

TITAN PHARMACEUTICALS INC

Form 10-Q

November 15, 2010

[Table of Contents](#)

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, D.C. 20549**

**FORM 10-Q**

**x    Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**  
**For the quarterly period ended September 30, 2010.**

**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 000-27436**

**Titan Pharmaceuticals, Inc.**

**(Exact name of registrant as specified in its charter)**

Edgar Filing: TITAN PHARMACEUTICALS INC - Form 10-Q

**Delaware**  
(State or Other Jurisdiction of

**94-3171940**  
(I.R.S. Employer

**Incorporation or Organization)**

**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 has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). \* Yes ☐ No ☐

\* The registrant has not yet been phased into the interactive data requirements.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐

Accelerated filer ☐

Non-accelerated filer ☐ (Do not check if a smaller reporting company)

Smaller reporting company ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

There were 59,247,742 shares of the Registrant's Common Stock issued and outstanding on November 12, 2010.

**Table of Contents**

**Titan Pharmaceuticals, Inc.**

**Index to Form 10-Q**

**Part I. Financial Information**

Item 1.	<u>Financial Statements and notes (unaudited)</u>	3
	<u>Condensed Consolidated Balance Sheets as of September 30, 2010 and December 31, 2009</u>	3
	<u>Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2010 and 2009</u>	4
	<u>Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2010 and 2009</u>	5
	<u>Notes to Condensed Consolidated Financial Statements</u>	6
Item 2.	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	11
Item 3.	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	14
Item 4T.	<u>Controls and Procedures</u>	14

**Part II. Other Information**

Item 1A.	<u>Risk Factors</u>	15
Item 5.	<u>Exhibits</u>	16
	<b><u>SIGNATURES</u></b>	17

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

	<b>September 30, 2010 (unaudited)</b>	<b>December 31, 2009 (Note 1)</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 6,401	\$ 3,300
Accounts receivable	1,904	66
Prepaid expenses and other current assets	181	250
Total current assets	8,486	3,616
Property and equipment, net	61	110
Total assets	\$ 8,547	\$ 3,726
<b>Liabilities and Stockholders' Deficit</b>		
Current liabilities		
Accounts payable	\$ 1,730	\$ 335
Accrued clinical trials expenses	1,080	123
Other accrued liabilities	382	564
Current portion of long-term debt	1,394	525
Total current liabilities	4,586	1,547
Long-term debt, net of discount	6,113	2,386
Total liabilities	10,699	3,933
Commitments and contingencies		
Stockholders' deficit		
Common stock, at amounts paid-in	256,436	256,436
Additional paid-in capital	15,617	15,027
Accumulated deficit	(275,446)	(272,911)
Total stockholders' deficit attributable to the controlling interest	(3,393)	(1,448)
Non-controlling interest	1,241	1,241
Total stockholders' deficit	(2,152)	(207)
Total liabilities and stockholders' deficit	\$ 8,547	\$ 3,726

See Notes to Condensed Consolidated Financial Statements

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

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2010</b>	<b>2009</b>	<b>2010</b>	<b>2009</b>
Revenue				
Grant revenue	\$ 3,203	\$	\$ 5,251	\$
Royalty revenue	396		2,104	
License revenue	1		12	52
Total revenue	3,600		7,367	52
Operating expenses:				
Research and development	3,044	709	6,770	1,741
General and administrative	691	876	2,638	2,723
Total operating expenses	3,735	1,585	9,408	4,464
Loss from operations	(135)	(1,585)	(2,041)	(4,412)
Other income (expense):				
Interest income (expense), net	(124)		(364)	2
Other expense	(125)	(8)	(130)	(8)
Other expense, net	(249)	(8)	(494)	(6)
Net loss	(384)	(1,593)	(2,535)	(4,418)
Less: net loss attributable to the non-controlling interests				
Net loss attributable to the controlling interest	\$ (384)	\$ (1,593)	\$ (2,535)	\$ (4,418)
Basic and diluted net loss per share	\$ (0.01)	\$ (0.03)	\$ (0.04)	\$ (0.08)
Weighted average shares used in computing basic and diluted net loss per share	59,248	58,297	59,248	58,291

See Notes to Condensed Consolidated Financial Statements

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

	<b>Nine Months Ended September 30,</b>	
	<b>2010</b>	<b>2009</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (2,535)	\$ (4,418)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	69	136
Amortization of loan discount	22	
Loss on disposal of assets		3
Gain on sale of investments		(9)
Share-based compensation	336	1,233
Changes in operating assets and liabilities:		
Accounts receivable	(1,838)	(141)
Prepaid expenses and other assets	69	337
Accounts payable and other accrued liabilities	2,170	(1,565)
<b>Net cash used in operating activities</b>	<b>(1,707)</b>	<b>(4,424)</b>
<b>Cash flows from investing activities:</b>		
Purchases of furniture and equipment	(20)	(10)
Disposals of furniture and equipment		2
Proceeds from maturities of marketable securities		9
<b>Net cash provided by (used in) investing activities</b>	<b>(20)</b>	<b>1</b>
<b>Cash flows from financing activities:</b>		
Issuance of common stock, net		476
Proceeds from long-term debt	5,000	
Payments on long-term debt	(172)	
<b>Net cash provided by financing activities</b>	<b>4,828</b>	<b>476</b>
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>3,101</b>	<b>(3,947)</b>
Cash and cash equivalents at beginning of period	3,300	4,672
<b>Cash and cash equivalents at end of period</b>	<b>\$ 6,401</b>	<b>\$ 725</b>

