

TITAN PHARMACEUTICALS INC

Form 10-Q

November 09, 2012

[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, 2012.

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 **94-3171940**
(State or Other Jurisdiction of **(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 Securities Exchange Act of 1934 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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. 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 75,215,713 shares of the Registrant's Common Stock issued and outstanding on November 2, 2012.

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 Balance Sheets as of September 30, 2012 and December 31, 2011</u>	3
	<u>Condensed Statements of Operations and Comprehensive Loss for the three and nine months ended September 30, 2012 and 2011</u>	4
	<u>Condensed Statements of Cash Flows for the nine months ended September 30, 2012 and 2011</u>	5
	<u>Notes to Condensed Financial Statements</u>	6
Item 2.	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	13
Item 3.	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	17
Item 4.	<u>Controls and Procedures</u>	17

Part II. Other Information

Item 1A.	<u>Risk Factors</u>	18
Item 5.	<u>Exhibits</u>	18

<u>SIGNATURES</u>	21
--------------------------	----

Table of Contents**Part I. Financial Information****Item 1. Financial Statements****TITAN PHARMACEUTICALS, INC.****CONDENSED BALANCE SHEETS**

(in thousands)

	September 30, 2012 (unaudited)	December 31, 2011 (Note 1)
Assets		
Current assets:		
Cash	\$ 5,062	\$ 5,406
Receivables	3,530	3,720
Prepaid expenses and other current assets	788	836
Total current assets	9,380	9,962
Property and equipment, net	1,364	255
Total assets	\$ 10,744	\$ 10,217
Liabilities and Stockholders Deficit		
Current liabilities:		
Accounts payable	\$ 4,878	\$ 4,789
Accrued clinical trials expenses	650	161
Other accrued liabilities	234	173
Deferred revenue	1,700	
Warrant liability, current	931	
Current portion of long-term debt, net of discount	2,500	
Total current liabilities	10,893	5,123
Warrant liabilities	7,277	3,611
Royalty liability	10,087	9,309
Long-term debt, net of discount	9,618	12,253
Total liabilities	37,875	30,296
Commitments and contingencies		
Stockholders deficit:		
Common stock, at amounts paid-in	262,052	256,436
Additional paid-in capital	20,666	18,433
Accumulated deficit	(309,849)	(294,948)
Total stockholders deficit	(27,131)	(20,079)
Total liabilities and stockholders deficit	\$ 10,744	\$ 10,217

See Notes to Condensed Financial Statements

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

	Three Months Ended September 30,		Nine months Ended September 30,	
	2012	2011	2012	2011
Revenues:				
Royalty revenue	\$ 1,228	\$ 973	\$ 3,816	\$ 2,291
Grant revenue		39	42	364
Total revenue	1,228	1,012	3,858	2,655
Operating expenses:				
Research and development	2,995	2,230	8,037	9,915
General and administrative	890	739	3,750	2,480
Total operating expenses	3,885	2,969	11,787	12,395
Loss from operations	(2,657)	(1,957)	(7,929)	(9,740)
Other income (expense):				
Interest expense, net	(1,634)	(1,194)	(5,095)	(3,238)
Other expense, net	(49)	(43)	(143)	(87)
Non-cash gain (loss) on changes in the fair value of warrants	(3,673)	2,390	(1,734)	760
Other income (expense), net	(5,356)	1,153	(6,972)	(2,565)
Net loss and comprehensive loss	\$ (8,013)	\$ (804)	\$ (14,901)	\$ (12,305)
Basic and diluted net loss per common share	\$ (0.12)	\$ (0.01)	\$ (0.23)	\$ (0.21)
Weighted average shares used in computing basic and diluted net loss per common share	66,839	59,386	63,748	59,290

See Notes to Condensed Financial Statements

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

	Nine months Ended September 30,	
	2012	2011
Cash flows from operating activities:		
Net loss	\$ (14,901)	\$ (12,305)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	13	26
Amortization of discount on long-term debt		1,272
Interest on royalty liability	778	
Non-cash (gain) loss on changes in fair value of warrants	1,734	(760)
Stock-based compensation	2,233	808
Changes in operating assets and liabilities:		
Receivables	190	(1,572)
Prepaid expenses and other assets	48	(605)
Accounts payable and other accrued liabilities	639	848
Deferred revenue	1,700	
Net cash used in operating activities	(7,566)	(12,288)
Cash flows from investing activities:		
Purchases of furniture and equipment	(1,122)	(58)
Disposals of furniture and equipment		2
Net cash used in investing activities	(1,122)	(56)
Cash flows from financing activities:		
Proceeds from issuing common stock and warrants, net of issuance costs	7,516	
Proceeds from the exercise of warrants, net of issuance costs	963	
Proceeds from long-term debt, net		19,500
Payments on long-term debt	(135)	(7,564)
Net cash provided by financing activities	8,344	11,936
Net increase (decrease) in cash and cash equivalents	(344)	(408)
Cash and cash equivalents at beginning of period	5,406	3,180
Cash and cash equivalents at end of period	\$ 5,062	\$ 2,772

See Notes to Condensed Financial Statements

Table of Contents

TITAN PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

(unaudited)

1. Organization and Summary of Significant Accounting Policies

The Company

We are a biopharmaceutical company developing proprietary therapeutics primarily for the treatment of central nervous system (CNS) disorders. Our product development programs focus primarily on important pharmaceutical markets with significant unmet medical needs and commercial potential. We are directly developing our product candidates and also utilize corporate, academic and government partnerships as appropriate. Such 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.

Our principal asset is Probuphine[®], the first slow-release implant formulation of buprenorphine hydrochloride (buprenorphine), designed to maintain a stable, round-the-clock blood level of the medicine in patients for up to six months following a single treatment. The outpatient treatment of opioid addiction with daily dosed sublingual buprenorphine formulations represented a \$1.3 billion market in the U.S. in 2011, and a seven day transdermal patch formulation of buprenorphine for the treatment of chronic pain was launched in the U.S. in 2011. The development of Probuphine for the treatment of opioid addiction is complete. This novel implant formulation is inserted subdermally in a patient's upper arm providing continuous medication, and has the potential to enhance patient compliance to treatment, and limit diversion for illicit use and accidental exposure to the sublingual formulations. The New Drug Application (NDA) was submitted to the FDA in October 2012 and seeks approval for treatment of opioid dependence. Our goal is to enter into one or more partnerships to commercialize Probuphine in the U.S. and foreign markets, as well as to potentially develop the product for the treatment of chronic pain.

