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 September 30, 2001.

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	**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 ☒ No ☐

There were 27,651,081 shares of the Registrant's Common Stock issued and outstanding on November 2, 2001.

Titan Pharmaceuticals, Inc.
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Part I. Financial Information

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

	September 30, 2001 (unaudited)	December 31, 2000 (Note A)
Assets		
Current assets		
Cash and cash equivalents	$ 6,232	$ 20,300
Marketable securities	102,681	97,223
Prepaid expenses, receivables, and other current assets	979	326
Total current assets	109,892	117,849
Furniture and equipment, net	596	593
	$ 110,488	$ 118,442
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 590	$ 1,304
Accrued clinical trials expenses	987	432
Other accrued liabilities	943	727
Total current liabilities	2,520	2,463
Minority interest - Series B preferred stock of Ingenex, Inc.	1,241	1,241
Stockholders' equity		
Common stock, at amounts paid in	191,613	190,763
Additional paid-in capital	8,785	8,744
Deferred compensation	(797)	(1,254)
Accumulated deficit	(95,346)	(84,206)
Accumulated other comprehensive income	2,472	691
Total stockholders' equity	106,727	114,738
	$ 110,488	$ 118,442

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 for complete financial statements presentation.

See Notes to Condensed Consolidated Financial Statements

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2001	2000	2001	2000

Contract revenue	$ 303	$ 280	$ 924	$ 841
Grant revenue	227	-	559	55
License revenue	-	415	2,500	415
Total revenue	530	695	3,983	1,311
Operating expenses:				
Research and development	5,756	4,576	16,096	11,887
Acquired in-process research and development	-	4,969	-	4,969
General and administrative	1,312	1,247	4,107	2,808
Total operating expenses	7,068	10,792	20,203	19,664
Loss from operations	(6,538)	(10,097)	(16,220)	(18,353)
Other income (expense):				
Interest income, net	1,770	1,392	5,172	3,605
Other expense	(19)	(6)	(92)	(34)
Other income, net	1,751	1,386	5,080	3,571
Net loss	$ (4,787)	$ (8,711)	$ (11,140)	$ (14,782)
Basic and diluted net loss per share	$ (0.17)	$ (0.34)	$ (0.40)	$ (0.59)
Weighted average shares used in computing basic and diluted net loss per share	27,643	25,872	27,577	25,171

See Notes to Condensed Consolidated Financial Statements

TITAN PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(unaudited)
(in thousands of dollars)

	Nine Months Ended September 30,	
	2001	**2000**
Cash flows from operating activities:		
Net loss	$ (11,140)	$ (14,782)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization	413	119
Non-cash compensation related to stock options	498	291
Acquired in-process research and development	-	4,969
Changes in operating assets and liabilities:		
Prepaid expenses, receivables and other current assets	(865)	191
Accounts payable and other accrued liabilities	57	(261)
Unearned contract revenue	-	30
Net cash used in operating activities	(11,037)	(9,443)
Cash flows from investing activities:		
Purchases of furniture and equipment, net	(204)	(245)
Purchases of marketable securities	(61,299)	(100,555)
Maturities and sales of marketable securities	57,622	27,278
Net cash used in investing activities	(3,881)	(73,522)
Cash flows from financing activities:		
Issuance of common stock, net	850	42,845
Net cash provided by financing activities	850	42,845
Net decrease in cash and cash equivalents	(14,068)	(40,120)
Cash and cash equivalents at beginning of period	20,300	46,454
Cash and cash equivalents at end of period	6,232	6,334
Marketable securities at end of period	102.681	73.463

Cash, cash equivalents and marketable securities at end of period	$ 108,913	$ 79,797

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 other serious and life threatening diseases. We conduct a small portion of our operations through two subsidiaries: Ingenex, Inc. and ProNeura, Inc. At September 30, 2001, we owned 81% of Ingenex (assuming the conversion of all preferred stock to common stock) and 79% of ProNeura. 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 complete financial statements. 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 nine-month period ended September 30, 2001 are not necessarily indicative of the results that may be expected for the year ending December 31, 2001.

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, 2000.

Revenue Recognition

Revenue under collaborative agreements is recorded when earned as defined under the terms of the respective agreements and collectibility is reasonably assured. Payments for our research and development efforts under contractual arrangements are recognized ratably over the period in which the related work is performed. Nonrefundable license fees, with respect to which we have no future performance obligations, are recognized upon receipt. Government grants, which support our research efforts in specific projects, generally provide for reimbursement of approved costs as defined in the grant documents. Grant revenues are recognized when subsidized project costs are incurred.