See Notes to Condensed Consolidated Financial Statements

**Table of Contents**

**TITAN PHARMACEUTICALS, INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**(unaudited)**

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

We are a biopharmaceutical company developing proprietary therapeutics primarily for the treatment of central nervous system ( CNS ) disorders. We currently have two key assets:

(1) Fanapt® (iloperidone), an atypical antipsychotic compound approved in the U.S. for the treatment of schizophrenia and being marketed in the U.S. by Novartis Pharma AG. We are entitled to a royalty of 8-10% on U.S. net sales of Fanapt.

(2) Probuphine , a slow release implant formulation of buprenorphine that is capable of maintaining a stable, round the clock blood level of the medicine in patients for six months following a single treatment. Probuphine is in Phase 3 clinical development for the treatment of opioid addiction, and we are currently conducting a confirmatory Phase 3 clinical study, which is expected to be completed in early second quarter 2011 with study results available by mid second quarter 2011.

The ProNeura drug delivery technology underlying Probuphine has the potential to be used in developing products for the treatment of other chronic conditions where maintaining stable, round the clock blood levels of a drug can benefit the patient and improve medical outcomes (e.g. chronic pain, Parkinson's disease).

We are directly developing our product candidates and also utilize resources provided through partnerships with other companies and government organizations. These collaborations have helped to fund product development and have enabled us to retain significant economic interest in our products. We operate in only one business segment, the development of pharmaceutical products.

***Basis of Presentation***

The accompanying unaudited condensed consolidated financial statements include the accounts of Titan Pharmaceuticals, Inc. and its subsidiaries after elimination of all significant intercompany accounts and transactions. These financial statements have been prepared in accordance with U.S. generally accepted accounting principles 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 U.S. 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, 2010 are not necessarily indicative of the results that may be expected for the year ending December 31, 2010, or any future interim periods.

The balance sheet at December 31, 2009 has been derived from the audited financial statements at that date, but does not include all of the information and footnotes required by United States generally accepted accounting principles for complete financial statements. These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and footnotes thereto for the year ended December 31, 2009 included in the Titan Pharmaceuticals, Inc. Registration Statement on Form 10/A, as filed with the Securities and Exchange Commission ( SEC ).

The preparation of financial statements in conformity with U.S. generally accepted accounting principles 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.

We have evaluated events that have occurred after September 30, 2010 and through the date that the unaudited financial statements were issued.

We expect to continue to incur substantial additional operating losses from costs related to the continuation of product and technology development, clinical trials, and administrative activities. We believe that our working capital at September 30, 2010, together with proceeds available from the two grants which were awarded by the National Institutes of Health ( NIH ) and the ongoing royalty revenues from sales of



## Edgar Filing: TITAN PHARMACEUTICALS INC - Form 10-Q

Fanapt will be sufficient to support the ongoing Phase 3 clinical study of Probuphine and operations into the second quarter of 2011.

We may need to seek additional financing sources to fund our product development activities, and will be required to obtain substantial funding to commercialize any products other than Fanapt that we may successfully develop. If we are unable to complete a debt or equity offering, or otherwise obtain sufficient financing when and if needed, we may be required to reduce, defer or discontinue one or more of our product development programs.

**Table of Contents**

**TITAN PHARMACEUTICALS, INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(unaudited)**

*Controlling interest in Subsidiary*

At September 30, 2010, we owned 81% of Ingenex (assuming the conversion of all preferred stock to common stock). Ingenex is not an operating company and has no assets, and it is expected that it will be dissolved by year end 2010.

***Revenue Recognition***

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

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

Collaborative arrangements typically consist of non-refundable and/or exclusive technology access fees, cost reimbursements for specific research and development spending, and various milestone and future product royalty payments. If the delivered technology does not have stand-alone value or if we do not have objective or reliable evidence of the fair value of the undelivered component, the amount of revenue allocable to the delivered technology is deferred. Non-refundable upfront fees with stand-alone value that are not dependent on future performance under these agreements are recognized as revenue when received, and are deferred if we have continuing performance obligations and have no evidence of fair value of those obligations. Cost reimbursements for research and development spending are recognized when the related costs are incurred and when collections are reasonably expected. 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 a milestone is reached.

