

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Robert E. Farrell, Chief Financial Officer

Dated: March 14, 2005

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release of Titan Pharmaceuticals, Inc. dated March 14, 2005.



**Titan Pharmaceuticals, Inc.**

Company:  
Robert Farrell  
Executive Vice President & CFO  
650-244-4990

Media/Investors:  
Jonathan Fassberg  
The Trout Group  
212-477-9077

**FOR IMMEDIATE RELEASE****TITAN REPORTS FOURTH QUARTER AND YEAR END 2004 RESULTS**

**South San Francisco, CA — March 14, 2005** — Titan Pharmaceuticals, Inc. (AMEX: TTP) today announced financial results for the fourth quarter and fiscal year ended December 31, 2004.

Net loss for fourth quarter 2004 was approximately \$7.8 million, or \$0.24 per share, compared to \$10.5 million, or \$0.38 per share, for fourth quarter 2003. The Company's net loss for fiscal year 2004 was approximately \$26.0 million, or \$0.83 per share, compared to \$29.9 million, or \$1.07 per share, for fiscal year 2003. The lower net loss for the fourth quarter and for fiscal year 2004 related to a one-time, non-cash, \$3.9 million charge during 2003 to research and development expense that the Company incurred in connection with the acquisition of DITPA, a novel product in development for the treatment of congestive heart failure.

Revenues for fourth quarter 2004 were approximately \$30,000, compared to \$61,000 for fourth quarter 2003. For fiscal year 2004, revenues were approximately \$31,000, compared to \$89,000 for fiscal year 2003. Revenues during 2004 and 2003 were derived from fees received under various licensing agreements. Interest income, net of other expenses, for the fourth quarter 2004 was approximately \$161,000 compared to \$176,000 for the fourth quarter 2003. For fiscal year 2004, interest income, net of other expenses, was approximately \$376,000 compared to \$1.3 million for fiscal year 2003, with the difference related to both lower interest rates and lower average cash balances.

In March 2004, we received net proceeds of approximately \$14.4 million from the sale of our common stock. At December 31, 2004, the Company had approximately \$36.3 million in cash and marketable securities.

"Titan made important progress in several of our development programs in 2004," stated Dr. Louis R. Bucalo, Chairman, President and CEO. "We are now well positioned for further potential progress in 2005, with two products to move forward in 2005 in Phase III clinical testing, and two additional products currently in randomized, controlled Phase II clinical testing."

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Progress in 2004 includes the following:

The iloperidone development program for treatment of schizophrenia was reinitiated through establishment of a license and development agreement with Vanda Pharmaceuticals.

Titan's Probuphine product for opiate addiction successfully completed a pilot clinical study, and manufacturing scale up for Phase III testing was initiated. Regulatory guidance from FDA was determined for Phase III clinical development.

Spheramine received Fast Track designation, and enrollment and treatment progressed to over half of the total patients in the Phase IIb clinical study.

A Phase II, randomized double blind clinical study of DITPA was launched in 150 CHF patients with low serum T3 levels, and a second randomized, double blind study in 150 CHF patients was initiated, funded by the Department of Veterans Affairs Cooperative Studies Program.

Gallium maltolate completed a Phase I clinical study in advanced cancer patients demonstrating achievement of significant serum gallium levels. Preclinical studies were completed in models of rheumatoid arthritis demonstrating efficacy. An exclusive license was obtained to patents covering the use of gallium in the treatment of rheumatoid arthritis, and additional patent applications were filed for gallium maltolate in this indication. A new gallium maltolate formulation was developed demonstrating further enhanced bioavailability in preclinical studies.

Further detail regarding Titan's clinical development programs is provided below.

## **Clinical Development Programs**

### *Iloperidone*

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. Vanda was founded by Dr. Argeris N. Karabelas, former CEO of Novartis Pharmaceuticals, and Dr. Mihael Polymeropoulos, former Vice President of Pharmacogenetics at Novartis Pharmaceuticals. Under its agreement with Novartis, Vanda will now pursue advancement of the iloperidone Phase III development program. All of Titan's rights and economic interests in iloperidone, including royalties on sales of iloperidone, remain essentially unchanged under the agreement.

### *Probuphine®*

In June 2004, we presented final results from our pilot clinical study of Probuphine, a novel long-term treatment for opiate addiction that utilizes our proprietary ProNeura drug delivery system, at the International Society of Addiction Medicine in Helsinki. The data presented 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 with Probuphine. Treatment with Probuphine was also safe and well tolerated in this pilot study, with no significant adverse events. We are currently scaling up our manufacturing process development for Probuphine in support of planned Phase III clinical development activities and commercial supply. We expect to initiate randomized Phase III clinical testing of Probuphine in the treatment of opiate addiction in the second half of 2005. The Company also plans to initiate pilot clinical testing of Probuphine in chronic pain in 2005.

