

TITAN PHARMACEUTICALS INC
Form 10-Q
August 09, 2004

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

Quarterly Report Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of
1934 for the Period Ended June 30, 2004.

or

Transition Report Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of
1934 for the Transition Period From _____
to _____.

Commission file number 0-27436

Titan Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or Other Jurisdiction of
Incorporation or Organization)

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

400 Oyster Point Blvd., Suite 505, South San Francisco, California 94080
(Address of Principal Executive Offices including zip code)

(650) 244-4990
(Registrant's Telephone Number, Including Area Code)

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant is an accelerated filer (as defined on Rule 12B-2 of the Exchange Act). Yes No

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There were 32,119,635 shares of the Registrant's Common Stock issued and outstanding on August 2, 2004.

Titan Pharmaceuticals, Inc.

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Part I. Financial Information

TITAN PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)

| | June 30, 2004 (unaudited) | December 31, 2003 (Note A) |
|---|---------------------------------|----------------------------------|
| Assets | | |
| Current assets | | |
| Cash and cash equivalents | \$ 5,223 | \$ 6,832 |
| Marketable securities | 43,246 | 39,723 |
| Related party receivables | 52 | 123 |
| Prepaid expenses, receivables, and other current assets | 1,215 | 1,241 |
| Total current assets | 49,736 | 47,919 |
| Furniture and equipment, net | 896 | 789 |
| Investment in other companies | 300 | 300 |
| | \$ 50,932 | \$ 49,008 |
| Liabilities and Stockholders Equity | | |
| Current liabilities | | |
| Accounts payable | \$ 634 | \$ 1,505 |
| Accrued clinical trials expenses | 893 | 634 |
| Other accrued liabilities | 1,106 | 1,202 |
| Total current liabilities | 2,633 | 3,341 |
| Minority interest - Series B preferred stock of Ingenex, Inc. | 1,241 | 1,241 |
| Stockholders equity | | |
| Common stock, at amounts paid-in | 209,834 | 195,331 |
| Additional paid-in capital | 9,202 | 9,047 |
| Deferred compensation | (179) | (211) |
| Accumulated deficit | (171,677) | (159,741) |
| Accumulated other comprehensive income | (122) | |
| Total stockholders equity | 47,058 | 44,426 |
| | \$ 50,932 | \$ 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.

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, | | | | | |
|--|-----------------------------|---------|---------------------------|----------|----------|----------|----|----------|
| | 2004 | 2003 | 2004 | 2003 | | | | |
| License revenue | \$ | \$ | 2 | \$ | 28 | | | |
| Total revenue | | | 2 | 1 | 28 | | | |
| Operating expenses: | | | | | | | | |
| Research and development | | 4,598 | 5,735 | 9,711 | 11,377 | | | |
| General and administrative | | 1,118 | 1,257 | 2,486 | 2,638 | | | |
| Total operating expenses | | 5,716 | 6,992 | 12,197 | 14,015 | | | |
| Loss from operations | | (5,716) | (6,990) | (12,196) | (13,987) | | | |
| Other income (expense): | | | | | | | | |
| Interest income, net | | 178 | 325 | 337 | 796 | | | |
| Other expense | | (17) | (16) | (77) | (20) | | | |
| Other income, net | | 161 | 309 | 260 | 776 | | | |
| Net loss | \$ | (5,555) | \$ | (6,681) | \$ | (11,936) | \$ | (13,211) |
| Basic and diluted net loss per share | \$ | (0.17) | \$ | (0.24) | \$ | (0.39) | \$ | (0.48) |
| Weighted average shares used in computing basic and diluted net loss per share | | 32,108 | 27,643 | 30,558 | 27,643 | | | |

See Notes to Condensed Consolidated Financial Statements

TITAN PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

(in thousands)

| | Six Months Ended June 30, | |
|---|---------------------------|------------------|
| | 2004 | 2003 |
| Cash flows from operating activities: | | |
| Net loss | \$ (11,936) | \$ (13,211) |
| Adjustments to reconcile net loss to net cash provided by (used in) operating activities: | | |
| Depreciation and amortization | 207 | 219 |
| Non-cash compensation related to stock options | 187 | 177 |
| Write-down of securities available-for-sale | 50 | |
| Changes in operating assets and liabilities: | | |
| Prepaid expenses, receivables and other assets | 97 | (662) |
| Accounts payable and other accrued liabilities | (708) | 46 |
| Net cash used in operating activities | (12,103) | (13,431) |
| Cash flows from investing activities: | | |
| Purchases of furniture and equipment, net | (314) | (169) |
| Purchases of marketable securities | (18,494) | (32,561) |
| Proceeds from maturities of marketable securities | 14,800 | 48,540 |
| Proceeds from sales of marketable securities | | 9,000 |
| Net cash provided by investing activities | (4,008) | 24,810 |
| Cash flows from financing activities: | | |
| Issuance of common stock, net | 14,502 | 10 |
| Net cash provided by financing activities | 14,502 | 10 |
| Net increase in cash and cash equivalents | (1,609) | 11,389 |
| Cash and cash equivalents at beginning of period | 6,832 | 7,155 |
| Cash and cash equivalents at end of period | 5,223 | 18,544 |
| Marketable securities at end of period | 43,246 | 41,097 |
| Cash, cash equivalents and marketable securities at end of period | \$ 48,469 | \$ 59,641 |

