TITAN PHARMACEUTICALS INC
Form 10-Q
November 14, 2011
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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, 2011

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)

Delaware	**94-3171940**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**

400 Oyster Point Blvd., Suite 505, South San Francisco, California 94080

(Address of Principal Executive Offices, Including Zip Code)

(650) 244-4990

(Registrant s Telephone Number, Including Area Code)

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x 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 x 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 x

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

There were 59,385,570 shares of the Registrant s Common Stock issued and outstanding on November 8, 2011.

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Titan Pharmaceuticals, Inc.

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Part I. Financial Information

Item 1. Financial Statements

TITAN PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands)

	September 30, 2011 (unaudited)	December 31, 2010 (Note 1)
Assets		
Current assets:		
Cash and cash equivalents	$ 2,772	$ 3,180
Receivables	2,797	1,225
Prepaid expenses and other current assets	899	294
Total current assets	6,468	4,699
Property and equipment, net	83	53
Total assets	$ 6,551	$ 4,752
Liabilities and Stockholders Deficit		
Current liabilities:		
Accounts payable	$ 3,026	$ 2,457
Accrued expenses	1,357	1,078
Current portion of long-term debt	2,000	1,870
Total current liabilities	6,383	5,405
Warrant liability	4,713	
Long-term debt, net of discount	13,005	5,400
Total liabilities	24,101	10,805
Commitments and contingencies (Note 5)		
Stockholders deficit:		
Common stock, at amounts paid-in	256,436	256,436
Additional paid-in capital	18,064	17,256
Accumulated deficit	(292,050)	(279,745)
Total stockholders deficit	(17,550)	(6,053)
Total liabilities and stockholders deficit	$ 6,551	$ 4,752

See Notes to Condensed Consolidated Financial Statements

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TITAN PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(unaudited)

(in thousands, except per share amount)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Revenues:				
Royalty revenue	$ 973	$ 396	$ 2,291	$ 2,104
Grant revenue	39	3,203	364	5,251
License revenue		1		12
Total revenue	1,012	3,600	2,655	7,367
Operating expenses:				
Research and development	2,230	3,044	9,915	6,770
General and administrative	739	691	2,480	2,638
Total operating expenses	2,969	3,735	12,395	9,408
Loss from operations	(1,957)	(135)	(9,740)	(2,041)
Other income (expense):				
Interest expense, net	(1,194)	(124)	(3,238)	(364)
Other expense, net	(43)	(125)	(87)	(130)
Non-cash gain on changes in the fair value of stock warrants	2,390		760	
Other income (expense), net	1,153	(249)	(2,565)	(494)
Net loss	$ (804)	$ (384)	$ (12,305)	$ (2,535)
Basic and diluted net loss per share	$ (0.01)	$ (0.01)	$ (0.21)	$ (0.04)
Weighted average shares used in computing basic and diluted net loss per share	59,386	59,248	59,290	59,248

See Notes to Condensed Consolidated Financial Statements

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TITAN PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

(unaudited)

	Nine Months Ended September 30,	
	2011	**2010**
Cash flows from operating activities:		
Net loss	$ (12,305)	$ (2,535)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	26	69
Amortization of loan discount	1,272	22
Stock-based compensation	808	336
Non-cash gain on changes in fair value of stock warrants	(760)	
Changes in operating assets and liabilities:		
Receivables	(1,572)	(1,838)
Prepaid expenses and other assets	(605)	69
Accounts payable and other accrued liabilities	848	2,170
Net cash used in operating activities	(12,288)	(1,707)
Cash flows from investing activities:		
Purchases of furniture and equipment	(58)	(20)
Disposals of furniture and equipment	2	
Net cash used in investing activities	(56)	(20)
Cash flows from financing activities:		
Proceeds from long-term debt, net	19,500	5,000
Payments on long-term debt	(7,564)	(172)
Net cash provided by financing activities	11,936	4,828
Net (decrease) increase in cash and cash equivalents	(408)	3,101
Cash and cash equivalents at beginning of period	3,180	3,300
Cash and cash equivalents at end of period	$ 2,772	$ 6,401

See Notes to Condensed Consolidated Financial Statements

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TITAN PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

1. Organization and Summary of Significant Accounting Policies

The Company

We are a biopharmaceutical company developing proprietary therapeutics 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 (including a royalty of 2.5% of U.S. net sales that is owed to a third party).