Probuphine is the first product to utilize ProNeura[™], a novel, proprietary, long-term drug delivery technology. The ProNeura technology has the potential to be used in developing products for the treatment of other chronic conditions, such as Parkinson's disease, where maintaining stable, round-the-clock blood levels of a drug could potentially benefit the patient and improve medical outcomes.

Finally, we are also entitled to royalty revenue of 8-10% of net sales of Fanapt[®] (iloperidone), an atypical antipsychotic compound being marketed in the U.S. for the treatment of schizophrenia by Novartis Pharma AG (Novartis) under a sub-license agreement based on a licensed U.S. patent that expires in October 2016 (does not include a possible six month pediatric extension). Substantially all of this future royalty revenue has been sold to Deerfield Management (Deerfield), a healthcare investment fund, in exchange for cash and debt considerations which have been used to advance the development of Probuphine and for general corporate purposes.

Basis of Presentation

The accompanying unaudited condensed 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 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, 2012 are not necessarily indicative of the results that may be expected for the year ending December 31, 2012, or any future interim periods.

The balance sheet at December 31, 2011 has been derived from the audited financial statements at that date, but does not include all of the information and footnotes required by U.S. generally accepted accounting principles for complete financial statements. These unaudited condensed financial statements should be read in conjunction with the audited financial statements and footnotes thereto included in the Titan Pharmaceuticals, Inc. Annual Report on Form 10-K/A for the year ended December 31, 2011, 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.

Edgar Filing: TITAN PHARMACEUTICALS INC - Form 10-Q

The accompanying financial statements have been prepared assuming we will continue as a going concern. We expect to continue to incur substantial additional operating losses from costs related to the continuation of research and development

Table of Contents

and administrative activities across product development functions including clinical and non-clinical testing, process development and manufacturing and regulatory affairs. We believe that our working capital at September 30, 2012, along with the proceeds from the subsequent exercise of outstanding warrants, is sufficient to sustain our planned operations through March 2013. In the event we are unable to enter into a corporate partnership or licensing arrangement that provides us with the funds required to complete the regulatory process and commercialize Probuphine (if approved), we will need to obtain additional financing, either through the sale of debt or equity securities, in order for us to continue our Probuphine program and other product development activities. 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 the Probuphine program and other product development activities. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Revenue Recognition

We generate revenue principally from collaborative research and development arrangements, technology licenses, and government grants. Consideration received for revenue arrangements with multiple components is allocated among the separate units of accounting based on their respective selling prices. The selling price for each unit is based on vendor-specific objective evidence, or VSOE, if available, third party evidence if VSOE is not available, or estimated selling price if neither VSOE nor third party evidence is available. 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) collectability 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, 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 collectability is reasonably assured. 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 collectability is reasonably assured. Pursuant to certain license agreements, we earn royalties on the sale of Fanapt by Novartis Pharma AG in the U.S. As described in Note 5, Commitments and Contingencies, we are obligated to pay royalties on such sales to Sanofi-Aventis and another third party. 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 condensed statements of operations and comprehensive loss.

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 of costs associated with outsourced clinical research organization activities, sponsored research studies, product registration, patent application and prosecution, and investigator sponsored trials. We

Edgar Filing: TITAN PHARMACEUTICALS INC - Form 10-Q

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

Table of Contents

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.

Recent Accounting Pronouncements

There have been no recent accounting pronouncements or changes in accounting pronouncements during the three and nine months ended September 30, 2012, as compared to the recent accounting pronouncements described in our Annual Report on Form 10-K/A, that are of significance, or potential significance to us.

Subsequent Events

We have evaluated events that have occurred after September 30, 2012 and through the date that the financial statements are issued.

Fair Value Measurements

We measure the fair value of financial assets and liabilities based on authoritative guidance which defines fair value, establishes a framework consisting of three levels for measuring fair value, and expands disclosures about fair value measurements. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. There are three levels of inputs that may be used to measure fair value:

Level 1 quoted prices in active markets for identical assets or liabilities

Level 2 quoted prices for similar assets and liabilities in active markets or inputs that are observable;

Level 3 inputs that are unobservable (for example cash flow modeling inputs based on assumptions).

Financial instruments, including cash, receivables, accounts payable and accrued liabilities are carried at cost, which we believe approximates fair value due to the short-term nature of these instruments. Our warrant liabilities are classified within level 3 of the fair value hierarchy because the value is calculated using significant judgment based on our own assumptions in the valuation of these liabilities.

For the three months ended September 30, 2012, as a result of the fair value adjustment of the warrant liabilities, we recorded a non-cash loss on an increase in the fair value of \$3,673,000 in our condensed statements of operations and comprehensive loss. See Note 7, Warrant Liabilities for further discussion on the calculation of the fair value of the warrant liabilities.

The following table rolls forward the fair value of the Company's warrant liabilities, the fair value of which is determined by Level 3 inputs for the three and nine month periods ended September 30, 2012 and 2011 (in thousands):

	Three Months Ended September 30,		Nine months Ended September 30,	
	2012	2011	2012	2011
Fair value, beginning of period	\$ 4,535	\$ 7,103	\$ 3,611	\$
Issuance of warrants			2,863	5,473
Change in fair value	3,673	(2,390)	1,734	(760)
Fair value, end of period	\$ 8,208	\$ 4,713	\$ 8,208	\$ 4,713

Table of Contents**2. Stock Plans**

The following table summarizes the stock-based compensation expense recorded for awards under the stock option plans for the three and nine month periods ended September 30, 2012 and 2011:

(in thousands, except per share amounts)	Three Months Ended September 30,		Nine months Ended September 30,	
	2012	2011	2012	2011
Research and development	\$ 148	\$ 70	\$ 878	\$ 229
General and administrative	217	169	1,355	579
Total stock-based compensation expenses	\$ 365	\$ 239	\$ 2,233	\$ 808

No tax benefit was recognized related to stock-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.

