TITAN PHARMACEUTICALS INC
Form 10-Q
May 16, 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 March 31, 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 ¨ No ¨ *The registrant has not yet been phased into the interactive data requirements.

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

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company 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 59,247,742 shares of the Registrant s Common Stock issued and outstanding on May 11, 2011.

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Part I. Financial Information

Item 1. Financial Statements

TITAN PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands)

	March 31, 2011 (unaudited)	December 31, 2010 (Note 1)
Assets		
Current assets:		
Cash and cash equivalents	$ 800	$ 3,180
Receivables	2,155	1,225
Prepaid expenses and other current assets	220	294
Total current assets	3,175	4,699
Property and equipment, net	43	53
Total assets	$ 3,218	$ 4,752
Liabilities and Stockholders Deficit		
Current liabilities		
Accounts payable	$ 4,963	$ 2,457
Accrued clinical trials expenses	569	705
Other accrued liabilities	820	373
Current portion of long-term debt	2,362	1,870
Total current liabilities	8,714	5,405
Long-term debt, net of discount	4,930	5,400
Total liabilities	13,644	10,805
Commitments and contingencies		
Stockholders deficit		
Common stock, at amounts paid-in	256,436	256,436
Additional paid-in capital	17,395	17,256
Accumulated deficit	(284,257)	(279,745)
Total stockholders deficit	(10,426)	(6,053)
Total liabilities and stockholders deficit	$ 3,218	$ 4,752

See Notes to Condensed Consolidated Financial Statements

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TITAN PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share amount)

(unaudited)

	Three Months Ended March 31,	
	2011	**2010**
Revenues:		
Royalty revenue	$ 716	$ 1,653
Grant revenue	232	761
License revenue		11
Total revenue	948	2,425
Operating expenses:		
Research and development	3,738	1,670
General and administrative	793	935
Total operating expenses	4,531	2,605
Loss from operations	(3,583)	(180)
Other income (expense):		
Interest expense, net	(931)	(120)
Other income (expense)	2	(5)
Other income (expense), net	(929)	(125)
Net loss	$ (4,512)	$ (305)
Basic and diluted net loss per share	$ (0.08)	$ (0.01)
Weighted average shares used in computing basic and diluted net loss per share	59,248	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)

	Three Months Ended March 31,	
	2011	**2010**
Cash flows from operating activities:		
Net loss	$ (4,512)	$ (305)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	10	26
Amortization of loan discount	294	8
Stock-based compensation	139	137
Changes in operating assets and liabilities:		
Receivables	(930)	(5,448)
Prepaid expenses and other assets	74	45
Accounts payable and other accrued liabilities	2,817	3,884
Net cash used in operating activities	(2,108)	(1,653)
Cash flows from investing activities:		
Purchases of furniture and equipment		(4)
Net cash used in investing activities		(4)
Cash flows from financing activities:		
Payments on long-term debt	(272)	
Net cash used in financing activities	(272)	
Net decrease in cash and cash equivalents	(2,380)	(1,657)
Cash and cash equivalents at beginning of period	3,180	3,300
Cash and cash equivalents at end of period	$ 800	$ 1,643

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.

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

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

We are directly developing our product candidates and 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 significant economic interest in our products. We operate in only one business segment, the development of pharmaceutical products.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements include the accounts of Titan Pharmaceuticals, Inc. and its subsidiaries after elimination of all significant intercompany accounts and transactions. These financial statements have been prepared in accordance with U.S. generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by U.S. generally accepted accounting principles for 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 month period ended March 31, 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 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 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. generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

We expect to continue to incur substantial additional operating losses from costs related to the continuation of product and technology development, clinical trials, and administrative activities. We believe that our working capital at March 31, 2011, together with the revenues from royalties on the sale of Fanapt and the recent $20.0 million debt financing, is sufficient to sustain our planned operations into the first quarter of 2012.

We will need to seek additional financing sources 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. and Canada, and by Vanda Pharmaceuticals, Inc. in the rest of the world. As described in Note 5, Commitments and Contingencies, we are obligated to pay royalties on such sales to Sanofi-Aventis. As we have no performance obligations under the license agreements, we have recorded the royalties earned, net of royalties we are obligated to pay, as revenue in our consolidated statement of operations.