(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 the final stages of Phase 3 clinical development for the treatment of opioid addiction with efficacy already demonstrated in two controlled Phase 3 clinical studies and a good safety and tolerability profile in all trials.

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 we 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 a 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 subsidiary after elimination of all significant intercompany accounts and transactions. These financial statements have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) 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. GAAP 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, 2011 are not necessarily indicative of the results that may be expected for the year ending December 31, 2011, or any future interim periods.

The balance sheet at December 31, 2010 has been derived from the audited consolidated financial statements at that date, but does not include all of the information and footnotes required by U.S. GAAP for complete financial statements. These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and footnotes thereto included in the Titan Pharmaceuticals, Inc. Annual Report on Form 10-K for the year ended December 31, 2010, as filed with the Securities and Exchange Commission (SEC).

The preparation of financial statements in conformity with U.S. GAAP 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 expect to continue to incur substantial additional operating losses from costs related to the continuation of product and technology development, clinical trials, the regulatory process, and administrative activities. We believe that our working capital at September 30, 2011, together with the revenues from royalties on the sale of Fanapt, is sufficient to sustain our planned operations to the end of the year. Because of a delay in our timeline that arose from an FDA requirement for inclusion of an additional primary analysis for the Phase 3 study, we need to raise additional financing during the fourth quarter of this year to fund our product development activities, and we will be required to obtain

substantial funding to commercialize any products other than iloperidone 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.

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Majority-Owned Subsidiary

In December 2010, Ingenex, Inc., our majority-owned subsidiary, was dissolved under the laws of Delaware. At the time of dissolution, we owned 81% of Ingenex (assuming the conversion of all preferred stock to common stock). Ingenex was not an operating company and had no assets.

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. 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 Consolidated Statement of Operations.

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.

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Warrants Issued in Connection with Equity Financing

We generally account for warrants issued in connection with equity financings as a component of equity, unless there is a deemed possibility that we may have to settle warrants in cash. For warrants issued with deemed possibility of cash settlement, we record the fair value of the issued warrants as a liability at each reporting period and record changes in the estimated fair value as a non-cash gain or loss in the Condensed Consolidated Statements of Operations.

Recent Accounting Pronouncements

In June 2011, the FASB issued Accounting Standards Update (ASU) No. 2011-05 *Presentation of Comprehensive Income* that improves the comparability, consistency, and transparency of financial reporting and increases the prominence of items reported in other comprehensive income by eliminating the option to present components of other comprehensive income as part of the statement of changes in stockholders equity. The amendments in this standard require that all non-owner changes in stockholders equity be presented either in a single continuous statement of comprehensive income or in two separate but consecutive statements. Under either method, adjustments must be displayed for items that are reclassified from other comprehensive income (OCI) to net income, in both net income and OCI. The standard does not change the current option for presenting components of OCI gross or net of the effect of income taxes, provided that such tax effects are presented in the statement in which OCI is presented or disclosed in the notes to the financial statements. Additionally, the standard does not affect the calculation or reporting of earnings per share. For public entities, the amendments in this ASU are effective for fiscal years, and interim periods within those years, beginning after December 15, 2011 and are to be applied retrospectively, with early adoption permitted. We do not expect the adoption of this standard to have a material impact on our consolidated financial statements.

In May 2011, the FASB issued ASU No. 2011-04 which amends GAAP to conform to the measurement and disclosure requirements in International Financial Reporting Standards (IFRS). The amendments in this ASU change the wording used to describe the requirements in U.S. GAAP for measuring fair value and for disclosing information about fair value measurements. The amendments include the following:

- Those that clarify the FASB s intent regarding the application of existing fair value measurement and disclosure requirements; and
- Those that change a particular principle or requirement for measuring fair value or for disclosing information about fair value measurements.

In addition, to improve consistency in application across jurisdictions some changes in wording are necessary to ensure that GAAP and IFRS fair value measurement and disclosure requirements are described in the same way (for example, using the word shall rather than should to describe the requirements in GAAP). The amendments in this ASU are to be applied prospectively and are effective during interim and annual periods beginning after December 15, 2011. We will evaluate the requirements and do not believe that the adoption of this update will have a material impact on our consolidated financial statements at this time.