We use the Black-Scholes-Merton option-pricing model with the following assumptions to estimate the stock-based compensation expense for the three and nine month periods ended September 30, 2012 and 2011:

	Three Months Ended September 30,		Nine months Ended September 30,	
	2012	2011	2012	2011
Weighted-average risk-free interest rate	0.9%	2.3%	0.9%	2.3%
Expected dividend payments				
Expected holding period (years) ¹	5.1	5.4	5.1	5.4
Weighted-average volatility factor ²	1.74	1.71	1.74	1.71
Estimated forfeiture rates for options granted to management ³	23%	23%	23%	23%
Estimated forfeiture rates for options granted to non-management ³	41%	41%	41%	41%

- (1) Expected holding periods are based on the simplified method provided in Staff Accounting Bulletin No. 107 for plain vanilla options.
- (2) Weighted average volatility is based on the historical volatility of our common stock.
- (3) Estimated forfeiture rates are based on historical data.

No options or awards were granted during the three month periods ended September 30, 2012 and 2011.

The following table summarizes option activity for the nine month period ended September 30, 2012:

(in thousands, except per share amounts)	Options	Weighted Average Exercise Price	Weighted Average Remaining Option Term	Aggregate Intrinsic Value
Outstanding at January 1, 2012	5,414	\$ 1.61	6.53	\$ 802
Granted	1,718	1.14		
Exercised				
Expired or cancelled	(290)	5.54		
Forfeited				
Outstanding at September 30, 2012	6,842	\$ 1.33	6.09	\$ 559

Edgar Filing: TITAN PHARMACEUTICALS INC - Form 10-Q

Exercisable at September 30, 2012	5,800	\$ 1.35	6.65	\$ 498
-----------------------------------	-------	---------	------	--------

As of September 30, 2012 there was approximately \$0.6 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 0.5 years.

No shares of restricted stock were awarded to employees, directors and consultants during the three and nine month periods ended September 30, 2012.

Table of Contents

The following table summarizes restricted stock activity for the nine month period ended September 30, 2012:

(in thousands, except per share amounts)	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2012	181	\$	9.3	\$ 206
Awarded				
Exercised or released	(181)			
Cancelled				
Outstanding at September 30, 2012		\$		\$
Vested at September 30, 2012		\$		\$

As of September 30, 2012 there was no unrecognized compensation expense related to non-vested awards.

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, 2012 and 2011, we had outstanding options and warrants allowing for the purchase of 31.7 million and 18.6 million shares of common stock, 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 for the periods presented is comprised solely of our net loss. We had no unrealized gains or losses at September 30, 2012 and 2011. Comprehensive losses for the three and nine month periods ended September 30, 2012 were \$8.0 million and \$14.9 million, respectively, and for the three and nine month periods ended September 30, 2011 were \$0.8 million and \$12.3 million, respectively.

5. Commitments and Contingencies**Financing Agreements**

In December 2009, we entered into a loan and security agreement with Oxford Finance Corporation (Oxford) pursuant to which we received a three-year term loan in the principal amount of \$3.0 million that bore interest at the rate of 13% per annum. We paid Oxford an initial facility fee of \$60,000 and were obligated to make a final payment fee of \$180,000. Commencing in January 2010, the loan was repayable in monthly interest payments of \$32,500 through June 2010 followed by monthly interest and principal installments of \$117,665 commencing in July 2010 through December 2012. The loan was secured by our assets and had 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 was amortized to interest expense over the life of the debt. Interest on the term loan, consisting of the stated interest rate, initial facility fee, final payment fee and amortization of the discount, was recognized using the interest method. The effective annual interest rate on the loan was approximately 21.1%.

In September 2010, we amended our loan and security agreement with Oxford. Pursuant to this amendment, we received a 39 month term loan in the principal amount of \$5.0 million that bore interest at the rate of 13% per annum. We paid Oxford an initial facility fee of \$125,000 and were obligated to make a final payment fee of \$300,000. Commencing in October 2010, the loan was repayable in monthly interest payments of \$54,167 through June 2011 followed by monthly interest and principal installments of \$196,108 commencing in July 2011 through December 2013. The loan was secured by our assets and had 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

Edgar Filing: TITAN PHARMACEUTICALS INC - Form 10-Q

debt discount was amortized to interest expense over the life of the debt. Interest on the term loan, consisting of the stated interest rate, initial facility fee, final payment fee and amortization of the discount, was recognized using the interest method. The effective annual interest rate on the loan was approximately 22.6%. This loan was repaid in full in April 2011.

On March 15, 2011, we entered into several agreements with entities affiliated with Deerfield Management Company, L.P. (collectively, Deerfield) pursuant to which Deerfield agreed to provide \$20.0 million in funding to us. Funding

Table of Contents

occurred on April 5, 2011 and we used approximately \$7.6 million of proceeds from the Deerfield funding to repay Oxford in full, including required final payments aggregating \$480,000. Pursuant to the terms of a facility agreement, we issued Deerfield promissory notes in the aggregate principal amount of \$20.0 million. The long-term debt bears interest at 8.5% per annum, payable quarterly, and was originally repayable over five years, with 10% of the principal amount due on the first anniversary, 15% due on the second anniversary, and 25% due on each of the next three anniversaries. We paid Deerfield a facility fee of \$0.5 million. The long-term debt is secured by our assets and has a provision for pre-payment. Deerfield has the right to have the long-term debt repaid at 110% of the principal amount in the event we complete a major transaction, which includes, but is not limited to, a merger or sale of our company or the sale of Probuphine. In connection with the facility agreement, we issued Deerfield six-year warrants (Deerfield Warrants) to purchase 6,000,000 shares of our common stock at an exercise price of \$1.57 per share (see Note 7, Warrant Liabilities for further discussion). We also entered into a royalty agreement with Deerfield, in exchange for \$3.0 million (see Note 6, Royalty Liability for further discussion).