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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Recent Accounting Pronouncements

In April 2010, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update No. 2010-17 (ASU 2010-17), *Revenue Recognition Milestone Method*, which provides a new guidance on the use of the milestone method of recognizing revenue for research and development arrangements under which consideration to be received by the vendor is contingent upon the achievement of certain milestones. ASU 2010-17 is effective for fiscal years, and interim periods within such fiscal years, beginning on or after June 15, 2010, with early adoption permitted. We do not expect the adoption of this guidance to have a material impact on our consolidated financial statements.

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

Subsequent Events

We have evaluated events that have occurred after March 31, 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 month periods ended March 31, 2011 and 2010:

	Three Months Ended March 31,	
(in thousands, except per share amounts)	**2011**	**2010**
Research and development	$ 56	$ 14
General and administrative	83	123
Total share-based compensation expenses	$ 139	$ 137

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 month periods ended March 31, 2011 and 2010:

	Three Months Ended March 31,	
	2011	**2010**
Weighted-average risk-free interest rate	3.4%	2.3%
Expected dividend payments		
Expected holding period (years)[1]	9.2	4.2
Weighted-average volatility factor[2]	1.39	1.89
Estimated forfeiture rates for options granted to management[3]	23%	23%
Estimated forfeiture rates for options granted to non-management[3]	41%	41%

(1) Expected holding periods are based on historical data.

(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 period ended March 31, 2011. Based upon the above methodology, the weighted-average fair value of options and awards granted during the three month period ended March 31, 2010 was $2.24.

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The following table summarizes option activity for the three month period ended March 31, 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				
Exercised				
Expired or canceled	(72)	22.98		
Forfeited	(55)	1.77		
Outstanding at March 31, 2011	4,849	$ 2.01	6.63	$ 1,641
Exercisable at March 31, 2011	3,680	$ 2.31	6.13	$ 1,056

As of March 31, 2011 there was approximately $1.2 million of total unrecognized compensation expense related to non-vested stock options. This expense is expected to be recognized over a weighted-average period of 2.2 years.

No shares of restricted stock were awarded to employees, directors and consultants during the three month period ended March 31, 2011. The following table summarizes restricted stock activity for the three month period ended March 31, 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	$ 0.01	9.3	$ 167
Awarded				
Exercised				
Cancelled				
Outstanding at March 31, 2011	139	$ 0.01	9.0	$ 205
Vested at March 31, 2011	138	$ 0.01	9.0	$ 203

As of March 31, 2011 there was approximately $1,000 of total unrecognized compensation expense related to non-vested awards. This expense is expected to be recognized over a weighted-average period of 0.5 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 March 31, 2011 and 2010, options and warrants totaled 18.0 million and 13.0 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 month periods ended March 31, 2011 and 2010 were $4.5 million and $0.3 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 the Company. A portion of the proceeds will be used to repay the Company s outstanding indebtedness to Oxford Capital Financing (Oxford). Pursuant to the terms of a facility agreement, we will issue promissory notes to Deerfield 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 will pay 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

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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 agreements were not funded until April 5, 2011, and were not included in the Condensed Consolidated Balance Sheet as of March 31, 2011.

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

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

Royalty Payments

In 1997, we entered into an exclusive license agreement with Sanofi-Aventis SA (formerly Hoechst Marion Roussel, Inc.). The agreement gave us a worldwide license to the patent rights and know-how related to the antipsychotic agent Fanapt (iloperidone), including the ability to develop, use, sublicense, manufacture and sell products and processes claimed in the patent rights. Upon commercialization of the product, the license agreement provides that we will pay royalties based on net sales. Net sales of Fanapt by Novartis during the three month periods ended March 31, 2011 and 2010 were approximately $8.9 million and $20.7 million, respectively, and we are obligated to pay royalties of approximately $1.3 million and $3.1 million to Sanofi-Aventis on March 31, 2011 and 2010, respectively, which were included in Accounts Receivable and Accounts Payable on the Condensed Consolidated Balance Sheets.