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Subsequent Events

We have evaluated events that have occurred after September 30, 2011 and through the date that the financial statements are issued.

2. Stock 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, 2011 and 2010:

.	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands, except per share amounts)	**2011**	**2010**	**2011**	**2010**
Research and development	$ 70	$ 45	$ 229	$ 15
General and administrative	169	80	579	321
Total share-based compensation expenses	$ 239	$ 125	$ 808	$ 336

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.

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, 2011 and 2010:

	Three Months Ended September 30,		Nine months Ended September 30,	
	2011	**2010**	**2011**	**2010**
Weighted-average risk-free interest rate	2.3%	0.83%	2.3%	2.3%
Expected dividend payments				
Expected holding period (years)[1]	5.4	4.0	5.4	4.2
Weighted-average volatility factor[2]	1.71	1.93	1.71	1.89
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 historical data for the three and nine months ended September 30, 2010. For the three and nine month periods ended September 30, 2011, we used 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, 2011 and 2010.

The following table summarizes option activity for the nine month period ended September 30, 2011:

(in thousands, except per share amounts)	**Options**	**Weighted Average Exercise Price**	**Weighted Average Remaining Option Term**	**Aggregate Intrinsic Value**

Outstanding at January 1, 2011	4,976	$ 2.29	5.99	$ 968
Granted	734	1.44		
Exercised				
Expired or cancelled	(241)	15.01		
Forfeited	(55)	1.77		
Outstanding at September 30, 2011	5,414	$ 1.61	6.79	$ 1,408
Exercisable at September 30, 2011	3,980	$ 1.76	6.20	$ 1,027

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As of September 30, 2011 there was approximately $1.4 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 1.6 years.

No shares of restricted stock were awarded during the three month period ended September 30, 2011. The following table summarizes restricted stock activity for the nine month period ended September 30, 2011:

(in thousands, except per share amounts)	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2011	139	$ 0.04	9.3	$ 167
Awarded	181			
Exercised or released	(138)	0.04		
Cancelled				
Outstanding at September 30, 2011	182	$	9.5	$ 248
Vested at September 30, 2011		$		$

As of September 30, 2011 there was approximately $0.1 million of total unrecognized compensation expense related to non-vested awards. This expense is expected to be recognized over a weighted-average period of 0.5 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, 2011 and 2010, options and warrants totaled 18.6 million and 11.8 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. The only component of other comprehensive income or loss is unrealized gains and losses on our marketable securities. Comprehensive losses for the three and nine month periods ended September 30, 2011 were $0.8 million and $12.3 million, respectively, and for the three and nine month periods ended September 30, 2010 were $0.4 million and $2.5 million, respectively.

5. Commitments and Contingencies

Financing Agreements

On March 15, 2011, we entered into several agreements with entities affiliated with Deerfield Management, a healthcare investment fund (collectively, Deerfield); pursuant to which Deerfield agreed to provide $20.0 million in funding to us. The agreements were funded on April 5, 2011 and $7.7 million of the proceeds were used to repay our outstanding indebtedness to Oxford Capital Financing (Oxford). Pursuant to the terms of a facility agreement, we issued promissory notes to Deerfield in the aggregate principal amount of $20.0 million. The loan bears interest at 8.5% per annum, payable quarterly, 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 $500,000. The facility is secured by our assets and has a provision for pre-payment. Deerfield has the option 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,

beginning on 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. Deerfield received six-year warrants to purchase 6,000,000 shares of common stock at an exercise price of $1.57 per share.

The $20.0 million note was recorded at its face value less a note discount consisting of $3.0 million, a $500,000 loan fee, and the $7.1 million fair value of the associated warrants. The note discount totaling $8.9 million is being amortized using the interest method. The effective annual interest rate on the note is 33% based on the note discount amortization, stated interest rate and note term. The $3.0 million received under the royalty agreement was recorded as a loan in accordance with appropriate accounting guidance. Interest on the loan will be recorded using the interest method based on the estimated future royalties expected to be paid under the royalty agreement. The current effective annual interest rate on the loan is 58.2%.