We recorded the promissory notes with an aggregate principal amount of \$20.0 million at its face value less a note discount consisting of (i) \$3.0 million cash discount, (ii) a \$500,000 loan fee, and (iii) the \$5.5 million fair value of the associated warrants. The note discount totaling \$9.0 million is being amortized using the interest method. The effective annual interest rate on the note was 33% based on the note discount amortization, stated interest rate and note term. The agreements were not funded until April 5, 2011.

On November 14, 2011, we entered into several agreements with Deerfield pursuant to which we agreed to provide a substantial portion of the remaining future royalties on the sales of Fanapt to Deerfield in exchange for \$5.0 million in cash that was recorded as royalty liability (see Note 6, Royalty Liability for further discussion), a \$10.0 million reduction in the principal amount owed to Deerfield under the existing facility agreement and a revised principal repayment schedule of \$2.5 million per year for four years commencing in April 2013 to retire the remaining long-term debt of \$10.0 million. We evaluated the November 2011 principal reduction and other amendments to the \$20.0 million facility agreement and determined that the modifications should be accounted for as a troubled debt restructuring on a prospective basis. As a result, we will recognize the difference between the carrying value of the long-term debt and the total required future principal and interest payments as interest expense over the remaining term using the interest method. The effective interest rate was less than 1%.

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 periods ended September 30, 2012 and 2011 were approximately \$15.3 million and \$12.2 million, respectively, and we are obligated to pay royalties of approximately \$2.3 million and \$1.8 million to Sanofi-Aventis on September 30, 2012 and December 31, 2011, respectively, which were included in receivables and accounts payable on the Condensed Balance Sheets.

6. Royalty Liability

On March 15, 2011, under a royalty agreement, in exchange for \$3.0 million that was recorded as royalty liability, we agreed to pay Deerfield 2.5% of the net sales of Fanapt, constituting a portion of the royalty revenue that we are entitled to under our sublicense agreement with Novartis. The agreements with Deerfield also provide us with the option to repurchase the royalty rights for \$40.0 million.

The \$3.0 million received under the March 2011 royalty agreement was recorded as a royalty liability in accordance with the appropriate accounting guidance as the related agreement includes a provision which allows us to repurchase the royalty rights from Deerfield through a payment of a lump sum. Interest on the royalty liability is being recognized using the interest method based on the estimated future royalties expected to be paid under the royalty agreement. The current effective annual interest rate is approximately 51%.

Under the November 14, 2011 royalty agreement, in exchange for an additional \$5.0 million royalty liability, Deerfield is entitled to the balance of our portion of the royalties on Fanapt (5.5% to 7.5% of net sales, net of the 2.5% previously agreed to have been provided to Deerfield) up to specified threshold levels of net sales of Fanapt and 40% of the royalties above the threshold level. We retain 60% of the royalties on net sales of Fanapt above the threshold levels, subject to an agreement that half of any such retained royalties will go towards repayment of our outstanding debt to Deerfield.

Table of Contents

The \$5.0 million received under the November 2011 royalty agreement was recorded as a royalty liability in accordance with the appropriate accounting guidance as the related agreement includes a provision which allows us to repurchase the royalty rights from Deerfield through a payment of a lump sum. Interest on this royalty obligation is being recognized using the interest method based on the estimated future royalties expected to be paid under the royalty agreement. The current effective annual interest rate is approximately 78%.

7. Warrant Liabilities

On March 15, 2011, in connection with our Deerfield facility agreement, we issued Deerfield six-year warrants to purchase 6,000,000 shares of our common stock at an exercise price of \$1.57 per share. The warrants were immediately exercisable and expire on March 15, 2017. The warrants contain a provision where the warrant holder has the option to receive cash, equal to the Black Scholes fair value of the remaining unexercised portion of the warrant, as cash settlement in the event that there is a fundamental transaction (contractually defined to include various merger, acquisition or stock transfer activities). Due to this provision, ASC 480 *Distinguishing Liabilities from Equity* requires that these warrants be classified as liabilities. The fair values of these warrants have been determined using the Binomial Lattice (Lattice) valuation model, and the changes in the fair value are recorded in the condensed statements of operations and comprehensive loss. The Lattice model provides for assumptions regarding volatility and risk-free interest rates within the total period to maturity. As a result of the April 9, 2012 common stock offering (See Note 8, Stockholders Equity for further discussion), and pursuant to the terms of the Deerfield Warrants, the exercise price of the Deerfield Warrants was adjusted to \$1.25 per share.

The key assumptions used to value the warrants were as follows:

Assumption	September 30, 2012
Expected price volatility	75%
Expected term (in years)	4.46
Risk-free interest rate	0.54%
Dividend yield	0.00%
Weighted-average fair value of warrants	\$ 0.55

On April 9, 2012, in connection with subscription agreements with certain institutional investors for the purchase and sale of 6,517,648 shares of our common stock, we issued (i) six-year warrants to purchase 6,517,648 shares of common stock at an exercise price of \$1.15 per share (the Series A Warrants) and (ii) six-month warrants to purchase 6,517,648 shares of common stock at an exercise price of \$0.85 per share (the Series B Warrants) (together with the Series A Warrants, the Warrants). The warrants contain a provision where the warrant holder has the option to receive cash, equal to the Black Scholes fair value of the remaining unexercised portion of the warrant, as cash settlement in the event that there is a fundamental transaction (contractually defined to include various merger, acquisition or stock transfer activities). Due to this provision, ASC 480 *Distinguishing Liabilities from Equity* requires that these warrants be classified as liabilities. The fair values of these warrants have been determined using the Binomial Lattice (Lattice) valuation model, and the changes in the fair value are recorded in the condensed statements of operations and comprehensive loss. The Lattice model provides for assumptions regarding volatility and risk-free interest rates within the total period to maturity.