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## *Spheramine®*

Significant progress was made in 2004 in advancing development of Spheramine, our novel cell therapy product for the potential treatment of Parkinson's disease. In July 2004, we successfully completed the safety review following the treatment of the second cohort of 24 patients in our Phase IIb clinical study. We are now enrolling the third and final cohort of 32 patients in this randomized, double blind, controlled study, and expect to complete the study in the second half of 2006. The Company was advised by the U.S. Food and Drug Administration (FDA) that additional information regarding study inclusion/exclusion criteria, criteria for patient selection, and related monitoring procedures should be updated and submitted to FDA prior to further patient treatment in this study. Patient enrollment continues and the Company anticipates that further patient treatment should occur on schedule, subsequent to submission to, and approval by FDA of the additional requested documentation. Our corporate partner for the development of Spheramine, Schering AG, Germany, is funding this study. Also in 2004, we announced that the FDA granted Fast Track designation for Spheramine for the treatment of Parkinson's disease.

## *DITPA*

In December 2004, we initiated a placebo controlled Phase IIb clinical study with DITPA in Class III and Class IV CHF patients with low T3 levels. Researchers have demonstrated that approximately 30% of patients with advanced (NYHA Class III and IV) congestive heart failure have abnormally low levels of T3, the active form of thyroid hormone needed by heart cells, and that low levels of T3 are a strong independent predictor of increased mortality in CHF patients. This Phase IIb randomized, placebo controlled study will evaluate 150 patients with NYHA Class III-IV CHF and low serum T3 levels. Patients will receive either of two doses of DITPA or placebo for six months. The study will be performed at 35 centers in the U.S. The study will evaluate clinical and laboratory parameters related to severity of CHF, including change in global clinical status, echocardiographic parameters, BNP levels, exercise testing and quality of life measurements, in addition to safety.

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.

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

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## *Pivanex®*

In June 2004, we announced that treatment with Pivanex was discontinued in a randomized Phase II study with docetaxel due to safety concerns. Data collection for this study is now complete, and preliminary analysis indicates no significant difference in survival in the two treatment arms. Final study analysis is expected to be complete in the second quarter of 2005. Following these results, the Company has refocused priorities and Pivanex studies in chronic lymphocytic leukemia and melanoma are being discontinued.

## *Gallium Maltolate*

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

In 2004 we also evaluated gallium maltolate in animal models of rheumatoid arthritis that demonstrated that oral dosing of gallium maltolate reduced the severity of disease related endpoints in a dose-dependent manner. Based on these results, the Company believes gallium maltolate may have potential in the treatment of rheumatoid arthritis.

## **About Titan Pharmaceuticals**

Titan Pharmaceuticals, Inc. (AMEX: TTP) is a biopharmaceutical company focused on the development and commercialization of novel treatments for central nervous system disorders, cardiovascular disease and cancer. Titan's products in development utilize novel technologies that have the potential to significantly improve the treatment of these diseases. Titan also establishes partnerships with government institutions and other leading pharmaceutical development companies. For more information, please visit the Company's website at [www.titanpharm.com](http://www.titanpharm.com)

The press release may contain "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Such statements include, but are not limited to, any statements relating to the Company's development program and any other statements that are not historical facts. Such statements involve risks and uncertainties, including, but not limited to, those risks and uncertainties relating to difficulties or delays in development, testing, regulatory approval, production and marketing of the Company's drug candidates, unexpected adverse side effects or inadequate therapeutic efficacy of the Company's drug candidates that could slow or prevent product development or commercialization, the uncertainty of patent protection for the Company's intellectual property or trade secrets and the Company's ability to obtain additional financing if necessary. Such statements are based on management's current expectations, but actual results may differ materially due to various factors, including those risks and uncertainties mentioned or referred to in this press release.

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**TITAN PHARMACEUTICALS, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
(in thousands, except per share amount)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2004	2003	2004	2003
	(Unaudited)			
License and contract revenue	\$ 30	\$ 61	\$ 31	\$ 89
Total revenue	30	61	31	89
Operating expenses:				
Research and development	5,846	5,619	20,415	22,258
Acquired research and development	759	3,896	759	3,896
General and administrative	1,384	1,231	5,237	5,109
Total operating expenses	7,989	10,746	26,411	31,263
Loss from operations	(7,959)	(10,685)	(26,380)	(31,174)
Interest income, net of other expense	161	176	376	1,285
Net loss	\$ (7,798)	\$ (10,509)	\$ (26,004)	\$ (29,889)
Basic and diluted net loss per share	\$ (0.24)	\$ (0.38)	\$ (0.83)	\$ (1.07)
Shares used in computing basic and diluted net loss per share	32,271	27,907	31,381	27,907

**CONDENSED CONSOLIDATED BALANCE SHEETS**

	December 31, 2004	December 31, 2003
	(unaudited)	(Note A)
Assets		
Cash, cash equivalents, and marketable securities	\$ 36,322	\$ 46,555
Prepaid expenses, receivables, and other current assets	1,110	1,364
Total current assets	37,432	47,919
Furniture and equipment, net	1,044	789
Investment in other companies	150	300
	\$ 38,626	\$ 49,008
Liabilities and Stockholders' Equity		
Current liabilities	\$ 3,672	\$ 3,341
Minority interest - Series B preferred stock of Ingenex, Inc.	1,241	1,241
Stockholders' Equity	33,713	44,426
	\$ 38,626	\$ 49,008

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.