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In September 2010, we amended our loan and security agreement with Oxford pursuant to which we received a 39 month term loan in the principal amount of $5.0 million bearing 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 July 2011 followed by monthly interest and principal installments of $196,108 payable commencing in August 2011 through January 2014. 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 debt discount was amortized to interest expense. The Oxford indebtedness was repaid on April 5, 2011 with proceeds from the Deerfield transaction.

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 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 $117,625 payable 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. The Oxford indebtedness was repaid on April 5, 2011 with proceeds from the Deerfield transaction.

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, 2011 and 2010 were approximately $12.2 million and $4.9 million, respectively, and we were obligated on September 30, 2011 and 2010, respectively, to pay royalties of approximately $1.8 million and $0.7 million to Sanofi-Aventis, which were included in Receivables and Accounts Payable on the accompanying Condensed Consolidated Balance Sheets.

6. Warrant Liability

In March 2011, we issued warrants in connection with a financing agreement with several entities affiliated with Deerfield (see Note 5). The terms of the warrants require shares to be delivered upon the warrant s exercise and also require possible cash payments to the warrant holders upon the occurrence of specified major transactions involving our common stock, such as an acquisition of our company. Under appropriate accounting guidance, our potential obligation to cash-settle the warrants if specified major transactions occur is at the option of the holder. As a result, the warrants were classified as liabilities. The fair value of these warrants was $4.7 million at September 30, 2011 and has been estimated based on a Binomial Lattice Option Pricing Model. Changes in the fair value of the warrant liability between the initial valuation and the quarter ending September 30, 2011 were recorded accompanying in the Condensed Consolidated Statements of Operations at the end of the third quarter.

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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 and other agencies, the impact of competitive products, product development, commercialization and technological difficulties, the Company s 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 the first quarter of 2010, and also further develop and potentially commercialize an injectable form of the drug, known as a depot formulation (currently in Phase I/II clinical testing). We are entitled to a royalty of 8-10% of net sales (including a royalty of 2.5% of net sales that is owed to a third party) 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 upon approval of pediatric indication. 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 potential royalties on any future sales in such markets are not expected to be significant. Following is a list of the remaining countries outside the U.S. where the Sanofi-Aventis patents claiming the compound iloperidone still provide patent protection:

Lichtenstein	November 2012
Georgia	November 2012
Korea	July 2013
Philippines	May 2014

We do not incur any ongoing expenses associated with this product.

Probuphine: A slow release implant formulation of buprenorphine in the final stages of Phase 3 clinical development for the treatment of opioid addiction that is capable of maintaining around the clock stable blood level of the drug in patients for six months following a single treatment. In July 2011, we announced positive top-line safety and efficacy results of this product from a confirmatory Phase 3 study. This study was partially funded through a $7.6 million grant from the National Institutes of Health (NIH) and was conducted at 20 U.S. sites. We have previously announced positive safety and efficacy results of this product in other Phase 3 studies including a placebo-controlled Phase 3 study completed in the summer of 2008, with results published in the Journal of the American Medical Association (JAMA), October 2010. We met with the FDA on October 25, 2011 for a Pre-New Drug Application (Pre-NDA) meeting regarding Probuphine. Based upon this meeting, we believe that our Phase 3 clinical program completed to date is acceptable to the FDA to support submission of an NDA via the 505(b)(2) pathway and that no additional clinical efficacy or safety studies are required to support the submission. We also received clear guidance from the FDA on the

requirements for submitting an NDA for consideration to be designated as a Priority Review. We have received initial comments from the FDA regarding manufacturing and non-clinical information and are in ongoing discussions with the agency to confirm these requirements. The global market for buprenorphine products was approximately $13 billion in 2010 and continues to grow. We are seeking to enter into one or more partnership arrangements with appropriate pharmaceutical companies to potentially commercialize Probuphine.

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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. In August 2010, we were awarded a two year $0.5 million grant by the NIH under the Small Business Innovation Research (SBIR) program to conduct non-clinical studies in a model of Parkinson s disease using previously approved dopamine agonists and the ProNeura drug delivery technology. The non-clinical studies are in progress and the NIH has approved funding for the second year of the grant. Results of this study are expected during the first half of 2012. We have also licensed certain rights from the University of Iowa to potentially use gallium maltolate for the treatment of chronic bacterial infections.