During the three month period ended September 30, 2012, Series B Warrants to purchase 1,133,824 shares of common stock were exercised at a price of \$0.85 per share

The key assumptions used to value the warrants were as follows:

Assumption	September 30, 2012	
	Series A Warrants	Series B Warrants
Expected price volatility	75%	75%
Expected term (in years)	5.53	0.02
Risk-free interest rate	0.73%	0.06%
Dividend yield	0.00%	0.00%
Weighted-average fair value of warrants	\$ 0.61	\$ 0.17

Table of Contents**8. Stockholders' Equity*****Common Stock***

On September 12, 2012, we entered into a Stock Purchase and Option Agreement (the "Agreement") with an affiliate of the party with which we have been engaged in negotiations for a license for Probuphine®. Pursuant to the Agreement, we sold 3,400,000 shares of our common stock for an aggregate purchase price of \$4.25 million, or \$1.25 per share, and agreed to an exclusive option period for execution of the proposed license agreement. In the event that for any unforeseen reason the license agreement is not executed prior to the expiration of the option period (December 31, 2012), we will be free to negotiate and complete a license arrangement with any third party. The \$1.7 million premium, or \$0.50 per share, has been allocated to the fair value of the option agreement and has been recorded as deferred revenue at September 30, 2012.

On April 9, 2012, we entered into subscription agreements with certain institutional investors for the purchase and sale, in a registered direct offering, of (i) 6,517,648 shares of our common stock (the "Shares"), (ii) 6,517,648 Series A Warrants and (iii) 6,517,648 Series B Warrants for gross proceeds of \$5,540,000 (the "Offering"). The closing of the sale of the Shares and Warrants occurred on April 13, 2012 and April 18, 2012. As a result of the Offering, and pursuant to the terms of the Deerfield Warrants, the exercise price of the Deerfield Warrants (See Note 7, "Warrant Liabilities" for further discussion) was adjusted to \$1.25 per share.

We recorded the gross proceeds from the offering, net of (i) issuance costs of \$0.5 million and (ii) the fair value of the warrants of \$2.9 million (see Note 7, "Warrant Liabilities"), as common stock paid-in in the accompanying condensed balance sheets.

In September 2012, Series B Warrants to purchase 1,133,824 shares of common stock were exercised resulting in gross proceeds of approximately \$964,000.

9. Subsequent Events

In October 2012, Series B Warrants to purchase 4,627,941 shares of common stock were exercised resulting in gross proceeds of approximately \$3,934,000.

In October 2012, we were notified by Novartis Pharma AG ("Novartis") that Novartis had decided to cease further development of the long-acting injectable, or depot, formulation of iloperidone. Novartis will continue to commercialize Fanapt®, the oral formulation of iloperidone, in the U.S. and under the terms of the Company's Sublicense Agreement with Novartis dated November 20, 1997, Novartis is obligated to pay royalties to Titan on net sales of all formulations of iloperidone for the life of the applicable patents. As reported in November 2011, the Company sold substantially all of its remaining future royalties on the sales of Fanapt® to Deerfield, and accordingly the future royalty payments owed to the Company by Novartis will continue to be transmitted to Deerfield upon receipt from Novartis per the terms of the agreement with Deerfield. See Note 6 "Royalty Liabilities" for further discussion of the Company's royalty liabilities.

In October 2012 we submitted a New Drug Application to the U.S. Food and Drug Administration for the investigational product Probuphine® for the maintenance treatment of opioid dependence in adult patients.

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, the Company's ability to establish corporate partnerships to support the development and commercialization of its products, the Company's ability to establish corporate partnerships to support the development and commercialization of its products, the Company's ability to obtain additional financing, the effect of our accounting policies, and other risks detailed in our Securities Exchange Commission 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.

Edgar Filing: TITAN PHARMACEUTICALS INC - Form 10-Q

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

Table of Contents

Overview

Our principal asset is Probuphine[®], the first novel slow-release implant formulation of buprenorphine hydrochloride (buprenorphine), designed to maintain a stable, round-the-clock blood level of the medicine in patients for up to six months following a single treatment. The outpatient treatment of opioid addiction with daily dosed sublingual buprenorphine formulations represents a \$1.3 billion market in the U.S., and a seven day transdermal patch formulation of buprenorphine for the treatment of chronic pain was launched in the U.S. in 2011. Probuphine is inserted subdermally in a patient's upper arm providing continuous medication, and has the potential to enhance patient compliance to treatment, and limit diversion for illicit use and accidental exposure to the sublingual formulations. The clinical and manufacturing development of Probuphine for the treatment of opioid addiction is complete. The New Drug Application (NDA) was submitted to the FDA in October 2012 and seeks approval for treatment of opioid dependence. Over the past several months, we have been working with our contract manufacturer to scale-up the manufacturing process for commercial production. The new facility is complete and the manufacturing equipment has been qualified. The commercial scale production capability has been demonstrated and the appropriate information incorporated into the NDA.

Our goal is to enter into one or more partnerships to commercialize Probuphine in the U.S. and foreign markets, and towards this end, on September 12, 2012 we entered into a Stock Purchase and Option Agreement with an affiliate of the potential licensee of rights to commercialize Probuphine. Under the agreement, we sold 3,400,000 shares of common stock at \$1.25 per share (representing a premium of approximately 67% to the closing price of our common stock on the OTC Bulletin Board on the prior day) and agreed to an exclusive option period to execute the proposed licensing agreement (which option expires on December 31, 2012) so that the potential partner can complete certain internal structural tasks.

Probuphine is the first product to utilize ProNeura[™], our novel, proprietary, long-term drug delivery technology. Our ProNeura technology has the potential to be used in developing products for the treatment of other chronic conditions, such as Parkinson's disease, where maintaining stable, round-the-clock blood levels of dopamine agonists may benefit the patient and improve medical outcomes. Patents covering certain dopamine agonist implants have already been issued or allowed in Europe, Japan, Australia, Canada, South Korea, Mexico, New Zealand, South Africa, and Hong Kong, while prosecution of the patent application continues in the U.S., Israel, India, and China.