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

We are a biopharmaceutical company developing proprietary therapeutics for the treatment of central nervous system disorders, cancer, and cardiovascular disease. We operate in one business segment, the development of biopharmaceutical products.

Basis of Presentation

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 year balances have been reclassified to conform to the current year 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, 2004 are not necessarily indicative of the results that may be expected for the year ending December 31, 2004.

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 for the year ended December 31, 2003.

Revenue Recognition

We generate revenue principally from collaborative research and development arrangements, technology licenses, and government grants. Revenue arrangements with multiple components are divided into separate units of accounting if certain criteria are met, including whether the

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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 components, the amount of revenue allocable to the delivered technology is deferred. Non-refundable upfront fees with stand-alone value that are not dependent on future performance under these agreements are recognized as revenue when received, and are deferred if Titan has continuing performance obligations and has no evidence of fair value for those obligations. Payments received related to substantive, performance-based at-risk milestones are recognized as revenue upon achievement of the clinical success or regulatory event specified in the underlying contracts, which represent the culmination of the earnings process. Amounts received in advance are recorded as deferred revenue until the technology is transferred, costs are incurred, or milestone is reached.

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

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

Operating Subsidiaries

We conduct some of our operations through two subsidiaries: Ingenex, Inc. and ProNeura, Inc. At June 30, 2004, we owned 81% of Ingenex (assuming the conversion of all preferred stock to common stock) and 79% of ProNeura.

Recent Accounting Pronouncements

In March 2004, the Emerging Issues Task Force (EITF) reached several consensuses on accounting guidance and disclosure of other-than-temporary impairment of debt and equity securities discussed in Issue No. 03-01, *The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments*. These consensuses apply to investments in debt and equity securities within the scope of Statements 115 and 124. They also apply to investments in equity securities that are both outside Statement 115's scope and not accounted for by the equity method, a group referred to as cost method investments. The impairment accounting guidance is effective for reporting periods beginning after June 15, 2004; the disclosure requirements for annual reporting periods ending after June 15, 2004.

2. 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

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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, | |
|--|---|------------|---------------------------|-------------|
| | 2004 | 2003 | 2004 | 2003 |
| | (in thousands, except per share amount) | | | |
| Net loss, as reported | \$ (5,555) | \$ (6,681) | \$ (11,936) | \$ (13,211) |
| Add: Stock-based employee compensation expense included in reported net loss | 71 | 83 | 134 | 177 |
| Deduct: Estimated stock-based employee compensation expense determined in accordance with SFAS 123 for all stock option grants | (385) | (416) | (607) | (1,308) |
| Pro forma net loss | \$ (5,869) | \$ (7,014) | \$ (12,409) | \$ (14,342) |
| Basic and diluted net loss per share, as reported | \$ (0.17) | \$ (0.24) | \$ (0.39) | \$ (0.48) |
| Pro forma basic and diluted net loss per share | \$ (0.18) | \$ (0.25) | \$ (0.41) | \$ (0.52) |

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 the three-month periods ended June 30, 2004 and 2003: weighted-average volatility factor of 0.70 and 0.70, respectively; no expected dividend payments; weighted-average risk-free interest rates in effect of 3.8% and 2.1%, respectively; and a weighted-average expected life of 4.5 and 3.0 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 period. For the periods ended June 30, 2004 and 2003, the effect of an additional 6,479,890 and 6,524,548 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 is unrealized gains and losses on our marketable securities. Comprehensive loss for the three and six months ended June 30, 2004 were \$5.8 million and \$12.1 million, respectively, and for the three and six months ended June 30, 2003 were \$6.7 million and \$13.4 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

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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.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

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

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

Overview

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

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)

Probuphine: for the treatment of opiate addiction

DITPA: for the treatment of congestive heart failure

Pivanex: for the treatment of chronic lymphocytic leukemia

Gallium maltolate: for the treatment of several cancers and bone related disease

Following is an update on the status and progress of Titan's core development programs:

Iloperidone

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In June 2004, we announced that Vanda Pharmaceuticals, Inc. had acquired from Novartis Pharma AG the worldwide rights to develop and commercialize iloperidone, Titan's 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 Titan's rights and economic interests in iloperidone, including royalties on sales of iloperidone, remain essentially unchanged under the agreement.

