

TITAN PHARMACEUTICALS INC  
Form 10-Q  
November 14, 2013

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

**FORM 10-Q**

**Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

**For the quarterly period ended September 30, 2013.**

**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**  
**(State or Other Jurisdiction of  
Incorporation or Organization)**

**94-3171940**  
**(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 Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

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

Edgar Filing: TITAN PHARMACEUTICALS INC - Form 10-Q

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

Large accelerated filer  Accelerated filer   
Non-accelerated filer  (Do not check if a smaller reporting company) Smaller reporting company

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

There were 82,544,222 shares of the Registrant’s Common Stock issued and outstanding on November 8, 2013.

**Titan Pharmaceuticals, Inc.**

**Index to Form 10-Q**

**Part I. Financial Information**

Item 1.	Financial Statements and notes (unaudited)	3
	Condensed Balance Sheets as of September 30, 2013 and December 31, 2012	3
	Condensed Statements of Operations and Comprehensive Income (Loss) for the three and nine months ended September 30, 2013 and 2012	4
	Condensed Statements of Cash Flows for the nine months ended September 30, 2013 and 2012	5
	Notes to Condensed Financial Statements	6
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	15
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	18
Item 4.	Controls and Procedures	18

**Part II. Other Information**

Item 1A.	Risk Factors	19
Item 5.	Exhibits	19
<b>SIGNATURES</b>		<b>22</b>

## Part I. Financial Information

## Item 1. Financial Statements

## TITAN PHARMACEUTICALS, INC.

## CONDENSED BALANCE SHEETS

(in thousands)

	September 30, 2013 (unaudited)	December 31, 2012 (Note 1)
Assets		
Current assets:		
Cash	\$ 8,998	\$ 18,102
Receivables	4,590	4,646
Prepaid expenses and other current assets	262	687
Total current assets	13,850	23,435
Property and equipment, net	1,670	1,392
Total assets	\$ 15,520	\$ 24,827
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	\$ 5,293	\$ 3,767
Accrued clinical trials expenses	423	532
Other accrued liabilities	306	219
Deferred contract revenue	6,228	14,375
Current portion of long-term debt, net of discount		2,500
Total current liabilities	12,250	21,393
Warrant liabilities	2,248	8,240
Royalty liability		8,962
Long-term debt, net of discount		9,360
Total liabilities	14,498	47,955
Commitments and contingencies		
Stockholders' deficit:		
Common stock, at amounts paid-in	279,560	265,986
Additional paid-in capital	21,670	21,014
Accumulated deficit	(300,208)	(310,128)
Total stockholders' equity (deficit)	1,022	(23,128)
Total liabilities and stockholders' equity (deficit)	\$ 15,520	\$ 24,827

See Notes to Condensed Financial Statements

## TITAN PHARMACEUTICALS, INC.

**CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)**  
**(in thousands, except per share amount)**  
**(unaudited)**

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Revenues:				
License revenue	\$ 2,198	\$	\$ 8,146	\$
Royalty revenue		1,228	1,424	3,816
Grant revenue				42
Total revenue	2,198	1,228	9,570	3,858
Operating expenses:				
Research and development	1,679	2,995	7,380	8,037
General and administrative	647	890	2,439	3,750
Total operating expenses	2,326	3,885	9,819	11,787
Loss from operations	(128)	(2,657)	(249)	(7,929)
Other income (expense):				
Interest expense, net		(1,634)	(1,568)	(5,095)
Other income (expense), net	(7)	(49)	10,431	(143)
Non-cash gain (loss) on changes in the fair value of warrants	(1,010)	(3,673)	1,306	(1,734)
Other income (expense), net	(1,017)	(5,356)	10,169	(6,972)
Net income (loss) and comprehensive income (loss)	\$ (1,145)	\$ (8,013)	\$ 9,920	\$ (14,901)
Basic net income (loss) per common share	\$ (0.01)	\$ (0.12)	\$ 0.12	\$ (0.23)
Diluted net income (loss) per common share	\$ (0.00)	\$ (0.07)	\$ 0.11	\$ (0.19)
Weighted average shares used in computing basic net income	82,544	66,839	81,125	63,748
(loss) per common share				
Weighted average shares used in computing diluted net income	82,544	66,839	81,832	70,189
(loss) per common share				

