TITAN PHARMACEUTICALS INC
Form 10-Q
November 09, 2004

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

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

or

o 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	**94-3171940**
(State or Other Jurisdiction of Incorporation or Organization)	(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 ý No o

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

There were 32,302,602 shares of the Registrant s Common Stock issued and outstanding on November 1, 2004.

Titan Pharmaceuticals, Inc.

Index to Form 10-Q

SIGNATURES

Part I. Financial Information

TITAN PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands)

	September 30, 2004 (unaudited)	December 31, 2003 (Note A)
Assets		
Current assets		
Cash and cash equivalents	$ 5,956	$ 6,832
Marketable securities	37,227	39,723
Related party receivables	50	123
Prepaid expenses, receivables, and other current assets	1,138	1,241
Total current assets	44,371	47,919
Furniture and equipment, net	1,059	789
Investment in other companies	150	300
	$ 45,580	$ 49,008
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 678	$ 1,505
Accrued clinical trials expenses	1,504	634
Other accrued liabilities	1,142	1,202
Total current liabilities	3,324	3,341
Minority interest - Series B preferred stock of Ingenex, Inc.	1,241	1,241
Stockholders' equity		
Common stock, at amounts paid-in	209,889	195,331
Additional paid-in capital	9,260	9,047
Deferred compensation	(152)	(211)
Accumulated deficit	(177,947)	(159,741)
Accumulated other comprehensive income	(35)	
Total stockholders' equity	41,015	44,426
	$ 45,580	$ 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 Sept. 30,		Nine Months Ended Sept. 30,	
	2004	2003	2004	2003
License revenue	$	$	$ 1	$ 28
Total revenue			1	28
Operating expenses:				
Research and development	4,858	5,262	14,569	16,639
General and administrative	1,367	1,239	3,853	3,878
Total operating expenses	6,225	6,501	18,422	20,517
Loss from operations	(6,225)	(6,501)	(18,421)	(20,489)
Other income (expense):				
Interest income, net	175	265	512	1,062
Other expense	(220)	67	(297)	47
Other income (expense), net	(45)	332	215	1,109
Net loss	$ (6,270)	$ (6,169)	$ (18,206)	$ (19,380)
Basic and diluted net loss per share	$ (0.20)	$ (0.22)	$ (0.59)	$ (0.70)
Weighted average shares used in computing basic and diluted net loss per share	32,137	27,653	31,084	27,646

See Notes to Condensed Consolidated Financial Statements

TITAN PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

(in thousands)

	Nine Months Ended Sept. 30,	
	2004	**2003**
Cash flows from operating activities:		
Net loss	$ (18,206)	$ (19,380)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization	334	329
Loss on investment activities	150	
Non-cash compensation related to stock options	272	240
Write-down of securities available-for-sale	110	
Changes in operating assets and liabilities:		
Prepaid expenses, receivables and other assets	176	(354)
Accounts payable and other accrued liabilities	(17)	(160)
Net cash used in operating activities	(17,181)	(19,325)
Cash flows from investing activities:		
Purchases of furniture and equipment, net	(604)	(199)
Purchases of marketable securities	(18,449)	(47,308)
Proceeds from maturities of marketable securities	20,800	58,103
Proceeds from sales of marketable securites		9,000
Net cash provided by investing activities	1,747	19,596
Cash flows from financing activities:		
Issuance of common stock, net	14,558	47
Net cash provided by financing activities	14,558	47
Net increase in cash and cash equivalents	(876)	318
Cash and cash equivalents at beginning of period	6,832	7,155
Cash and cash equivalents at end of period	5,956	7,473
Marketable securities at end of period	37,227	46,147
Cash, cash equivalents and marketable securities at end of period	$ 43,183	$ 53,620

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 nine-month periods ended September 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 currently 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 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 September 30, 2004, we owned 81% of Ingenex (assuming the conversion of all preferred stock to common stock) and 79% of ProNeura. In October 2004, we entered into a share exchange agreement with two of the minority shareholders of ProNeura that increased our ownership percentage to 89% in exchange for the issuance of 144,599 shares of our common stock. We intend to acquire the remaining minority interest through a merger of ProNeura with and into Titan.