Under a sublicense agreement with Novartis Pharma AG (Novartis), we are entitled to royalty revenue of 8-10% of net sales of Fanapt (iloperidone), an atypical antipsychotic compound being marketed in the U.S. by Novartis for the treatment of schizophrenia, based on a licensed U.S. patent that expires in October 2016 (does not include a possible six month pediatric extension). During 2011, we entered into several agreements with Deerfield Management (Deerfield), a healthcare investment fund, in which we agreed to pay most of this future royalty stream to Deerfield and have been using the proceeds to advance the development of Probuphine and for general corporate purposes. We have retained a portion of the royalty revenue from net sales of Fanapt in excess of specified annual threshold levels; however, based on sales levels to date, it is unlikely that we will receive any revenue from Fanapt in the next several years, if ever.

Recent Accounting Pronouncements

See Note 1 to the accompanying unaudited condensed financial statements included in Part 1, Item 1 of this Quarterly Report on Form 10-Q for information on recent accounting pronouncements.

Results of Operations for the Three and Nine months Ended September 30, 2012 and September 30, 2011

Our net loss for the three month period ended September 30, 2012 was approximately \$8.0 million, or approximately \$0.12 per share, compared to our net loss of approximately \$0.8 million, or approximately \$0.01 per share, for the comparable period in 2011. Our net loss for the nine month period ended September 30, 2012 was approximately \$14.9 million, or approximately \$0.23 per share, compared to our net loss of approximately \$12.3 million, or approximately \$0.21 per share, for the comparable period in 2011.

We generated royalty revenues during the three and nine month periods ended September 30, 2012 of approximately \$1.2 million and \$3.8 million, respectively. We generated royalty revenues during the three and nine month periods ended September 30, 2011 of approximately \$1.0 million and \$2.3 million, respectively. Royalty revenues during the three and nine month periods ended September 30, 2012 and 2011 consisted of royalties on sales of Fanapt. We generated no grant revenues during the three month period ended September 30, 2012. We generated grant revenues during the nine month period ended September 30, 2012 of approximately \$42,000. Grant revenues during the nine month period ended September 30, 2012 consisted of proceeds from the NIH grant related to our ProNeura program. We generated grant revenues during the three and nine month periods ended September 30, 2011 of approximately \$39,000 and \$0.4 million, respectively.

Research and development expenses for the three month period ended September 30, 2012 were approximately \$3.0 million, compared to approximately \$2.2 million for the comparable period in 2011, an increase of approximately \$0.8

Table of Contents

million, or 36%. Research and development expenses for the nine month period ended September 30, 2012 were approximately \$8.0 million, compared to approximately \$9.9 million for the comparable period in 2011, a decrease of approximately \$1.9 million, or 19%. The increase in research and development costs during the three month period ended September 30, 2012 was primarily associated with an increase in external research and development expenses associated with the preparation and submission of the NDA related to our Probuphine product which was submitted to the FDA in October 2012. The decrease in research and development costs during the nine month period ended September 30, 2012 was primarily associated with a decrease in external research and development expenses related to the Phase 3 clinical trials of our Probuphine product which were completed in 2011. External research and development expenses include direct expenses such as CRO charges, investigator and review board fees, patient expense reimbursements and contract manufacturing expenses. During the three and nine month periods ended September 30, 2012, external research and development expenses relating to our Probuphine product development program were approximately \$1.7 million and \$4.3 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, 2012 were approximately \$0.9 million, compared to approximately \$0.7 million for the comparable period in 2011, an increase of approximately \$0.2 million, or 29%. General and administrative expenses for the nine month period ended September 30, 2012 were approximately \$3.8 million, compared to approximately \$2.5 million for the comparable period in 2011, an increase of approximately \$1.3 million, or 52%. The increase in general and administrative expenses during the three month period ended September 30, 2012 was primarily related to increases in legal fees of approximately \$0.1 million, non-cash stock compensation costs of approximately \$48,000, facilities and other administrative costs of approximately \$39,000 and employee related costs of approximately \$17,000. This was offset in part by decreases in consulting and professional fees of approximately \$62,000, and travel related costs of approximately \$23,000. The increase in general and administrative expenses during the nine month period ended September 30, 2012 was primarily related to increases in consulting and professional fees of approximately \$0.3 million, non-cash stock compensation and employee related costs of approximately \$0.8 million and facilities and other administrative costs of approximately \$0.1 million.

Net other expense for the three month period ended September 30, 2012 was approximately \$5.4 million, compared to net other income of approximately \$1.2 million in the comparable period in 2011. Net other expense for the nine month period ended September 30, 2012 was approximately \$7.0 million compared to approximately \$2.6 million in the comparable period in 2011. The increases in net other expense during the three month period ended September 30, 2012, was primarily related to an approximately \$3.7 million non-cash loss related to increases in the fair value of outstanding warrants and approximately \$1.6 million of interest expense compared to an approximately \$2.4 million non-cash gain related to decreases in the fair value of outstanding warrants and approximately \$1.2 million of interest expense during the comparable period in 2011. The increase in interest expense of approximately \$0.4 million was related to the Deerfield loans. The increase in net other expense during the nine month period ended September 30, 2012, was primarily related to an approximately \$1.7 million non-cash loss related to increases in the fair value of outstanding warrants and approximately \$5.1 million of interest expense compared to an approximately \$0.8 million non-cash gain related to decreases in the fair value of outstanding warrants and approximately \$3.2 million of interest expense during the comparable period in 2011. The increase in interest expense of approximately \$1.9 million was related to the Deerfield loans.

Liquidity and Capital Resources

We have funded our operations since inception primarily through the sale of our securities and the issuance of debt, as well as with proceeds from warrant and option exercises, corporate licensing and collaborative agreements, and government-sponsored research grants. At September 30, 2012, we had a working capital deficit of approximately \$1.5 million compared to working capital of approximately \$4.8 million at December 31, 2011.

Our operating activities used approximately \$7.6 million of net cash during the nine months ended September 30, 2012. This consisted primarily of the net loss for the period of approximately \$14.9 million, offset in part by approximately \$1.7 million related to non-cash losses on changes in the fair value of warrants, and approximately \$0.2 million related to decreases in receivables, which includes approximately \$2.3 million which will have to be paid to Sanofi-Aventis for royalties earned on sales of Fanapt, approximately \$0.8 million related to interest on our royalty liabilities, non-cash charges of approximately \$2.2 million related to stock-based compensation expenses, approximately \$0.6 million related to increases in accounts payable and other accrued liabilities and approximately \$1.7 million related to increases in deferred revenue. Uses of cash in operating activities were primarily to fund product development programs and administrative expenses. Our license agreement with Sanofi-Aventis requires 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 \$34,000.