See Notes to Condensed Financial Statements

## TITAN PHARMACEUTICALS, INC.

**CONDENSED STATEMENTS OF CASH FLOWS**  
**(in thousands)**  
**(unaudited)**

	Nine months Ended September 30, 2013	2012
Cash flows from operating activities:		
Net income (loss)	\$ 9,920	\$ (14,901)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and amortization	19	13
Non-cash gain on settlement of long-term debt	(1,860)	
Non-cash gain on termination of royalty purchase agreement	(8,962)	
Interest on royalty liability		778
Non-cash gain (loss) on changes in fair value of warrants	(1,306)	1,734
Stock-based compensation	656	2,233
Changes in operating assets and liabilities:		
Receivables	56	190
Prepaid expenses and other assets	425	48
Accounts payable and other accrued liabilities	1,504	639
Deferred contract revenue	(8,147)	1,700
Net cash used in operating activities	(7,695)	(7,566)
Cash flows from investing activities:		
Purchases of furniture and equipment	(297)	(1,122)
Net cash used in investing activities	(297)	(1,122)
Cash flows from financing activities:		
Proceeds from issuing common stock from the exercise of stock options	113	
Proceeds from the exercise of warrants, net of issuance costs	1,275	963
Proceeds from issuing common stock and warrants, net of issuance costs		7,516
Payments on long-term debt	(2,500)	(135)
Net cash provided by (used in) financing activities	(1,112)	8,344
Net decrease in cash and cash equivalents	(9,104)	(344)
Cash and cash equivalents at beginning of period	18,102	5,406
Cash and cash equivalents at end of period	\$ 8,998	\$ 5,062

See Notes to Condensed Financial Statements

TITAN PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS  
(unaudited)

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

*The Company*

We are a biopharmaceutical company developing proprietary therapeutics for the treatment of serious medical disorders. Our product development programs focus primarily on important pharmaceutical markets with significant unmet medical needs and commercial potential. We are directly developing our product candidates and also utilize corporate, academic and government partnerships as appropriate. Our principal asset is Probuphine®, the first slow release implant formulation of buprenorphine in development for the treatment of opioid dependence. It is designed to maintain a stable, around the clock blood level of the medicine in patients for six months following a single treatment. We operate in only one business segment, the development of pharmaceutical products.

*Basis of Presentation*

The accompanying unaudited condensed 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, 2013 are not necessarily indicative of the results that may be expected for the year ending December 31, 2013, or any future interim periods.

The balance sheet at December 31, 2012 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. GAAP for complete financial statements. These unaudited condensed financial statements should be read in conjunction with the audited financial statements and footnotes thereto included in the Titan Pharmaceuticals, Inc. Annual Report on Form 10-K/A for the year ended December 31, 2012, 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.

The accompanying financial statements have been prepared assuming we will continue as a going concern. We believe that our working capital at September 30, 2013, together with the \$5.0 million in proceeds from the sale of common stock to our licensee, Braeburn Pharmaceuticals Sprl (“Braeburn”), under a recent agreement, is sufficient to fund our planned operations into January 2015, inclusive of estimated expenses for preparation of our response to the Complete Response Letter (“CRL”) regarding the Probuphine New Drug Application (“NDA”) that we received from the U.S. Food and Drug Administration (“FDA”). We have a meeting scheduled for November 19, 2013 with the FDA, and briefing material addressing the issues raised in the CRL have been submitted in preparation for this meeting. The goal of the meeting is to achieve clarity on next steps and to determine the appropriate timing of the submission of our response to the CRL, which should help determine the nature, timing and extent of our requirements for additional capital. If Braeburn were to terminate the license agreement, we would not have sufficient funds available to us to complete the FDA regulatory process and, in the event of ultimate approval, commercialize Probuphine without raising additional capital. If we are unable to complete a debt or equity offering, or otherwise obtain sufficient financing in such event, our business and prospects would be materially adversely impacted. Furthermore, in the event

of termination or any substantial reduction in the milestone payment payable to us if the FDA ultimately approves Probuphine, we may be unable to continue our current Parkinson's disease development program and would not be able to initiate any additional programs without obtaining additional financing, either through the sale of debt or equity securities.