2. 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, 2001 and 2000, the effect of an additional 4,662,448 and 5,595,246 shares, respectively, related to our convertible preferred stock, options and warrants were not included in the computation of diluted earnings per share because they are anti-dilutive.

3. Comprehensive Income (Loss)

Comprehensive income (loss) is comprised of net income (loss) and other comprehensive income (loss). The only component of other comprehensive income (loss) is unrealized gains and losses from our marketable securities. Comprehensive loss for the three and nine months ended September 30, 2001 were $3.9 million and $9.4 million, respectively, and for the three and nine months ended September 30, 2000 were $8.4 million and $14.6 million, respectively.

4. Loan to Officer

In February 2001, we provided a loan to an officer. The loan bears a fixed interest rate of 8.50% per year and is due and payable in February 2002. As of September 30, 2001, the amount outstanding on the loan was $0.4 million.

5. Iloperidone Sublicense Agreement for the Japanese Market

In April 2001, we entered into an amendment to our agreement with Novartis Pharma AG for the development and commercialization of iloperidone in Japan. Iloperidone is a novel antipsychotic agent that is currently in a world-wide Phase III development program. This amendment expands upon Titan and Novartis' previously executed and ongoing agreement for worldwide development, manufacturing, and marketing of iloperidone outside Japan. Under the amendment, in exchange for rights to iloperidone in Japan, Titan received a $2.5 million license fee in May 2001, and will receive future payments contingent upon the achievement of certain regulatory milestones as well as royalties on product sales in Japan consistent with the previous agreement. We recognized the $2.5 million as license revenue as we have no further performance obligations under the original agreement or this amendment.

6. Stock Option Plans

In August 2001, we adopted the 2001 Employee Non-Qualified Stock Option Plan (the "2001 NQ Plan") pursuant to which 1,000,000 shares of common stock were reserved and authorized for issuance for option grants to employees and consultants who are neither officers nor directors of Titan. We issued options to purchase an aggregate of 338,310 shares of common stock under the 2001 NQ Plan to employees at an exercise price of $11.63 per share. In addition, in August 2001, we issued options under our 1998 Stock Option Plan to members of management and the Board of Directors.

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," "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. Additional factors include our ability to protect our patents and proprietary rights, ability to comply with extensive government regulations, and other factors and risks detailed under the caption "Risk Factors" in the Company's 2000 Annual Report on Form 10-K and other filings with the U.S. Securities and Exchange Commission. Stockholders and prospective investors in the Company should carefully consider these risk factors. The Company disclaims any obligation to update these statements for subsequent events.

Spheramine®, CeaVac®, TriAb®, TriGem®, Pivanex® and CCM™ 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 other serious and life threatening diseases. Our product development programs focus on large pharmaceutical markets with significant unmet medical needs and commercial potential. We currently have nine products in development, seven of which are in clinical development, with two products in late stage human trials for safety and efficacy, known as Phase III clinical trials. We have five products in preliminary trials for human safety and efficacy, known as Phase I/II and Phase II clinical trials. In addition to these programs, we have two products in preclinical development. We are independently developing our product candidates and also utilizing strategic partnerships, including collaborations with Novartis Pharma AG and Schering AG, as well as collaborations with several government-sponsored clinical cooperative groups. These collaborations help fund product development and enable us to retain significant economic interest in our products.

Our Clinical Development Programs

The following table sets forth our products in clinical development:

Product	Potential Indication(s)	Status	Marketing Rights
Iloperidone	Schizophrenia, psychosis	Phase III	Novartis Pharma AG
Spheramine	Parkinson's disease	Phase I/II	Schering AG
CeaVac	Colorectal, gastrointestinal and pancreatic cancer	Phase III (colorectal cancer)	Titan Pharmaceuticals
TriAb	Breast and ovarian cancer	Phase II (breast cancer)	Titan Pharmaceuticals
TriGem	Small cell lung cancer, melanoma	Phase II (melanoma)	Titan Pharmaceuticals
Bivalent	Metastatic breast, non-small cell lung , and colorectal cancer	Phase II	Titan Pharmaceuticals
Pivanex	Non-small cell lung cancer	Phase II	Titan Pharmaceuticals
Gallium Maltolate	Myeloma, prostate and bladder cancer, lymphoma, HIV	Phase II (prostate cancer and multiple myeloma)	Titan Pharmaceuticals

Results of Operations

Revenues for the third quarter of 2001 were approximately $0.5 million, compared to $0.7 million for the same quarter in 2000. For the first nine months of 2001, revenues were $4.0 million, compared to $1.3 million for the same nine-month period in 2000. The increase in revenue for the nine-month period was primarily due to a $2.5 million license fee received from Novartis Pharma AG for the development and commercialization of iloperidone in Japan, and higher SBIR grant revenues from the National Institutes of Health in support of the development of Spheramine, our novel treatment for Parkinson's disease.