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

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

Royalties earned are based on third-party sales of licensed products and are recorded in accordance with contract terms when third-party results are reliably measurable and collectibility is reasonably assured. Pursuant to certain license agreements, we earn royalties on the sale of Fanapt by Novartis Pharma AG in the U.S. and Canada, and by Vanda Pharmaceuticals, Inc. in the rest of the

## Edgar Filing: TITAN PHARMACEUTICALS INC - Form 10-Q

world. As described in Note 5, Commitments and Contingencies, we are obligated to pay royalties on such sales to Sanofi-Aventis. As we have no performance obligations under the license agreements, we have recorded the royalties earned, net of royalties we are obligated to pay, as revenue in our consolidated statement of operations commencing with the nine month period ended September 30, 2010.

### ***Research and Development Costs and Related Accrual***

Research and development expenses include internal and external costs. Internal costs include salaries and employment related expenses, facility costs, administrative expenses and allocations of corporate costs. External expenses consist primarily of costs associated with outsourced clinical research organization activities, sponsored research studies, process development and product manufacturing expenses, product registration, patent application and prosecution, and investigator sponsored trials. We also record accruals for estimated ongoing clinical trial costs. Clinical trial costs represent costs incurred by clinical research organizations, ( CROs ), and clinical sites. These costs are recorded as a component of research and development expenses. Under our agreements, progress payments are typically made to investigators, clinical sites and CROs. We analyze the progress of the clinical trials, including levels of patient enrollment, invoices received and contracted costs when evaluating the adequacy of accrued liabilities. Significant judgments and estimates must be made and used in determining the accrued balance in any accounting period. Actual results could differ from those estimates under different assumptions. Revisions are charged to expense in the period in which the facts that give rise to the revision become known.

**Table of Contents****TITAN PHARMACEUTICALS, INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(unaudited)*****Recent Accounting Pronouncements***

In April 2010, the Financial Accounting Standards Board ( FASB ) issued Accounting Standards Update No. 2010-17 ( ASU 2010-17 ), *Revenue Recognition - Milestone Method*, which provides a new guidance on the use of the milestone method of recognizing revenue for research and development arrangements under which consideration to be received by the vendor is contingent upon the achievement of certain milestones. ASU 2010-17 is effective for fiscal years, and interim periods within such fiscal years, beginning on or after June 15, 2010, with early adoption permitted. We are currently evaluating the potential impact, if any, of the adoption of this guidance on our financial position, results of operations and cash flows.

In February 2010, the FASB issued Accounting Standards Update No. 2010-09 ( ASU 2010-09 ), *Subsequent Events, Amendments to Certain Recognition and Disclosure Requirements*, which clarifies certain existing evaluation and disclosure requirements in ASC 855 related to subsequent events. ASU 2010-09 requires SEC filers to evaluate subsequent events through the date on which the financial statements are issued and is effective immediately. The new guidance did not have an effect on our consolidated results of operations and financial condition.

In January 2010, the FASB issued Accounting Standards Update No. 2010-06 ( ASU 2010-06 ), which amends the use of fair value measures and the related disclosures. ASU 2010-06 requires new disclosures for transfers in and out of Level 1 and Level 2 fair value measurements. ASU 2010-06 is effective for the quarter ended September 30, 2010. The adoption of this new standard did not have an impact on our consolidated financial statements.

In October 2009, the FASB issued Accounting Standards Update No. 2009-13 ( ASU 2009-13 ), *Multiple-Deliverable Revenue Arrangements*, which eliminates the residual method of allocation, and instead requires companies to use the relative selling price method when allocating revenue in a multiple deliverable arrangement. ASU 2009-13 shall be effective in fiscal years beginning on or after June 15, 2010, with earlier application permitted. While we do not expect the adoption of this standard to have a material impact on our financial position or results of operations, this standard may have an impact in the event we enter into future collaborative or multiple-deliverable transactions or modify existing collaborative relationships.

**2. Stock Option Plans**

The following table summarizes the share-based compensation expense recorded for awards under the stock option plans for the three and nine month periods ended September 30, 2010 and 2009:

(in thousands, except per share amounts)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Research and development	\$ 45	\$ 126	\$ 15	\$ 164
General and administrative	80	160	321	1,069
Total share-based compensation expenses	\$ 125	\$ 286	\$ 336	\$ 1,233
Increase in basic and diluted net loss per share	\$ (0.00)	\$ (0.01)	\$ (0.01)	\$ (0.02)

No tax benefit was recognized related to share-based compensation expense since we have incurred operating losses and we have established a full valuation allowance to offset all the potential tax benefits associated with our deferred tax assets.

## Edgar Filing: TITAN PHARMACEUTICALS INC - Form 10-Q

We use the Black-Scholes-Merton option-pricing model with the following assumptions to estimate the share-based compensation expense for the three and nine month periods ended September 30, 2010 and 2009:

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2010</b>	<b>2009</b>	<b>2010</b>	<b>2009</b>
Weighted-average risk-free interest rate	0.83%	0.35%	2.3%	0.4%
Expected dividend payments				
Expected holding period (years) <sup>1</sup>	4.0	4.4	4.2	4.6
Weighted-average volatility factor <sup>2</sup>	1.93	1.84	1.89	1.84
Estimated forfeiture rates for options granted to management <sup>3</sup>	23%	21%	23%	21%
Estimated forfeiture rates for options granted to non-management <sup>3</sup>	41%	42%	41%	41%

- (1) Expected holding periods are based on historical data.
- (2) Weighted average volatility is based on the historical volatility of the Company's common stock.
- (3) Estimated forfeiture rates are based on historical data.