6. Subsequent Events

Financing Agreements

On April 5, 2011, we completed our transactions with Deerfield providing $20.0 million in funding to the Company. We used $7.7 million of the proceeds to repay the Company s outstanding indebtedness to Oxford. Pursuant to the terms of a facility agreement, we issued promissory notes to Deerfield in the aggregate principal amount of $20.0 million and paid Deerfield a facility fee of $500,000 on April 5, 2011.

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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 (FDA) 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 Securities and 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.

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 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 royalties on any future sales in such markets will generally be limited. We will review the potential of any royalty revenue on a country by country basis at the time of application for approval of the product. Following is a list of the remaining countries where the Sanofi-Aventis patents claiming the compound iloperidone still provide patent protection:

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

Probuphine: A slow release implant formulation of buprenorphine in Phase 3 clinical development for the treatment of opioid addiction that is capable of maintaining around the clock stable blood level of the drug in patients for six months following a single treatment. We have previously announced positive safety and efficacy results of this product in Phase 3 studies including a placebo-controlled Phase 3 study. In October 2009, we were awarded a $7.6 million grant from the National Institutes of Health (NIH) that covers approximately half of the expenses of the second Phase 3 controlled safety and efficacy study currently in progress. The confirmatory Phase 3 study is being conducted at 20 U.S. sites and completed patient enrollment in September 2010, almost three months ahead of schedule. The study results are expected in late second quarter 2011. Following availability of results we will review all the efficacy and safety data with the FDA during the third quarter 2011 and discuss the FDA requirements and NDA submission plans.

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 $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 results are expected by year end 2011. We have also licensed certain rights from the University of Iowa to potentially use gallium maltolate for the treatment of chronic bacterial infections.

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Our Products

Fanapt

Fanapt (Iloperidone), a mixed dopamine D2 / serotonin 5HT2A receptor antagonist, is a novel, atypical antipsychotic approved in the U.S. on May 6, 2009 for the treatment of adult patients with schizophrenia. The Phase 3 clinical development was conducted initially by our sub-licensee, Novartis, and completed by Novartis sub-licensee, Vanda. In July 2008, Vanda received a non-approval letter from the FDA requesting additional information about the product. Vanda addressed the questions asked by the FDA and provided additional clarification following which the FDA granted marketing approval as noted above. The approval was supported by two placebo-controlled Phase 3 clinical studies comparing Fanapt to placebo and active control in patients with schizophrenia, as well as safety data from more than 3,000 patients. Novartis reacquired rights to commercialize Fanapt in the U.S. and Canada and the development of a depot formulation will also be pursued by Novartis. Vanda has commercialization rights for the rest of the world for the oral formulation and the depot formulations, although Novartis has the first option to negotiate an agreement to co-market both of these products in the rest of the world. Based on the terms of our sub-license agreement with Novartis we are entitled to royalty revenue of 8% of annual worldwide net sales of Fanapt up to $200 million and 10% of annual worldwide net sales above $200 million (a portion of which must be paid to Deerfield). We do not incur any expenses associated with this product.

Probuphine

Probuphine is 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. The compound buprenorphine is already approved in the US and elsewhere for the treatment of opioid addiction as a sub-lingual formulation and for the treatment of pain as a trans-dermal patch and an injection. Probuphine is currently in Phase 3 clinical development for the treatment of opioid addiction and has completed three Phase 3 studies, including one controlled Phase 3 study demonstrating initial efficacy of the product. The safety of Probuphine and the implant procedure has also been preliminarily demonstrated in these clinical studies. In 2009, Titan was awarded a $7.6 million grant by the NIH in partial support of the second controlled Phase 3 study, the total external cost of which is estimated at approximately $14.6 million. This confirmatory study is currently in progress with top-line results expected late in the second quarter of 2011. Completion of additional clinical and manufacturing development is necessary prior to filing for approval which includes third party manufacturing development and testing, and a long term safety study (one year treatment) all of which are currently in progress. However, it should be recognized that Probuphine may still not be successfully developed and may require additional capital for clinical studies, if any, which may be required by the FDA. We may experience unanticipated problems relating to product development and cannot predict whether we will successfully develop and commercialize any products.