Table of Contents

Net cash used by investing activities of approximately \$1.1 million during the nine months ended September 30, 2012 consisted primarily of approximately \$1.1 million related to purchases of manufacturing equipment.

Net cash provided by financing activities of approximately \$8.3 million during the nine month period ended September 30, 2012 consisted primarily of approximately \$7.5 million of net proceeds from the sale of common stock and warrants, net of issuance costs and \$1.0 million of net proceeds from the exercise of warrants to purchase common stock. This was offset in part by payments of approximately \$0.1 million related to payments on our long-term debt.

On March 15, 2011, we entered into several agreements with entities affiliated with Deerfield pursuant to which Deerfield agreed to provide \$20.0 million in funding to the Company. Funding occurred on April 5, 2011. Pursuant to the terms of a facility agreement, we issued Deerfield promissory notes in the aggregate principal amount of \$20.0 million. The loan bears interest at 8.5% per annum and the facility is repayable over five years, with 10% of the principal amount due on the first anniversary, 15% due on the second anniversary, and 25% due on each of the next three anniversaries. We paid Deerfield a facility fee of \$0.5 million. The facility is secured by our assets and has a provision for pre-payment. Deerfield has the right to have the loan repaid at 110% of the principal amount in the event we complete a major transaction, which includes, but is not limited to, a merger or sale of our company or the sale of Fanapt® or Probuphine . Under a royalty agreement, we agreed to pay Deerfield 2.5% of the aggregate royalties on net sales of Fanapt®, subsequent to the funding date, constituting a portion of the royalty revenue we receive from Novartis. The agreements with Deerfield also provide us with the option to repurchase the royalty rights for \$40.0 million.

At March 31, 2011 we had outstanding indebtedness in the aggregate principle amount of approximately \$7.3 million under our loan and security agreement, as amended, with Oxford bearing interest at the rate of 13% per annum. On April 5, 2011, we used \$7.7 million of proceeds from the Deerfield funding to repay Oxford in full, including final payments aggregating \$480,000.

On November 14, 2011, we entered into several agreements with Deerfield pursuant to which we agreed to provide a substantial portion of the remaining future royalties on the sales of Fanapt to Deerfield in exchange for \$5.0 million in cash that was recorded as royalty liability, a \$10.0 million reduction in the principal amount owed to Deerfield under the existing facility agreement and a revised principal repayment schedule of \$2.5 million per year for four years commencing in April 2013 to retire the remaining long-term debt of \$10.0 million.

On April 9, 2012, we entered into subscription agreements with certain institutional investors for the purchase and sale, in a registered direct offering, of (i) 6,517,648 shares of our common stock (the Shares), (ii) six-year warrants to purchase 6,517,648 shares of common stock (the Series A Warrants) and (iii) six-month warrants to purchase 6,517,648 shares of common stock (together with the Series A Warrants, the Warrants) for gross proceeds of \$5,540,000. The closing of the sale of the Shares and Warrants occurred on April 13, 2012 and April 18, 2012. Net proceeds were approximately \$5.0 million.

On September 12, 2012, we entered into a Stock Purchase and Option Agreement (the Agreement) with an affiliate of the party with which we have been engaged in negotiations for a license for Probuphine. Pursuant to the Agreement, we sold 3,400,000 shares of our common stock for an aggregate purchase price of \$4.25 million, or \$1.25 per share, and agreed to an exclusive option period for execution of the proposed license agreement. In the event that for any unforeseen reason the license agreement is not executed prior to the expiration of the option period (on December 31, 2012), we will be free to negotiate and complete a license arrangement with any third party.

In September and October 2012, Series B Warrants to purchase 1,133,824 and 4,627,941 shares of common stock, respectively, were exercised resulting in gross proceeds of approximately \$964,000 and \$3,934,000, respectively.

We expect to continue to incur substantial additional operating losses from costs related to the continuation of research and development and administrative activities across product development functions including clinical and non-clinical testing, process development and manufacturing and regulatory affairs. We believe that our working capital at September 30, 2012, along with the proceeds from the subsequent exercise of outstanding warrants, is sufficient to sustain our planned operations through March 2013, including a scheduled installment payment to Deerfield of approximately \$2.5 million in early April 2013. In the event we are unable to enter into a corporate partnership or licensing arrangement that provides us with the funds required to complete the regulatory process and commercialize Probuphine (if approved), we will need to obtain additional financing, either through the sale of debt or equity securities, in order for us to continue our Probuphine program and other product development activities. 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 the Probuphine program and other product development activities.

Table of Contents

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our market risk disclosures set forth in our Annual Report on Form 10-K/A for the year ended December 31, 2011 have not changed materially.

Item 4. 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, 2012, 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, 2012 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**

In addition to the other information set forth in this report, you should carefully consider the factors discussed in Part I, Item 1A. Risk Factors in our Annual Report on Form 10-K/A for the year ended December 31, 2011, which could materially affect our business, financial condition or future results. The risks described in our Annual Report on Form 10-K/A are not the only risks facing our Company. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results.