Spheramine

Enrollment in a randomized, controlled, blinded, multi-center Phase IIb clinical study of Spheramine in advanced Parkinson's disease is continuing, and we estimate that this study will be completed in the second half of 2005. Schering AG, Germany, Titan's corporate partner for the development of Spheramine, is fully funding the clinical development program for Spheramine.

In July 2004, we announced that the U.S. Food and Drug Administration had granted 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.

Pivanex

In June 2004, we announced that an interim safety analysis by an independent data monitoring committee (IDMC) for our Phase IIb study of Pivanex in non-small cell lung cancer had identified significant safety issues in the combination treatment of Pivanex with docetaxel. This randomized study evaluating treatment with Pivanex and docetaxel versus docetaxel alone had completed its enrollment target of 225 patients earlier this year. As a result of the IDMC finding and upon their recommendation, Titan has discontinued treatment with Pivanex for the remaining patients on the study. We will continue to monitor the study and perform a final analysis as planned. Titan plans to continue enrollment and further treatment with Pivanex as a single agent in the open label Phase IIa study in CLL. The single agent Pivanex study in melanoma will be discontinued.

Gallium Maltolate

Titan is conducting a dose ranging clinical study of gallium maltolate in patients with multiple myeloma, metastatic prostate cancer, metastatic bladder cancer and refractory lymphoma. This Phase I clinical study is expected to be completed in the second half of 2004. We are also continuing to optimize the formulation, and preclinical testing of gallium maltolate in other disease settings is also ongoing. Gallium maltolate is a novel oral agent for the treatment of cancer and bone disease.

Probuphine

Titan has completed a pilot clinical study of Probuphine, a novel long-term treatment for opiate addiction that utilizes Titan's proprietary ProNeura drug delivery system. In June 2004, the results were presented at the Annual Meeting of The International Society of Addiction Medicine in Helsinki and demonstrated that all 12 patients switched from daily sublingual buprenorphine therapy to Probuphine had maintenance of therapeutic benefit for a period of six months following a single treatment of Probuphine. Treatment with Probuphine was also safe and well tolerated in this pilot study, with no significant adverse events.

DITPA

DITPA has completed Phase I and preliminary controlled Phase II clinical testing in the treatment of congestive heart failure (CHF), and was shown in these studies to improve cardiac function without increasing heart rate. Based on these encouraging results, the U.S. Department of Veterans Affairs (VA) initiated a 150 patient, randomized, double blind Phase II clinical study in patients with Class II - IV CHF. This multicenter study is funded by a \$3.8 million grant from the VA. In addition, Titan plans to initiate placebo controlled Phase II clinical testing with DITPA in Class III and Class IV CHF patients with low thyroid hormone (T_3) levels in the second half of 2004.

We are directly developing our product candidates and also utilizing corporate partnerships, including a collaboration with Schering AG, Germany (Schering) for the development of Spheramine to treat Parkinson's disease. Spheramine development is primarily funded by Schering. Iloperidone development and commercialization for the treatment of schizophrenia and related psychotic disorders will now be pursued by Vanda Pharmaceuticals, as discussed above. We also utilize grants from government agencies to fund development of our product candidates.

At this time, we are not devoting any additional internal resources to the monoclonal antibodies CeaVac, TriAb, and TriGem. These treatments are currently being studied in certain cancers by national oncology cooperative groups funded by the National Cancer Institute.

Our products are at various stages of development and may not be successfully developed or commercialized. We do not currently have any products being commercially sold. Our proposed products will require significant further capital expenditures, development, testing, and regulatory clearances prior to commercialization. We may experience unanticipated problems relating to product development and cannot predict whether we will successfully develop and commercialize any products. For a full discussion of risks and uncertainties of our product development, see Risk Factors. Our products are at various stages of development and may not be successfully developed or commercialized in our 2003 Annual Report on Form 10-K.

Results of Operations

In the second quarter 2004, we had no revenues, compared to approximately \$2,000 of revenue for the same period in 2003. For the first six months of 2004, we had approximately \$1,000 of revenue, compared to approximately \$28,000 of revenue for the same six-month period in 2003.