Recent Accounting Pronouncements

See Note 1 to the accompanying unaudited condensed consolidated 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, 2011 and September 30, 2010

Our net loss for the three month period ended September 30, 2011 was approximately $0.8 million, or approximately $0.01 per share, compared to our net loss of approximately $0.4 million, or approximately $0.01 per share, for the comparable period in 2010. Our net loss for the nine month period ended September 30, 2011 was approximately $12.3 million, or approximately $0.21 per share, compared to our net loss of approximately $2.5 million, or approximately $0.04 per share, for the comparable period in 2010.

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. 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 earned grant revenues during the three and nine month periods ended September 30, 2011 of approximately $39,000 and $0.4 million, respectively. We earned grant revenues during the three and nine month periods ended September 30, 2010 of approximately $3.2 million and $5.3 million, respectively. We generated no revenues from licensing agreements during the three and nine month periods ended September 30, 2011. We generated revenues from licensing agreements during the three and nine month periods ended September 30, 2010 of approximately $1,000 and $12,000, respectively. Royalty revenues during the three and nine month periods ended September 30, 2011 consisted of royalties on sales of Fanapt. Grant revenues during the three and nine month periods ended September 30, 2011 consisted of proceeds from the NIH grants related to our Probuphine and ProNeura programs.

Research and development expenses for the three month period ended September 30, 2011 were approximately $2.2 million, compared to approximately $3.0 million for the comparable period in 2010, a decrease of $0.8 million, or 27%. Research and development expenses for the nine month period ended September 30, 2011 were approximately $9.9 million, compared to approximately $6.8 million for the comparable period in 2010, an increase of $3.1 million, or 46%. The decrease in research and development costs during the three month period ended September 30, 2011 was primarily associated with a decrease in external research and development expenses resulting from the conclusion of one of our Phase 3 clinical trials related to our Probuphine product. The increase in research and development costs during the nine month period ended September 30, 2011 was primarily associated with an increase in external research and development expenses during the first six months of 2011 associated with the completion of one Phase 3 clinical trial related to our Probuphine product in the second quarter of 2011 and the ongoing enrollment and treatment of patients in an additional Phase 3 clinical trial related to our Probuphine product which will be completed in the fourth quarter 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, 2011, external research and development expenses relating to our Probuphine product development program were approximately $1.3 million and $7.4 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, 2011 and 2010 were approximately $0.7 million in both periods. General and administrative expenses for the nine month period ended September 30, 2011 were approximately $2.5 million, compared to approximately $2.6 million for the comparable period in 2010, a decrease of $0.1 million, or 4%. The decrease in general and administrative expenses during the nine month period ended September 30, 2011 was primarily related to decreases in consulting and professional fees of approximately $0.3 million and legal fees of approximately $0.3 million. This was offset in part by increases in non-cash stock compensation costs of approximately $0.3 million and employee-related costs of $0.2 million.

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Net other income for the three month period ended September 30, 2011 was approximately $1.2 million, compared to net other expense of approximately $0.2 million in the comparable period in 2010. Net other expense for the nine month period ended September 30, 2011 was approximately $2.6 million compared to approximately $0.5 million in the comparable period in 2010. The net other income during the three month period ended September 30, 2011, was primarily related to a $2.4 million non-cash gain related to decreases in the fair value of the Deerfield warrants. This was offset in part by interest expense of approximately $1.2 million on the Deerfield loans. The increase in net other expense during the nine month period ended September 30, 2011 was primarily related to interest expense of approximately $2.3 million on the Deerfield loans and $0.7 million of interest expense related to the Oxford loans. This was offset in part by a $0.8 million non-cash gain related to decreases in the fair value of the Deerfield warrants.

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, 2011, we had working capital of approximately $0.1 million compared to a working capital deficit of approximately $0.7 million at December 31, 2010.