Research and development expenses for the third quarter 2001 were $5.8 million, compared to $4.6 million for the same quarter in 2000. For the first nine months of 2001, research and development expenses were $16.1 million, compared to $11.9 million for the same nine-month period in 2000. (The figures for 2000 do not include a one-time $5.0 million charge related to the acquisition of worldwide rights to gallium maltolate in the third quarter). Excluding the one-time charge in 2000, the planned increase in research and development is associated with our ongoing randomized, placebo-controlled Phase III clinical study of CeaVac in Dukes D colorectal cancer, as well as expenses associated with ongoing clinical trials with TriAb and Gallium Maltolate. Research and development expenses are expected to continue to increase moderately in the future. The rate of increase depends on a number of factors including progress in preclinical programs and clinical trials.

General and administrative expenses for the third quarter 2001 were $1.3 million compared to $1.2 million for the same quarter in 2000. For the first nine months of 2001, general and administrative expenses were $4.1 million, compared to $2.8 million for the same nine-month period in 2000. The increase was in support of our expanded clinical and preclinical operations, organizational development and certain stock option related non-cash compensation charges.

Other income, net, for the third quarter 2001 was $1.8 million compared to $1.4 million for the same quarter in 2000. For the first nine months of 2001, other income, net, was $5.1 million compared to $3.6 million for the same nine-month period in 2000. The increase, primarily in interest income, was a result of our significantly larger cash and marketable securities position.

As a result of the foregoing, we had a net loss for the third quarter 2001 of $4.8 million, or $0.17 per share, compared to $8.7 million, or $0.34 per share, for the same quarter in 2000. For the first nine months of 2001, our net loss was $11.1 million, or $0.40 per share, compared to $14.8 million, or $0.59 per share, for the same nine-month period in 2000.

Liquidity and Capital Resources

We funded our operations since inception primarily through an initial public offering and private placements of our securities, as well as proceeds from warrant and option exercises, corporate licensing and collaborative agreements, and government sponsored research grants. At September 30, 2001, we had $108.9 million of cash, cash equivalents, and marketable securities.

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

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

Our operating activities used $11.0 million of cash in the first nine months of 2001 and $9.4 million in the first nine months of 2000. 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 $0.6 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 currently planned operations through 2005.

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, 2000, have not changed significantly.

PART II

Item 1. Legal Proceedings

There were no material changes to the proceeding disclosed in our Form 10-K for the period ended December 31, 2000.

Item 4. Submission of Matters to a Vote of Security Holders

On August 9, 2001, the Company held its Annual Meeting of Stockholders. Matters voted upon at the meeting and the number of affirmative votes, negative votes, withheld votes and abstentions cast with respect to each such matter were as follows:

	Affirmative Votes	Withheld Votes
1. Election of the Company's Directors:		
Louis R. Bucalo, M.D.	19,050,580	1,715,055
Ernst-Gunter Afting, M.D., Ph.D.	20,510,489	255,146
Victor J. Bauer, Ph.D.	19,010,480	1,755,155
Eurelio M. Cavalier	17,379,959	3,385,676
Michael K. Hsu	20,474,689	290,946
Hubert Huckel, M.D.	20,510,489	255,146
Ley S. Smith	19,213,882	1,551,753
Konrad M. Weis, Ph.D.	20,510,389	255,246

		Affirmative Votes	Against Votes	Abstentions
2.	Approval of the appointment of Ernst & Young LLP as independent auditors	20,494,812	268,909	1,914

As a result of the foregoing, each of the nominees was elected director of the Company until the next annual meeting of stockholders or until their successor was elected and qualified, and Ernst & Young LLP was appointed as the Company's independent auditors.

Item 6. **Exhibits and Reports on Form 8-K**

(b) Reports on Form 8-K

We filed a current report on Form 8-K with the Securities Exchange Commission on July 24, 2001 to announce Titan and Novartis Pharma AG's plan to conduct additional clinical trials to further strengthen the profile of iloperidone for the treatment of schizophrenia.

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 14, 2001

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

November 14, 2001

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