Research and development (R&D) expenses for the second quarter 2004 were \$4.6 million, compared to \$5.7 million for the same quarter in 2003, a decrease of \$1.1 million, or 20%. For the first six months of 2004, R&D expenses were \$9.7 million, compared to \$11.4 million for the same six-month period in 2003, a decrease of \$1.7 million, or 15%. Higher R&D expenses in 2003 were associated primarily with our immunotherapy program. We are currently not devoting any additional resources to this program. 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. Including operating expenses for the second quarter 2004, our external R&D expenses to date relating to our core product development programs have been approximately: \$10.3 million related to Pivanex, \$3.6 million related to Probuphine, \$4.0 million related to gallium maltolate, \$6.8 million related to Spheramine, and \$0.3 million related to DITPA. Other 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. 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 second quarter 2004 were \$1.1 million, compared to \$1.3 million for the same quarter in 2003, a decrease of \$0.2 million, or 11%. For the first six months of 2004, general and administrative expenses were \$2.5 million, compared to \$2.6 million for the same six-month period in 2003, a decrease of \$0.1 million, or 6%. The decrease in general and administrative expenses from 2003 to 2004 was primarily due to a reduction in the number of our administrative personnel.

Other income, primarily interest income net of amortization and other expenses, for the second quarter 2004 was approximately \$0.2 million, compared to \$0.3 million in the same quarter in 2003. For the first six months of 2004, other income, net, was \$0.3 million, compared to \$0.8 million for the same six-month period in 2003. The decrease, primarily in interest income, was a result of a lower balance of cash and marketable securities.

Our net loss for the second quarter 2004 was \$5.6 million, or \$0.17 per share, compared to \$6.7 million, or \$0.24 per share, for the same quarter in 2003. For the first six months of 2004, our net loss was \$11.9 million, or \$0.39 per share, compared to \$13.2 million, or \$0.48 per share, for the same six-month period in 2003.

Liquidity and Capital Resources

We have funded our operations since inception 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, 2004, we had \$48.5 million of cash, cash equivalents, and marketable securities.

Our operating activities used \$12.1 million and \$13.4 million of cash in the first six months of 2004 and 2003, respectively. Uses of cash in operating activities were primarily to fund product development programs and administrative expenses. We have entered into various agreements with research institutions, universities, and other entities for the performance of research and development activities and for the acquisition of licenses related to those activities. The aggregate commitments we have under these agreements, including minimum license payments, for the next 12 months is approximately \$0.3 million. Certain of the licenses require us to pay royalties on future product sales, if any. In addition, in order to maintain license and other rights while products are under development, we must comply with customary licensee obligations, including the payment of patent related costs and diligent efforts in product development.

We expect to continue to incur substantial additional operating losses from costs related to continuation and expansion of product and technology development, clinical trials, and administrative activities. We believe that we currently have sufficient working capital to sustain our planned operations through mid-2006.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our market risk disclosures set forth in our Form 10-K for the period ended December 31, 2003, have not changed significantly.

Item 4. Controls and Procedures

We maintain disclosure controls and procedures, as such term is defined under Exchange Act Rule 13a-15(e), that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures. In designing and evaluating the disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives and in reaching a reasonable level of assurance our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. We have carried out an evaluation under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of June 30, 2004. Based upon their evaluation and subject to the foregoing, the Chief Executive Officer and Chief Financial Officer concluded that as of June 30,

2004 our disclosure controls and procedures were effective at the reasonable assurance level in ensuring that

material information relating to us, is made known to the Chief Executive Officer and Chief Financial Officer by others within our company during the period in which this report was being prepared.

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

PART II

Item 6. Exhibits and Reports on Form 8-K

(b) Exhibits

31 Rule 13a-14(A) Certifications.

32 Section 1350 Certifications.

(c) Reports on Form 8-K

On June 9, 2004, we filed a current report on Form 8-K to announce that Novartis Pharma AG has licensed 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, to Vanda Pharmaceuticals, Inc., a pharmaceutical development company headquartered in Rockville, Maryland.

On June 21, 2004, we filed a current report on Form 8-K to announce that an interim safety analysis by an independent data monitoring committee for our Phase IIb study of Pivanex in non-small cell lung cancer had identified significant safety issues in the combination treatment of Pivanex with docetaxel. As a result, we have discontinued treatment with the combination regimen for the remaining patients on study.

SIGNATURES

In accordance with the requirements of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

TITAN PHARMACEUTICALS, INC.

August 6, 2004

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

August 6, 2004

By: /s/ Robert E. Farrell
Robert E. Farrell
Executive Vice President and Chief Financial Officer