**Table of Contents****TITAN PHARMACEUTICALS, INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(unaudited)**

No options to purchase common stock were granted during the three month period ended September 30, 2010. Based upon the above methodology, the weighted-average fair value of options valued during the three month period ended September 30, 2009 was \$0.98.

The following table summarizes option activity for the nine month period ended September 30, 2010:

<b>(in thousands, except per share amounts)</b>	<b>Options</b>	<b>Weighted Average Exercise Price</b>	<b>Weighted Average Remaining Option Term</b>	<b>Aggregate Intrinsic Value</b>
Outstanding at January 1, 2010	6,070	\$ 3.68	6.42	\$ 4,794
Granted	150	2.36		
Exercised				
Expired or forfeited	(1,231)	9.19		
Outstanding at September 30, 2010	4,989	\$ 2.28	6.31	\$ 528
Exercisable at September 30, 2010	3,523	\$ 2.79	5.32	\$ 304

As of September 30, 2010 there was approximately \$0.9 million of total unrecognized compensation expense related to non-vested stock options. This expense is expected to be recognized over a weighted-average period of 2.7 years.

During the three months ended September 30, 2010, 82,800 shares of restricted stock were awarded. The following table summarizes restricted stock activity for the nine month period ended September 30, 2010:

<b>(in thousands, except per share amounts)</b>	<b>Shares</b>	<b>Weighted Average Fair Value</b>	<b>Weighted Average Remaining Contractual Term</b>	<b>Aggregate Intrinsic Value</b>
Outstanding at January 1, 2010	20	\$ 0.04	9.3	\$ 45
Awarded	119			
Exercised				
Cancelled				
Outstanding at September 30, 2010	139	\$ 0.01	9.5	\$ 141
Vested at September 30, 2010	96	\$ 0.01	9.5	\$ 97

As of September 30, 2010 there was approximately \$41,000 of total unrecognized compensation expense related to non-vested awards. This expense is expected to be recognized over a weighted-average period of 0.3 years.

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

We calculate basic net loss per share using the weighted average common shares outstanding for the periods presented. Diluted net income per share would include the impact of other dilutive equity instruments, primarily our options and warrants. For the periods ended September 30, 2010 and 2009, options and warrants totaled 11.8 million and 13.5 million shares, respectively. We reported net losses for the periods presented and, therefore, options and warrants were excluded from the calculation of diluted net loss per share as they were anti-dilutive.

### **4. Comprehensive Loss**

Comprehensive loss is comprised of net loss and other comprehensive income or loss. There were no components of other comprehensive income or loss during the three and nine month periods ended September 30, 2010 and 2009. Comprehensive losses for the three and nine month periods ended September 30, 2010 were \$0.4 million and \$2.5 million, respectively, and for the three and nine month periods ended September 30, 2009 were \$1.6 million and \$4.4 million, respectively.

**Table of Contents**

**TITAN PHARMACEUTICALS, INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(unaudited)**

**5. Commitments and Contingencies**

***Legal Proceedings***

In March 2005, Dr. Bernard Sabel initiated an appraisal proceeding in the Court of Chancery of the State of Delaware relating to the merger of our subsidiary ProNeura, Inc. into Titan. The complaint indicated that Mr. Sabel wanted the court to appraise the value of the 108,800 shares of the common stock of ProNeura owned by him. The complaint did not specify an amount that Mr. Sabel considered the fair value of the shares. In March 2009, we settled our dispute with Dr. Sabel related to the merger of our subsidiary ProNeura, Inc. into Titan. In April 2009, under the terms of the settlement, we paid \$600,000 to Dr. Sabel.

***Financing Agreements***

In September 2010, we amended our loan and security agreement with Oxford Capital Financing ( Oxford ) pursuant to which we received a thirty-nine month term loan in the principal amount of \$5,000,000 that bears interest at the rate of 13% per annum. We paid Oxford an initial facility fee of \$125,000 and are obligated to make a final payment fee of \$300,000. Commencing in October 2010, the loan is repayable in monthly interest payments of \$54,167 through July 2011 followed by monthly interest and principal installments of \$196,108 commencing in August 2011 through January 2014. The loan is secured by our assets and has a provision for pre-payment. We also issued to Oxford, in connection with the loan and security agreement, five-year warrants to purchase 287,356 shares of our common stock at an exercise price of \$0.87 per share. The relative fair value attributable to the warrants of \$254,580 was recorded as a discount to the debt and corresponding credit to additional paid-in capital. The debt discount is being amortized to interest expense over the life of the debt.