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.

On March 31, 2004, the FASB issued an Exposure Draft, Share-Based Payment - An Amendment of FASB Statements No. 123 and 95 (proposed FAS 123R), which currently is expected to be effective for public companies in periods beginning after June 15, 2005. The cumulative effect of adoption, if any, applied on a modified prospective basis, would be measured and recognized on July 1, 2005. FAS 123R would eliminate the ability to account for share-based compensation transactions using Accounting Principles Board Opinion No. 25 (or APB 25), Accounting for Stock Issued to Employees, and would instead require companies to recognize compensation expense, using a fair-value based method, for costs related to share-based payments including stock options and employee stock purchase plans. The FASB expects to issue a final standard by December 31, 2004. The adoption of FAS 123R could materially impact our results of operations

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 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 Sept. 30,		Nine months ended Sept. 30,	
	2004	2003	2004	2003
	(in thousands, except per share amount)			
Net loss, as reported	$ (6,270)	$ (6,169)	$ (18,206)	$ (19,380)
Add: Stock-based employee compensation expense included in reported net loss	67	62	201	240
Deduct: Estimated stock-based employee compensation expense determined in accordance with SFAS 123 for all stock option grants	(447)	(821)	(1,054)	(2,129)
Pro forma net loss	$ (6,650)	$ (6,928)	$ (19,059)	$ (21,269)
Basic and diluted net loss per share, as reported	$ (0.20)	$ (0.22)	$ (0.59)	$ (0.70)
Pro forma basic and diluted net loss per share	$ (0.21)	$ (0.25)	$ (0.61)	$ (0.77)

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 September 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 2.5% and 1.1%, respectively; and a weighted-average expected life of 2.0 and 1.1 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 September 30, 2004 and 2003, the effect of an additional 6,683,739 and 6,397,433 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 nine months ended September 30, 2004 were $6.1 million and $18.0

million, respectively, and for the three and nine months ended September 30, 2003 were $6.3 million and $19.7 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.

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 bone related diseases and certain cancers.

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

Iloperidone

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 early 2006. Schering AG, Germany, Titan s corporate partner for the development of Spheramine, is 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.

In July 2004, the safety review following treatment of the second cohort of 24 patients in our Phase IIb clinical study was completed successfully, and the Independent Data Monitoring Committee (IDMC) recommended that the study continue. We are now in the process of enrolling the third and final cohort of 32 patients in this study.

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 discontinued treatment with Pivanex for the remaining patients on the study. Data collection for this study is now complete, and final analysis is expected to be completed by the first quarter of 2005. Enrollment and further treatment with Pivanex as a single agent in the open label Phase IIa study in CLL is continuing. The single agent Pivanex study in melanoma was discontinued.

Gallium Maltolate

Titan is completing a dose ranging clinical study of gallium maltolate in patients with multiple myeloma, metastatic prostate cancer, metastatic bladder cancer and refractory lymphoma. Titan is also developing a new 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.

We are currently scaling up manufacturing process development for Probuphine in support of planned Phase III clinical development activities and commercial supply. We expect to initiate randomized clinical testing of Probuphine in the treatment of opiate addiction in mid-2005.

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. We are planning to initiate a placebo controlled Phase II clinical study with DITPA in Class III and Class IV CHF patients with low thyroid hormone (T3) levels. The FDA has completed its review of our IND for this study, and we expect to initiate the study in the fourth quarter of 2004. In July 2004, 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.

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 is being 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

Our net loss for the third quarter 2004 was approximately $6.3 million, or $0.20 per share, compared to approximately $6.2 million, or $0.22 per share, for the same quarter in 2003. For the first nine months of 2004, our net loss was approximately $18.2 million, or $0.59 per share, compared to approximately $19.4 million, or $0.70 per share, for the same nine-month period in 2003.

We had no revenues in the third quarters of 2004 and 2003. For the first nine months of 2004, we had approximately $1,000 of revenue, compared to approximately $28,000 of revenue for the same nine-month period in 2003.