***Revenue Recognition***

We generate revenue principally from collaborative research and development arrangements, technology licenses, and government grants. Consideration received for revenue arrangements with multiple components is allocated among the separate units of accounting based on their respective selling prices. The selling price for each unit is based on vendor-specific objective evidence, or VSOE, if available, third party evidence if VSOE is not available, or estimated selling price if neither VSOE nor third party evidence is available. The applicable revenue recognition criteria are then applied to each of the units.



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

- Technology license agreements typically consist of non-refundable upfront license fees, annual minimum access fees or royalty payments. Non-refundable upfront license fees and annual minimum payments received with separable stand-alone values are recognized when the technology is transferred or accessed, provided that the technology transferred or accessed is not dependent on the outcome of our continuing research and development efforts.
- Government grants, which support our research efforts in specific projects, generally provide for reimbursement of approved costs as defined in the notices of grants. Grant revenue is recognized when associated project costs are incurred.
- Royalties earned are based on third-party sales of licensed products and are recorded in accordance with contract terms when third-party results are reliably measurable and collectability is reasonably assured. Pursuant to certain license agreements, we earn royalties on the sale of Fanapt by Novartis Pharma AG in the U.S. As described in Note 6, “Commitments and Contingencies”, we are obligated to pay royalties on such sales to Sanofi-Aventis and the Deerfield Healthcare group of entities (“Deerfield”). As we had no performance obligations under the license agreements, we recorded the royalties earned, net of royalties we were obligated to pay to Sanofi-Aventis, as revenue in our Condensed Statements of Operations and Comprehensive Income (Loss). On March 28, 2013, we amended the agreements with Deerfield terminating our option to repurchase the royalty rights. As a result, we will no longer recognize royalty income related to the Fanapt royalty payments received from Novartis unless Fanapt sales exceed certain thresholds (see Note 7, “Royalty Liability” for further discussion).
- Collaborative arrangements typically consist of non-refundable and/or exclusive technology access fees, cost reimbursements for specific research and development spending, and various milestone and future product royalty payments. If the delivered technology does not have stand-alone value, the amount of revenue allocable to the delivered technology is deferred. Non-refundable upfront fees with stand-alone value that are not dependent on future performance under these agreements are recognized as revenue when received, and are deferred if we have continuing performance obligations and have no evidence of fair value of those obligations. Cost reimbursements for research and development spending are recognized when the related costs are incurred and when collectability is reasonably assured. Payments received related to substantive, performance-based “at-risk” milestones are recognized as revenue upon achievement of the clinical success or regulatory event specified in the underlying contracts, which represent the culmination of the earnings process. Amounts received in advance are recorded as deferred revenue until the technology is transferred, costs are incurred, or a milestone is reached.

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

Research and development expenses include internal and external costs. Internal costs include salaries and employment related expenses, facility costs, administrative expenses and allocations of corporate costs. External expenses consist of costs associated with outsourced clinical research organization activities, sponsored research studies, product registration, patent application and prosecution, and investigator sponsored trials. We 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.

### ***Recent Accounting Pronouncements***

In July 2013, the FASB issued ASU No. 2013-11, *Income Taxes (Topic 740): Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists*, providing guidance on the presentation of unrecognized tax benefits in the financial statements as either a reduction to a deferred tax asset or either a liability to better reflect the manner in which an entity would settle at the reporting date any additional income taxes that would result from the disallowance of a tax position when net operating loss carryforwards, similar tax losses or tax credit carryforwards exist. The amendments in this ASU do not require new recurring disclosures. The amendments in this ASU are effective for fiscal years, and interim periods within those years, beginning after December 15, 2013. The amendments in this ASU should be applied prospectively to all unrecognized tax benefits that exist at the effective date. We do not expect the adoption of the amendments in this ASU will have a significant impact on our financial statements.