In December 2009, we entered into a loan and security agreement with Oxford pursuant to which we received a three-year term loan in the principal amount of \$3,000,000 that bears interest at the rate of 13% per annum. We paid Oxford an initial facility fee of \$60,000 and are obligated to make a final payment fee of \$180,000. Commencing in January 2010, the loan is repayable in monthly interest payments of \$32,500 through June 2010 followed by monthly interest and principal installments of \$117,625 commencing in July 2010 through December 2012. The loan is secured by our assets and has a provision for pre-payment. We also issued to Oxford, in connection with the loan and security agreement, five-year warrants to purchase 42,254 shares of our common stock at an exercise price of \$2.13 per share. The relative fair value attributable to the warrants of \$88,995 was recorded as a discount to the debt and corresponding credit to additional paid-in capital. The debt discount is being amortized to interest expense over the life of the debt.

***Royalty Payments***

In 1997, we entered into an exclusive license agreement with Sanofi-Aventis SA (formerly Hoechst Marion Roussel, Inc.). The agreement gave us a worldwide license to the patent rights and know-how related to the antipsychotic agent Fanapt (iloperidone), including the ability to develop, use, sublicense, manufacture and sell products and processes claimed in the patent rights. Upon commercialization of the product, the license agreement provides that we will pay royalties based on net sales. Net sales of Fanapt by Novartis during the three month period ended September 30, 2010 were approximately \$4.9 million and we are obligated to pay royalties of approximately \$741,000 to Sanofi-Aventis which was included in Accounts Receivable and Accounts Payable on the September 30, 2010 balance sheet.

**6. Stockholders' Equity**

In December 2009, we completed the sale of 300,000 shares of our common stock to an institutional investor for gross proceeds of approximately \$510,000. Net proceeds were approximately \$478,000.



## Edgar Filing: TITAN PHARMACEUTICALS INC - Form 10-Q

In September and October 2009, members of our board of directors exercised options to purchase 659,862 shares of our common stock at prices ranging from \$0.79 to \$1.40 per share. Net proceeds were approximately \$555,000.

**Table of Contents****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 research and development efforts, the results of pre-clinical and clinical testing, the effect of regulation by the United States Food and Drug Administration (FDA) and other agencies, the impact of competitive products, product development, commercialization and technological difficulties, our ability to obtain additional financing, the effect of our accounting policies, and other risks detailed in our SEC filings.*

*Probuphine and ProNeura are trademarks of Titan Pharmaceuticals, Inc. This Form 10-Q also includes trade names and trademarks of companies other than Titan Pharmaceuticals, Inc.*

*References herein to we, us, Titan, and our company refer to Titan Pharmaceuticals, Inc. and its subsidiaries unless the context otherwise requires.*

**Overview**

We are a biopharmaceutical company developing proprietary therapeutics primarily for the treatment of central nervous system ( CNS ) disorders. We currently have two key assets as described below:

*Fanapt (iloperidone):* An atypical antipsychotic approved by the U.S. Food and Drug Administration ( FDA ) for the treatment of schizophrenia. Novartis Pharma AG ( Novartis ) has acquired the U.S. and Canadian rights to further develop and commercialize the approved oral formulation, which it launched in the U.S. in January 2010, and also further develop and potentially commercialize an injectable form of the drug, known as a depot formulation. We are entitled to a royalty of 8-10% of net sales based on intellectual property claiming iloperidone that we licensed from Sanofi-Aventis. In the U.S. the license covers all formulations of iloperidone through November 2016 (inclusive of a patent extension under the Patent Restoration Act), with a possible additional six month extension for development of pediatric indications. Vanda Pharmaceuticals, Inc. ( Vanda ) has the development and commercialization rights to the oral and depot formulations of this product for the rest of the world. Because patent coverage on the compound has now expired in most significant markets outside the U.S. and no patent term extensions are possible since the product was not approved in these countries prior to patent expiration, our royalties on any future sales in such markets will generally be limited. We will review the potential of any royalty revenue on a country by country basis at the time of application for approval of the product. Following is a list of the remaining countries where the Sanofi-Aventis patents claiming the compound iloperidone still provide patent protection:

Portugal	September 2011
Lichtenstein	November 2012
Georgia	November 2012
Korea	July 2013
Philippines	May 2014

*Probuphine:* A slow release implant formulation of buprenorphine in Phase 3 clinical development for the treatment of opioid addiction that is capable of maintaining a round the clock stable blood level of the drug in patients for six months following a single treatment. We have previously announced positive safety and efficacy results of this product in Phase 3 studies including a placebo controlled Phase 3 study. In October 2009 we were awarded a \$7.6 million grant from the National Institutes of Health ( NIH ) that will partially fund the second Phase 3 controlled safety and efficacy study required by the FDA for product registration. We have recently provided an update on the confirmatory Phase 3 study with full patient enrollment at 20 U.S. sites completed in September 2010, almost three months ahead of schedule, and study results are expected by mid second quarter 2011.