Our operating activities used approximately $12.3 million during the nine months ended September 30, 2011. This consisted primarily of the net loss for the period of approximately $12.3 million, $0.8 million related to non-cash gains on decreases in the fair value of warrants issued to Deerfield, $1.6 million related to increases in accounts receivable, which includes approximately $1.8 million which will have to be paid to Sanofi-Aventis for royalties earned on sales of Fanapt, and $0.6 million related to increases in prepaid expenses and other assets. This was offset in part by non-cash charges of approximately $0.8 million related to share-based compensation expenses, $1.3 million related to the amortization loan discounts, and approximately $0.8 million related to increases in accounts payable and other accrued liabilities. Uses of cash in operating activities were primarily to fund product development programs and administrative expenses. Our license agreements with Sanofi-Aventis and MIT 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 in investing activities of approximately $56,000 during the nine months ended September 30, 2011 consisted of approximately $58,000 related to purchases of equipment, which was offset in part by approximately $2,000 related to the disposal of equipment.

Net cash provided by financing activities of approximately $11.9 million during the nine month period ended September 30, 2011 consisted of approximately $19.5 million of net proceeds from the Deerfield transaction described below, which was offset by payments of approximately $7.6 million to repay our outstanding in debtedness to Oxford.

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 us. 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, payable quarterly, 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, in exchange for $3.0 million that was recorded as debt, 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.

On April 5, 2011, we used approximately $7.7 million of proceeds from the Deerfield funding to repay Oxford in full, including required final payments aggregating $480,000.

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We expect to continue to incur substantial additional operating losses from costs related to the continuation of product and technology development, clinical trials, the regulatory process, and administrative activities. We believe that our working capital at September 30, 2011, together with the revenues from royalties on the sale of Fanapt, is sufficient to sustain our planned operations to the end of the year. Because of a delay in our timeline that arose from an FDA requirement for inclusion of an additional primary analysis for the Phase 3 study, we need to raise additional financing during the fourth quarter of this year to fund our product development activities, and we will be required to obtain substantial funding to commercialize any products other than iloperidone 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.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

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

Item 4. Controls and Procedures

Disclosure Controls and Procedures

Our President, being our principal executive and principal 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 (Exchange Act) as of September 30, 2011, 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 Exchange Act) during the three months ended September 30, 2011 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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PART II

Item 1A. Risk Factors

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

Item 6. 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]
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 issued to Deerfield Management[13]
4.6	Registration Rights Agreement, dated as of March 15, 2011[13]
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[9]
10.5	Employment Agreement between the Registrant and Marc Rubin, dated May 16, 2009, as amended by agreement dated February 17, 2010[9]
10.6	Lease for the Registrant s facilities, amended as of October 1, 2004[6]
10.7	Amendments to lease for Registrant s facilities dated May 21, 2007 and March 12, 2009[9]
10.8*	License Agreement between the Registrant and Sanofi-Aventis SA effective as of December 31, 1996[7]
10.9*	Sublicense Agreement between the Registrant and Novartis Pharma AG dated November 20, 1997[8]
10.10*	License Agreement between the Registrant and the Massachusetts Institute of Technology dated September 28, 1995[1]
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[11]
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]

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No.	Description
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 Agreement, dated as of March 15, 2011 by and among the Company, Deerfield Private Design Fund II, L.P., Deerfield Special Situations Fund, L.P. and Deerfield TTNP Corporation[13]
10.20	Equity Option Agreement, dated as of March 15, 2011, by and among the Company, Deerfield TTNP Corporation, Deerfield Private Design International II, L.P., and Deerfield Special Situations Fund International Limited[13]
10.21	Royalty Repurchase Agreement, dated as of March 15, 2011, by and among the Company, Deerfield Private Design Fund II, L.P., and Deerfield Special Situations Fund, L.P. [13]
14	Code of Business Conduct and Ethics[14]
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
101.INS**	XBRL Instance Document
101.SCH**	XBRL Taxonomy Extension Schema Document
101.CAL**	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB**	XBRL Taxonomy Extension Label Linkbase Document
101.PRE**	XBRL Taxonomy Extension Presentation Linkbase Document

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 (File No. 000-27436).
10 Incorporated by reference from the Registrant s Current Report on Form 8-K dated June 16, 2010.
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 dated March 18, 2011.
14 Incorporated by reference from the Registrant s Annual Report on Form 10-K for the year ended December 31, 2003.
* 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.

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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 14, 2011

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