Item 5. Exhibits

No.	Description
3.1	Amended and Restated Certificate of Incorporation of the Registrant, as amended ⁹
3.2	By-laws of the Registrant ¹
3.3	Certificate of Designations of Junior Participating Preferred Stock of Titan Pharmaceuticals, Inc. ¹⁵
4.1	Registration Rights Agreement dated as of December 17, 2007 ²
4.2	Registration Rights Agreement dated as of December 8, 2009 ⁹
4.3	Warrant to Purchase Common Stock dated December 23, 2009 issued to Oxford Finance Corporation ⁹
4.4	Warrant to Purchase Common Stock dated September 27, 2010 issued to Oxford Finance Corporation ¹²
4.5	Form of Warrant ¹³
4.6	Registration Rights Agreement, dated as of March 15, 2011 ¹³
4.7	Rights Agreement, dated as of December 20, 2011 between the Registrant and Continental Stock Transfer and Trust Company, as Rights Agent ¹⁵
4.8	Amendment No. 1 to Rights Agreement, dated as of February 22, 2012 between the Registrant and Continental Stock Transfer and Trust Company, as Rights Agent ¹⁷
4.9	Amendment No. 2 to Rights Agreement, dated as of April 9, 2012 between the Registrant and Continental Stock Transfer and Trust Company, as Rights Agent ¹⁸
4.10	Form of Series A Warrant ¹⁸
4.11	Form of Series B Warrant ¹⁸
10.1	1998 Stock Option Plan ³
10.2	2001 Non-Qualified Employee Stock Option Plan ⁴
10.3	2002 Stock Option Plan ⁵
10.4	Employment Agreement between the Registrant and Sunil Bhonsle, dated May 16, 2009, as amended by agreement dated February 17, 2010 and December 30, 2011 ^{9,16}
10.5	Employment Agreement between the Registrant and Marc Rubin, dated May 16, 2009, as amended by agreement dated February 17, 2010 and December 30, 2011 ^{9,16}
10.6	Lease for the Registrant's facilities, amended as of October 1, 200 4
10.7	Amendments to lease for Registrant's facilities dated May 21, 2007 and March 12, 200 9
10.8*	License Agreement between the Registrant and Sanofi-Aventis SA effective as of December 31, 1996 ⁷

Edgar Filing: TITAN PHARMACEUTICALS INC - Form 10-Q

- 10.9* Sublicense Agreement between the Registrant and Novartis Pharma AG dated November 20, 1997⁸
- 10.10* License Agreement between the Registrant and the Massachusetts Institute of Technology dated September 28, 1995¹

Table of Contents

No.	Description
10.11	Loan and Security Agreement between the Registrant and Oxford Finance Corporation dated December 18, 2009 ⁹
10.12	Stock Purchase Agreement between the Registrant and certain investors dated December 8, 2009 ⁹
10.13	Amendment to Employment Agreement dated June 15, 2010 between the Registrant and Marc Rubin ¹⁰
10.14	Amendment to Employment Agreement dated June 15, 2010 between the Registrant and Sunil Bhonsle ¹⁰
10.15	Amendment to lease for Registrant s facilities dated June 15, 2010
10.16	Amended and Restated Loan and Security Agreement between the Registrant and Oxford Finance Corporation dated September 27, 2010 ¹²
10.17	Facility Agreement, dated as of March 15, 2011, by and among the Company, Deerfield Private Design Fund II, L.P., Deerfield Private Design International II, L.P., Deerfield Special Situations Fund, L.P., and Deerfield Special Situations Fund International Limited ¹³
10.18	Security Agreement, dated as of March 15, 2011, by and among the Company, Deerfield Private Design Fund II, L.P., Deerfield Private Design International II, L.P., Deerfield Special Situations Fund, L.P., and Deerfield Special Situations Fund International Limited ¹³
10.19	Royalty Purchase Agreement, dated November 14, 2011, by and among the Company, Deerfield Private Design Fund II, L.P., Deerfield Special Situations Fund, L.P. and Horizon Sante TTNP SARL ¹⁴
10.20	Amended and Restated Royalty Agreement, dated November 14, 2011 by and among the Company, Deerfield Private Design Fund II, L.P., Deerfield Special Situations Fund, L.P. and Horizon Sante TTNP SARL ¹⁴
10.21	Amended and Restated Royalty Repurchase Agreement, dated November 14, 2011, by and among the Company, Deerfield Private Design Fund II, L.P., and Horizon Sante TTNP SARL ¹⁴
10.22	Cash Management Agreement, dated November 14, 2011, by and among the Company, Deerfield Private Design Fund II, L.P., Deerfield Special Situations Fund, L.P. and Horizon Sante TTNP SARL ¹⁴
10.23	Paying Agent Agreement, dated November 14, 2011, by and among the Company, Deerfield Management Company, L.P. and U.S. Bank National Association ¹⁴
10.24	Agreement, dated as of November 14, 2011, by and among the Company, Deerfield Private Design Fund II, L.P., Deerfield Private Design International II, L.P., Deerfield Special Situations Fund, L.P., and Deerfield Special Situations Fund International Limited ¹⁴
10.25	Form of Subscription Agreement, dated April 9, 2012 ¹⁸
10.26	Corporate Presentation dated March 2012 ¹⁸
14.1	Code of Business Conduct and Ethics ¹⁰
31.1	Certification of the Principal Executive and Financial Officer pursuant to Rule 13(a)-14(a) of the Securities Exchange Act of 1934
32.1	Certification 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
101.INS**	XBRL Instance Document
101.SCH**	XBRL Taxonomy Extension Schema Document
101.CAL**	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF**	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB**	XBRL Taxonomy Extension Label Linkbase Document
101.PRE**	XBRL Taxonomy Extension Presentation Linkbase Document

Table of Contents

- (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.
- (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.
- (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 Quarterly Report on Form 10-Q for the period ended June 30, 2010.
- (12) Incorporated by reference from the Registrant s Quarterly Report on Form 10-Q for the period ended September 30, 2010.
- (13) Incorporated by reference from the Registrant s Current Report on Form 8-K filed on March 18, 2011.
- (14) Incorporated by reference from the Registrant s Current Report on Form 8-K filed on November 17, 2011.
- (15) Incorporated by reference from the Registrant s Current Report on Form 8-K filed on December 21, 2011.
- (16) Incorporated by reference from the Registrant s Current Report on Form 8-K filed on January 4, 2012.
- (17) Incorporated by reference from the Registrant s Annual Report on Form 10-K for the year ended December 31, 2011.
- (18) Incorporated by reference from the Registrant s Current Report on Form 8-K filed on April 10, 2012.
- * Confidential treatment has been granted with respect to portions of this exhibit.
- ** Pursuant to Rule 406T of Regulation S-T, the interactive files on Exhibit 101.1 hereto are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and otherwise are not subject to liability under those sections.

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 9, 2012

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