The ProNeura long-term drug delivery technology underlying Probuphine has the potential to be used in developing products for the treatment of other chronic conditions where maintaining stable, round the clock blood levels of a drug can benefit the patient and improve medical outcomes. We were recently awarded a \$0.5 million grant by the NIH under the Small Business Innovation Research (SBIR) program to conduct

## Edgar Filing: TITAN PHARMACEUTICALS INC - Form 10-Q

non-clinical studies in a model of Parkinson's disease using previously approved dopamine agonists and the ProNeura drug delivery technology. The first non-clinical study has just started and will provide data on the release characteristics of the product. We have also licensed certain rights from the University of Iowa to potentially use gallium maltolate for the treatment of chronic bacterial infections.

### ***Our Products***

Fanapt was approved by the FDA in May 2009 for the treatment of schizophrenia and Novartis has acquired the rights to commercialize it in the U.S. and Canada. Novartis announced that it commenced commercial launch of Fanapt in mid January 2010 and has reported net sales of approximately \$26.3 million through September 30, 2010.

## **Table of Contents**

Probuphine is currently in Phase 3 clinical development and has demonstrated safety and efficacy in three Phase 3 studies, including one controlled Phase 3 study. However, additional clinical and manufacturing development is necessary prior to registration and it may still not be successfully developed or commercialized. Titan has been awarded a \$7.6 million grant by the NIH in partial support of the second controlled Phase 3 study, the total external cost of which is estimated at approximately \$14.6 million. We will also require significant further capital, currently estimated at approximately \$3.9 million, to support third party expenses related to manufacturing development and testing, and possibly an addition \$6.0 million for a long term safety study (one year treatment) prior to commercialization without giving effect to the cost of additional clinical studies, if any, that may be required by the FDA. We may experience unanticipated problems relating to product development and cannot predict whether we will successfully develop and commercialize any products.

Titan was recently awarded an SBIR grant supporting the development of a long-term, non-fluctuating dopamine agonist treatment for Parkinson's disease. The first year award in the amount of \$300,000 will be available to Titan starting August 1, 2010, and an additional \$195,000 for the second year starting August 1, 2011 has been recommended subject to availability of funds and satisfactory progress of the project. The grant will be administered by the National Institute of Neurological Disorders and Stroke (NINDS).

### ***Results of Operations for the Three and Nine Months Ended September 30, 2010 and September 30, 2009***

Our net loss for the three month period ended September 30, 2010 was approximately \$0.4 million, or approximately \$0.01 per share, compared to our net loss of approximately \$1.6 million, or approximately \$0.03 per share, for the comparable period in 2009. Our net loss for the nine month period ended September 30, 2010 was approximately \$2.5 million, or approximately \$0.04 per share, compared to our net loss of approximately \$4.4 million, or approximately \$0.08 per share, for the comparable period in 2009.

We generated royalty revenues during the three and nine month periods ended September 30, 2010 of approximately \$0.4 million and \$2.1 million, respectively. We had no royalty revenue during the comparable periods in 2009. We generated grant revenues during the three and nine month periods ended September 30, 2010 of approximately \$3.2 million and \$5.3 million, respectively. We had no grant revenue during the comparable periods in 2009. We generated revenues of \$1,000 from licensing agreements during the three month period ended September 30, 2010 and approximately \$12,000 during the nine month period ended September 30, 2010. We generated no revenues from licensing agreements during the three month period ended September 30, 2009 and approximately \$52,000 during the nine month period ended September 30, 2009. Royalty revenues during the three and nine month periods ended September 30, 2010 consisted of royalties on sales of Fanapt. Grant revenues during the three and nine month periods ended September 30, 2010 consisted of proceeds from the NIH grant related to our Probuphine program.

Research and development expenses for the three month period ended September 30, 2010 were approximately \$3.0 million, compared to approximately \$0.7 million for the comparable period in 2009, an increase of approximately \$2.3 million, or 329%. Research and development expenses for the nine month period ended September 30, 2010 were approximately \$6.8 million, compared to approximately \$1.7 million for the comparable period in 2009, an increase of \$5.1 million, or 300%. The increase in research and development costs during the three and nine month periods ended September 30, 2010 was primarily associated with an increase in external research and development expenses associated with the initiation and ongoing expenses of the Phase 3 clinical trials related to our Probuphine product. External research and development expenses include direct expenses such as clinical research organization charges, investigator and review board fees, patient expense reimbursements and contract manufacturing expenses. During the three and nine month periods ended September 30, 2010, external research and development expenses relating to our Probuphine product development program were approximately \$2.5 million and \$5.1 million, respectively. Other research and development expenses include internal operating costs such as clinical research and development personnel-related expenses, clinical trials related travel expenses, and allocation of facility and corporate costs. As a result of the risks and uncertainties inherently associated with pharmaceutical research and development activities described elsewhere in this report, we are unable to estimate the specific timing and future costs of our clinical development programs or the timing of material cash inflows, if any, from our product candidates.