Research and development (R&D) expenses for the third quarter 2004 were approximately $4.9 million, compared to approximately $5.3 million for the same quarter in 2003, a decrease of $0.4 million, or 8%. For the first nine months of 2004, R&D expenses were approximately $14.6 million, compared to approximately $16.6 million for the same nine-month period in 2003, a decrease of $2.0 million, or 12%. The reduction in 2004 is a result of discontinuing internal resources and associated expenses for the cancer immunotherapy products. 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 external R&D expenses incurred in the third quarter 2004, our external R&D expenses to date relating to our core product development programs have been approximately: $11.4 million related to Pivanex, $3.8 million related to Probuphine, $4.2 million related to gallium maltolate, $7.0 million related to Spheramine, and $0.7 million related to DITPA. Other R&D 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 third quarter 2004 were approximately $1.4 million, compared to approximately $1.2 million for the same quarter in 2003, an increase of $0.2 million, or 17%. For the first nine months of 2004, general and administrative expenses were approximately $3.9 million, compared to approximately $3.9 million for the same nine-month period in 2003, or essentially unchanged. Higher personnel-related costs for the first nine months of 2004 were offset by a decrease in other general and administrative costs, including professional fees.

Other expense for the third quarter 2004 was approximately $0.1 million, compared to other income of approximately $0.3 million in the same quarter in 2003. The decrease consisted primarily of a decrease of $0.2 million in interest income and a $0.2 million charge related to a loss on investing activities. For the first nine months of 2004, other income, net, was approximately $0.2 million, compared to approximately $1.1 million for the same nine-month period in 2003. The decrease, primarily in interest income, was a result of a lower balance of cash and marketable securities.

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 September 30, 2004, we had $43.2 million of cash, cash equivalents, and marketable securities compared to $46.6 million at December 31, 2003.

Our operating activities used $17.2 million in cash in the first nine months of 2004. This consisted primarily of the net loss for the period of $18.2 million offset in part by non-cash charges of $0.3 million related to depreciation and amortization expenses, $0.2 million related to a loss on investing activities, and $0.3 million related to the amortization of unearned stock-based compensation. 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.

Net cash provided by investing activities of $1.8 million in the nine-month period ended September 30, 2004 consisted of sales and maturities of marketable securities of $20.1 million, partially offset by purchases of marketable securities of $18.4 million and capital expenditures of $0.6 million. Cash invested in marketable securities decreased by $2.5 million in the nine-month period ended September 30, 2004.

Net cash provided by financing activities for the nine-month period ended September 30, 2004 was $14.6 million, which were the net proceeds from the sale of 3,075,000 shares of common stock under our effective shelf registration statement on Form S-3 (File 333-112513).

We expect to continue to incur substantial additional operating losses from costs related to the continuation and expansion of product and technology development, clinical trials, and administrative activities. We believe that we currently have funds sufficient for greater than one year of operations.

12

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 September 30, 2004. Based upon their evaluation and subject to the foregoing, the Chief Executive Officer and Chief Financial Officer concluded that as of September 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 July 12, 2004, we filed a current report on Form 8-K to announce that the U.S. Food and Drug Administration has granted Fast Track designation for Spheramine for the treatment of advanced Parkinson s disease.

On September 3, 2004, we filed a current report on Form 8-K to announce that Ernst & Young LLP informed Titan that Ernst & Young LLP will resign as our independent registered public accounting firm following completion of services related to the review of our interim financial statements included in this Quarterly Report on Form 10-Q.

On September 30, 2004, we filed a current report on Form 8-K to announce that we had entered into an engagement letter with Odenberg, Ullakko, Muranishi & Co. LLP (OUM) to serve as our independent registered public accounting firm for the fiscal year ending December 31, 2004. OUM s engagement as our new auditors will be effective as of the filing date of this Quarterly Report on Form 10-Q.

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.

November 9, 2004	By:	/s/ Louis R. Bucalo Louis R. Bucalo, M.D. Chairman, President and Chief Executive Officer
November 9, 2004	By:	/s/ Robert E. Farrell Robert E. Farrell, J.D. Executive Vice President and Chief Financial Officer