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

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 Months Ended March 31, 2011 and March 31, 2010

Our net loss for the three month period ended March 31, 2011 was approximately $4.5 million, or approximately $0.08 per share, compared to our net loss of approximately $0.3 million, or approximately $0.01 per share, for the comparable period in 2010.

We generated royalty revenues during the three month period ended March 31, 2011 of approximately $0.7 million, compared to approximately $1.7 million for the comparable period in 2010. We generated grant revenues during the three month period ended March 31, 2011 of approximately $0.2 million, compared to approximately $0.8 million for the comparable period in 2010. We generated no revenues from licensing agreements during the three month period ended March 31, 2011, compared to approximately $11,000 for the comparable period in 2010. Royalty revenues during the three month periods ended March 31, 2011 and 2010 consisted of royalties on sales of Fanapt. Grant revenues during the three month periods ended March 31, 2011 and 2010 consisted of proceeds from the NIH grants related to our Probuphine and ProNeura programs.

Research and development expenses for the three month period ended March 31, 2011 were approximately $3.7 million, compared to approximately $1.7 million for the comparable period in 2010, an increase of $2.0 million, or 118%. The increase in research and development costs during the three month period ended March 31, 2011 was primarily associated with an increase in costs related to the continuation of planned clinical trials of our Probuphine product. External research and development expenses include direct expenses such as clinical research organization charges, investigator and review board fees, patient expense reimbursements and contract manufacturing expenses. In the first quarter of 2011, our external research and development expenses

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relating to our Probuphine product development program were approximately $2.9 million. 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 March 31, 2011 were approximately $0.8 million, compared to approximately $0.9 million for the comparable period in 2010, a decrease of $0.1 million, or 11%. The decrease in general and administrative expenses during the three month period ended March 31, 2011 was primarily related to decreases in consulting and professional fees of approximately $0.2 million. This was offset in part by increases in legal fees of approximately $0.1 million.

Net other expense for the three month period ended March 31, 2011 was approximately $0.9 million compared to net other expense of approximately $0.1 million in the comparable period in 2010. The increase in net other expense during the three month period ended March 31, 2011 was related to interest expense of approximately $0.8 million resulting from our loan with Oxford.

Liquidity and Capital Resources

We have funded our operations since inception primarily through sales of our securities, as well as with proceeds from warrant and option exercises, corporate licensing and collaborative agreements, and government-sponsored research grants. At March 31, 2011, we had approximately $0.8 million of cash and cash equivalents compared to approximately $3.2 million at December 31, 2010. At March 31, 2011, we had a working capital deficit of approximately $5.5 million compared to a working capital deficit of approximately $0.7 million at December 31, 2010.

Our operating activities used approximately $2.1 million during the three months ended March 31, 2011. This consisted primarily of the net loss for the period of approximately $4.5 million and $0.9 million related to increases in accounts receivable, which includes approximately $1.3 million that will have to be paid to Sanofi-Aventis for royalties earned on sales of Fanapt. This was offset in part by non-cash charges of approximately $0.1 million related to share-based compensation expenses, approximately $2.9 million related to net changes in other operating assets and liabilities, and $0.3 million related to the amortization of the Oxford loan discount. 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 $50,000.

No cash was used in or provided by investing activities during the three months ended March 31, 2011.

Net cash used by financing activities of approximately $0.3 million during the three months ended March 31, 2011 consisted of payments on our existing term loans.

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.

We expect to continue to incur substantial additional operating losses from costs related to the continuation of product and technology development, clinical trials, and administrative activities. We believe that our working capital at March 31, 2011, together with the revenues from royalties on the sale of Fanapt and the $20.0 million debt financing, is sufficient to sustain our planned operations into the first quarter of

2012.

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Item 3. Quantitative and Qualitative Disclosures About Market Risk

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

Item 4T. Controls and Procedures

Disclosure Controls and Procedures

Our President, being our principal executive and financial officer, has evaluated the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934 as of March 31, 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 Securities Exchange Act of 1934) during the three months ended March 31, 2011 that have materially affected, or are reasonably likely to materially affect, the Company s internal control over financial reporting.

PART II

Item 1A. Risk Factors

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

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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]
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[8]
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[10]
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 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]

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No.	Description
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

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.

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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: May 16, 2011

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