General and administrative expenses for the three month period ended September 30, 2010 were approximately \$0.7 million, compared to approximately \$0.9 million for the comparable period in 2009, a decrease of approximately \$0.2 million, or 22%. General and administrative expenses for the nine month period ended September 30, 2010 were approximately \$2.6 million, compared to approximately \$2.7 million for the comparable period in 2009, a decrease of \$0.1 million, or 4%. The decrease in general and administrative expenses during the three month period ended September 30, 2010 was primarily related to decreases in non-cash stock compensation costs of approximately \$0.1 million, consulting and professional fees of approximately \$0.1 million and facilities and other administrative costs of approximately \$0.1 million. This was offset in part by increases in legal fees of approximately \$0.1 million. The decrease in general and administrative expenses during the nine month period ended September 30, 2010 was primarily related to decreases in non-cash stock compensation costs of approximately \$0.7 million, facilities and other administrative costs of approximately \$0.3 million and depreciation expenses of approximately \$0.1 million. This was offset in part by increases in legal fees of approximately \$0.5 million and consulting and professional fees of approximately \$0.5 million.

## Edgar Filing: TITAN PHARMACEUTICALS INC - Form 10-Q

Net other expense for the three month period ended September 30, 2010 was approximately \$249,000, compared to approximately \$8,000 in the comparable period in 2009. Net other expense for the nine month period ended September 30, 2010 was approximately \$494,000, compared to approximately \$6,000 in the comparable period in 2009. The increase in net other expense during the three months ended September 30, 2010, was primarily related to interest expense of approximately \$139,000 and loan fees of approximately \$125,000 resulting from our loans with Oxford. The increase in net other expense during the nine months ended September 30, 2010, was primarily related to interest expense of approximately \$379,000 and loan fees of approximately \$125,000 resulting from our loans with Oxford.

## **Table of Contents**

### ***Liquidity and Capital Resources***

We have funded our operations since inception primarily through sales of our securities, as well as with proceeds from warrant and option exercises, corporate licensing and collaborative agreements, government-sponsored research grants, royalties on sales of Fanapt and term loans. At September 30, 2010, we had approximately \$6.4 million of cash and cash equivalents compared to approximately \$3.3 million at December 31, 2009.

Our operating activities used approximately \$1.7 million during the nine months ended September 30, 2010. This consisted primarily of the net loss for the period of approximately \$2.5 million and \$1.8 million related to increases in accounts receivable, which includes approximately \$0.7 million which will have to be paid to Sanofi-Aventis for royalties earned on sales of Fanapt. This was offset in part by non-cash charges of approximately \$0.3 million related to share-based compensation expenses, approximately \$2.2 million related to increases in accounts payable and other accrued liabilities and approximately \$0.1 million related to net changes in other operating assets and liabilities. Uses of cash in operating activities were primarily to fund product development programs and administrative expenses. Our license agreements with Sanofi-Aventis and Massachusetts Institute of Technology require us to pay royalties on future product sales. In addition, in order to maintain license and other rights while products are under development, we must comply with customary licensee obligations, including the payment of patent-related costs, annual minimum license fees, meeting project-funding milestones and diligent efforts in product development. The aggregate commitments we have under these agreements, including minimum license payments, for the next 12 months is approximately \$100,000.

Net cash used by investing activities of approximately \$20,000 during the nine months ended September 30, 2010 consisted of purchases of office equipment.

Net cash provided by financing activities of approximately \$4.8 million during the nine month period ended September 30, 2010 consisted of proceeds from a new term loan of approximately \$5.0 million offset by payments on our existing term loan of approximately \$172,000.

In December 2009, we entered into a financing agreement with Oxford pursuant to which we received a three-year term loan in the principal amount of \$3.0 million that bears interest at the rate of 13% per annum. Under this agreement, we will make payments totaling approximately \$1.4 million during the next 12 months. We are obligated to make a final payment fee of \$180,000. The loan is secured by our assets and has a provision for pre-payment.

In September 2010, we amended our loan and security agreement with Oxford pursuant to which we received an additional thirty-nine month term loan in the principal amount of \$5.0 million that bears interest at the rate of 13% per annum. Under this agreement, we will make payments totaling approximately \$0.9 million during the next 12 months. We are obligated to make a final payment fee of \$300,000. The loan is secured by our assets and has a provision for pre-payment.

We expect to continue to incur substantial additional operating losses from costs related to the continuation of product and technology development, clinical trials, and administrative activities. We believe that our working capital at September 30, 2010, together with proceeds available from the two grants which were awarded by the National Institutes of Health ( NIH ) and the ongoing royalty revenues from sales of Fanapt will be sufficient to support the ongoing Phase 3 clinical study of Probuphine and operations into the second quarter of 2011.

We may need to seek additional financing sources to fund our product development activities, and will be required to obtain substantial funding to commercialize any products other than Fanapt that we may successfully develop. If we are unable to complete a debt or equity offering, or otherwise obtain sufficient financing when and if needed, we may be required to reduce, defer or discontinue one or more of our product development programs.

**Table of Contents**

**Item 3. Quantitative and Qualitative Disclosures About Market Risk**

This information has been omitted based on our status as a smaller reporting company.