### ***Subsequent Events***

We have evaluated events that have occurred after September 30, 2013 and through the date that the financial statements are issued.

### ***Fair Value Measurements***

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

- Level 1 quoted prices in active markets for identical assets or liabilities
- Level 2 quoted prices for similar assets and liabilities in active markets or inputs that are observable;
- Level 3 inputs that are unobservable (for example cash flow modeling inputs based on assumptions).

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

As a result of the fair value adjustment of the warrant liabilities, for the three months ended September 30, 2013, we recorded a non-cash loss on an increase in the fair value of \$1.0 million and for the nine months ended September 30, 2013, we recorded a non-cash gain on an decrease in the fair value of \$1.3 million, in our Condensed Statements of Operations and Comprehensive Income (Loss). See Note 8, "Warrant Liability" for further discussion on the calculation of the fair value of the warrant liabilities.

(in thousands)	Warrant liability
Total warrant liability at December 31, 2012	\$ 8,240
Fair value of warrants transferred to equity upon exercise	(4,686)
Adjustment to record warrants at fair value upon exercise and at September 30, 2013	(1,306)
Total warrant liability at September 30, 2013	\$ 2,248

## 2. Stock Plans

The following table summarizes the stock-based compensation expense recorded for awards under the stock option plans for the three and nine month periods ended September 30, 2013 and 2012:

(in thousands, except per share amounts)	Three Months Ended September 30,		Nine months Ended September 30,	
	2013	2012	2013	2012
Research and development	\$ 11	\$ 148	\$ 367	\$ 878
General and administrative	10	217	289	1,355
Total stock-based compensation expenses	\$ 21	\$ 365	\$ 656	\$ 2,233

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

We use the Black-Scholes-Merton option-pricing model with the following assumptions to estimate the stock-based compensation expense for the three and nine month periods ended September 30, 2013 and 2012:

	Three Months Ended September 30,		Nine months Ended September 30,			
	2013	2012	2013		2012	
Weighted-average risk-free interest rate	0.9	%	0.9	%	0.9	%
Expected dividend payments						

Edgar Filing: TITAN PHARMACEUTICALS INC - Form 10-Q

Expected holding period (years) <sup>1</sup>	3.8		5.1		4.0		5.1	
Weighted-average volatility factor <sup>2</sup>	1.05		1.74		1.48		1.74	
Estimated forfeiture rates for options granted to management <sup>3</sup>	23	%	23	%	23	%	23	%
Estimated forfeiture rates for options granted to non-management <sup>3</sup>	41	%	41	%	41	%	41	%

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

No options were granted during the three month periods ended September 30, 2013 and 2012.

The following table summarizes option activity for the nine month period ended September 30, 2013:

(in thousands, except per share amounts)	Options	Weighted Average Exercise Price	Weighted Average Remaining Option Term	Aggregate Intrinsic Value
Outstanding at January 1, 2013	6,842	\$ 1.33	6.65	\$ 722
Granted				
Exercised	(75)	1.50		
Expired or cancelled				
Forfeited				
Outstanding at September 30, 2013	6,767	\$ 1.32	5.97	\$
Exercisable at September 30, 2013	6,753	\$ 1.32	5.97	\$

As of September 30, 2013, there was approximately \$24,000 of total unrecognized compensation expense related to non-vested stock options. This expense is expected to be recognized over a weighted-average period of 0.4 years.

No shares of restricted stock were awarded to employees, directors and consultants during the three and nine month periods ended September 30, 2013.

### 3. Net Income (Loss) Per Share

Basic net income (loss) per share excludes the effect of dilution and is computed by dividing net income (loss) by the weighted-average number of shares outstanding for the period. Diluted net income (loss) per share reflects the potential dilution that could occur if securities or other contracts to issue shares were exercised into shares. In calculating diluted net income (loss) per share, the numerator is adjusted for the change in the fair value of the warrant liability (only if dilutive) and the denominator is increased to include the number of potentially dilutive common shares assumed to be outstanding during the period using the treasury stock method.

Edgar Filing: TITAN PHARMACEUTICALS INC - Form 10-Q

The following table sets forth the reconciliation of the numerator and denominator used in the computation of basic and diluted net income (loss) per common share for the three and nine months ended September 30, 2013 and 2012:

(in thousands, except per share amounts)	Three months ended September 30,		Nine months ended September 30,	
	2013	2012	2013	2012
Numerator:				
Net income (loss) used for basic earnings per share	\$ (1,145)	\$ (5,356)	\$ 9,920	\$ (14,901)
Less change in fair value of warrant liability	(1,010)	(3,673)	1,306	(1,734)
Net (loss) income used for diluted earnings per share	\$ (135)	\$ (1,683)	\$ 8,614	\$ (13,167)
Denominator:				
Basic weighted-average outstanding common shares	82,544	66,839	81,125	63,748
Effect of dilutive potential common shares resulting from options			624	78
Effect of dilutive potential common shares resulting from warrants			83	6,363
Weighted-average shares outstanding diluted	82,544	64,839	81,832	70,189
Net income (loss) per common share:				
Basic	\$ (0.01)	\$ (0.12)	\$ 0.12	\$ (0.23)
Diluted	\$ (0.00)	\$ (0.07)	\$ 0.11	\$ (0.19)

The table below presents common shares underlying stock options and warrants that are excluded from the calculation of the weighted average number of common shares outstanding used for the calculation of diluted net income (loss) per common share. These are excluded from the calculation due to their anti-dilutive effect for the three and nine months ended September 30, 2013 and 2012:

(in thousands)	Three months ended September 30,		Nine months ended September 30,	
	2013	2012	2013	2012
Weighted-average anti-dilutive common shares resulting from options	6,767	6,397	2,141	4,555
Weighted-average anti-dilutive common shares resulting from warrants	5,016	10,239	234	6,127
	11,783	16,636	2,375	10,682

#### 4. Comprehensive Income (Loss)

Comprehensive income and loss for the periods presented is comprised solely of our net income and loss. We had no items of other comprehensive income (loss) during the three and nine-month periods ended September 30, 2013 and 2012. Comprehensive loss for the three-month period ended September 30, 2013 was \$1.1 million. Comprehensive income for the nine-month period ended September 30, 2013 was \$9.9 million. Comprehensive loss for the three and nine-month periods ended September 30, 2012 was \$8.0 million and \$14.9 million, respectively.

## **5. Braeburn License**

In December 2012, we entered into a license agreement with Braeburn (the “Agreement”) granting Braeburn exclusive commercialization rights to Probuphine in the United States and Canada (the “Territory”), which was amended in November 2013 (See Note 10, “Subsequent Events”). As part of the Agreement, we received a non-refundable up-front license fee of \$15.75 million (approximately \$15.0 million, net of expenses). Additionally, we are entitled to receive a milestone payment upon approval by the FDA of the Probuphine NDA, sales and regulatory milestone payments and tiered royalties based on a percentage of net sales of Probuphine ranging from the mid-teens to the low twenties.

We have evaluated the revenue components of the Agreement, which includes multiple elements, to determine whether the components of the arrangement represent separate units of accounting.

We have determined that the non-refundable, up-front license fee of \$15.75 million (approximately \$15.0 million, net of expenses) and our costs up to the PDUFA date to be one deliverable which will be accounted for as a single unit of accounting. This amount will be recognized on a straight-line basis over the estimated period to reach the PDUFA date and meet the contract deliverables, including the transition of production and supply services of the product to Braeburn. Accordingly, we currently estimate the revenue recognition period for the up-front payment to be approximately 18 months from the date of the Agreement. Accordingly, we will recognize revenue for the up-front payment from December 14, 2012, the date of the Agreement, through June 14, 2014. As of September 30, 2013, we have recognized approximately \$8.8 million in license revenue and recorded deferred revenues of \$6.2 million related to the up-front payment. Internal and external research and development costs related to this product will be expensed in the period incurred.