**Item 4T. Controls and Procedures**

***Disclosure Controls and Procedures***

Our President, being our principal executive and financial officer, has evaluated the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934 as of September 30, 2010, the end of the period covered by this report, and has concluded that our disclosure controls and procedures were effective to ensure that the information required to be disclosed by us in reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC, and that such information is accumulated and communicated to our principal executive and principal financial officer as appropriate to allow timely decisions regarding required disclosure.

***Changes in Internal Control Over Financial Reporting***

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934) during the three months ended September 30, 2010 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

**Table of Contents**

**PART II**

**Item 1A. Risk Factors**

This information has been omitted based on our status as a smaller reporting company.



**Table of Contents**

**Item 5. Exhibits**

<b>No.</b>	<b>Description</b>
3.1	Amended and Restated Certificate of Incorporation of the Registrant, as amended <sup>9</sup>
3.2	By-laws of the Registrant <sup>1</sup>
4.1	Registration Rights Agreement dated as of December 17, 2007 <sup>2</sup>
4.2	Registration Rights Agreement dated as of December 8, 2009 <sup>9</sup>
4.3	Warrant to Purchase Common Stock dated December 23, 2009 issued to Oxford Finance Corporation <sup>9</sup>
4.4	Warrant to Purchase Common Stock dated September 27, 2010 issued to Oxford Finance Corporation
10.1	1998 Stock Option Plan <sup>3</sup>
10.2	2001 Non-Qualified Employee Stock Option Plan <sup>4</sup>
10.3	2002 Stock Option Plan <sup>5</sup>
10.4	Employment Agreement between the Registrant and Sunil Bhonsle, dated May 16, 2009, as amended by agreement dated February 17, 2010 <sup>9</sup>
10.5	Employment Agreement between the Registrant and Marc Rubin, dated May 16, 2009, as amended by agreement dated February 17, 2010 <sup>9</sup>
10.6	Lease for the Registrant's facilities, amended as of October 1, 200 <del>4</del>
10.7	Amendments to lease for Registrant's facilities dated May 21, 2007 and March 12, 200 <del>9</del>
10.9*	License Agreement between the Registrant and Sanofi-Aventis SA effective as of December 31, 1996 <sup>7</sup>
10.10*	Sublicense Agreement between the Registrant and Novartis Pharma AG dated November 20, 1997 <sup>8</sup>
10.11*	License Agreement between the Registrant and the Massachusetts Institute of Technology dated September 28, 1995 <sup>1</sup>
10.12	Loan and Security Agreement between the Registrant and Oxford Finance Corporation dated December 18, 2009 <sup>9</sup>
10.13	Stock Purchase Agreement between the Registrant and certain investors dated December 8, 2009 <sup>9</sup>
10.14	Amendment to Employment Agreement dated June 15, 2010 between the Registrant and Marc Rubin <sup>11</sup>
10.15	Amendment to Employment Agreement dated June 15, 2010 between the Registrant and Sunil Bhonsle <sup>11</sup>
10.16	Amendment to lease for Registrant's facilities dated June 15, 201 <del>0</del>
10.17	Amended and Restated Loan and Security Agreement between the Registrant and Oxford Finance Corporation dated September 27, 2010
14.1	Code of Business Conduct and Ethics <sup>10</sup>
31.1	Certification of the Principal Executive and Financial Officer pursuant to Rule 13(a)-14(a) of the Securities Exchange of 1934
32.1	Certificate of the Principal Executive and Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

- (1) Incorporated by reference from the Registrant's Registration Statement on Form SB-2 (File No. 33-99386).  
(2) Incorporated by reference from the Registrant's Current Report on Form 8-K dated December 27, 2007.  
(3) Incorporated by reference from the Registrant's definitive Proxy Statement filed on July 28, 2000.  
(4) Incorporated by reference from the Registrant's Annual Report on Form 10-K for the year ended December 31, 2001.  
(5) Incorporated by reference from the Registrant's Annual Report on Form 10-K for the year ended December 31, 2002.  
(6) Incorporated by reference from the Registrant's Annual Report on Form 10-K for the year ended December 31, 2005.

## Edgar Filing: TITAN PHARMACEUTICALS INC - Form 10-Q

- (7) Incorporated by reference from the Registrant's Annual Report on Form 10-KSB for the year ended December 31, 1996.
- (8) Incorporated by reference from the Registrant's Registration Statement on Form S-3 (File No. 333-42367).
- (9) Incorporated by reference from the Registrant's Registration Statement on Form 10 filed on January 14, 2010.
- (10) Incorporated by reference from the Registrant's Annual Report on Form 10-K for the year ended December 31, 2003.
- (11) Incorporated by reference from the Registrant's Current Report on Form 8-K dated June 16, 2010.
- (12) Incorporated by reference from the Registrant's Quarterly Report on Form 10-Q for the period ended June 30, 2010.
- \* Confidential treatment has been granted with respect to portions of this exhibit.

**Table of Contents**

**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 thereunto duly authorized.

**TITAN PHARMACEUTICALS, INC.**

Dated: November 15, 2010

By: /s/ SUNIL BHONSLE  
Name: **Sunil Bhonsle**  
Title: **President (Principal Executive and Principal Financial Officer)**