Under the Agreement, as amended, we are entitled to a \$15.0 million milestone payment from Braeburn within 10 days following the achievement of FDA approval of the NDA (See Note 10, "Subsequent Events"). As such, upon receipt of FDA approval our obligation will be fulfilled. As the milestone payment relates solely to past performance, i.e. FDA approval, we will recognize this regulatory milestone payment from Braeburn on the date of achievement of FDA approval in accordance with the milestone method of revenue recognition. Following FDA approval, we will be reimbursed by Braeburn for any development services and activities performed by us at Braeburn's request.

The Agreement also provides for a development committee. The duties of the development committee are to periodically report to each other, exchange information, and confer with and review the clinical development of the product and matters pertaining to regulatory approval. The development committee has no authority to approve or direct either party to take action, approve or withhold approval for any plan, budget, timeline or strategies, amend, modify or waive compliance with the license agreement, create new obligations or alter, increase or expand, or waive compliance with the license agreement, create new obligations not specified in the license agreement, or alter, increase or expand, or waive compliance by a party with obligations under the license agreement. The development committee can be disbanded upon mutual agreement of the parties and shall automatically disband six years after the NDA transfer date. Based on the above, we have determined that participation in the development committee is perfunctory and inconsequential, and is not considered a separate deliverable in the Agreement.

On May 28, 2013, we entered into an amendment (the "Amendment") to the Agreement with Braeburn primarily to modify certain of the termination provisions of the Agreement. The Amendment gives Braeburn the right to terminate the Agreement in the event that (A) after May 28, 2013, based on written or oral communications from or with the FDA, Braeburn reasonably determines either that the FDA will require significant development to be performed before approval of the Probuphine NDA can be given, such as, but not limited to, one or more additional controlled clinical studies with a clinical efficacy endpoint, or substantial post-approval commitments that may materially impact the products financial returns or that the FDA will require one or more changes in the proposed label, which change(s) Braeburn reasonably determines will materially reduce the authorized prescribed patient base, or (B) the NDA has not been approved by the FDA on or before June 30, 2014. The Amendment also provides that we will share in legal and consulting expenses in excess of a specified amount prior to approval of the NDA.

On July 2, 2013, we entered into a second amendment (the "Second Amendment") to the Agreement with Braeburn primarily to establish and provide the parameters for a committee comprised of representatives of Titan and Braeburn responsible for and with the authority to make all decisions regarding the development and implementation of a strategic plan to seek approval from the FDA of Probuphine® for subdermal use in the maintenance treatment of adult patients with opioid dependence, including development of the strategy for all written and oral communications with the FDA. The Second Amendment also makes Braeburn the primary contact for FDA communications regarding the Probuphine NDA.

On November 12, 2013, we entered into a third amendment (the "Third Amendment") to the Agreement. See Note 10, "Subsequent Events."



## 6. Commitments and Contingencies

### *Financing Agreements*

On March 15, 2011, we entered into several agreements with Deerfield, including a facility agreement (the “Facility Agreement”), pursuant to which we issued Deerfield promissory notes in the aggregate principal amount of \$20.0 million. The long-term debt bore interest at 8.5% per annum, payable quarterly, and was originally repayable over five years, with 10% of the principal amount due on the first anniversary, 15% due on the second anniversary, and 25% due on each of the next three anniversaries. In connection with the Facility Agreement, we issued Deerfield six-year warrants (the “Deerfield Warrants”) to purchase 6,000,000 shares of our common stock at an exercise price of \$1.57 per share. See Note 8, “Warrant Liability” for further discussion. As a result of our April 2012 sale of equity, and pursuant to the terms of the Deerfield Warrants, the exercise price of the Deerfield Warrants was adjusted to \$1.25 per share. We also entered into a royalty agreement with Deerfield (the “Royalty Agreement”) in exchange for \$3.0 million. See Note 7, “Royalty Liability” for further discussion.

We recorded the promissory notes with an aggregate principal amount of \$20.0 million at its face value less a note discount consisting of (i) \$3.0 million cash discount, (ii) a \$500,000 loan fee, and (iii) the \$5.5 million fair value of the associated warrants. The note discount totaling \$9.0 million was amortized using the interest method.

On November 14, 2011, we entered into several agreements with Deerfield (including an amended and restated Royalty Agreement) pursuant to which we agreed to pay the remaining future royalties on the sales of Fanapt to Deerfield in exchange for \$5.0 million in cash that was recorded as royalty liability (see Note 7, "Royalty Liability" for further discussion), a \$10.0 million reduction in the principal amount owed to Deerfield under the Facility Agreement and a revised principal repayment schedule of \$2.5 million per year for four years commencing in April 2013 to retire the remaining long-term debt of \$10.0 million. We evaluated the November 2011 principal reduction and other amendments to the Facility Agreement and determined that the modifications should be accounted for as a troubled debt restructuring on a prospective basis. As a result, we recognized the difference between the carrying value of the long-term debt and the total required future principal and interest payments as interest expense over the remaining term using the interest method.

On February 6, 2013, the Facility Agreement was amended to provide that the exercise price of the Deerfield Warrants could be satisfied through a reduction in the principal amount of our outstanding indebtedness to Deerfield. In February and March 2013, Deerfield exercised all of the Deerfield Warrants resulting in a reduction of our outstanding indebtedness to Deerfield of \$7.5 million and, accordingly, cancellation of our obligation to make the 2014, 2015 and 2016 installment payments under the Facility Agreement. This resulted in a gain of \$1.9 million which was recorded in Other Income. On April 1, 2013, we made the final principal payment of \$2.5 million under the Facility Agreement.

### ***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, 2013 and 2012 were approximately \$20.0 million and \$15.3 million, respectively, and we were obligated to pay royalties of approximately \$3.0 million and \$1.8 million to Sanofi-Aventis on September 30, 2013 and December 31, 2012, respectively, which were included in Accounts Receivable and Accounts Payable on the Condensed Balance Sheets.

### ***Legal Proceedings***

There are no ongoing legal proceedings against our company.

## **7. Royalty Liability**

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

The \$3.0 million received under the Royalty Agreement was recorded as a royalty liability in accordance with the appropriate accounting guidance as the related agreement includes a provision which allowed us to repurchase the royalty rights from Deerfield through a payment of a lump sum. Interest on the royalty liability was recognized using the interest method based on the estimated future royalties expected to be paid under the Royalty Agreement.

Under the November 14, 2011 amended and restated Royalty Agreement, in exchange for an additional \$5.0 million royalty liability, Deerfield is entitled to our portion of the royalties on Fanapt (5.5% to 7.5% of net sales, net of the 2.5% previously agreed to have been provided to Deerfield) up to specified threshold levels of net sales of Fanapt and 40% of the royalties above the threshold level. We retain 60% of the royalties on net sales of Fanapt above the

threshold levels. The \$5.0 million received was recorded as a royalty liability in accordance with the appropriate accounting guidance as the related agreement included a provision which allowed us to repurchase the royalty rights from Deerfield through a payment of a lump sum. Interest on this royalty obligation was recognized using the interest method based on the estimated future royalties expected to be paid under the Royalty Agreement.

On March 28, 2013, we amended the agreements with Deerfield terminating our option to repurchase the royalty rights. As a result, we recognized a gain on the extinguishment of the royalty liability of \$9.0 million, which was recorded in other income, because we are no longer required to account for it as a liability. Additionally, we will no longer recognize royalty income related to the Fanapt royalty payments received from Novartis unless Fanapt sales exceed certain thresholds.

## 8. Warrant Liability

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

On February 6, 2013, the Facility Agreement was amended to provide that the exercise price of the Deerfield Warrants could be satisfied through a reduction in the principal amount of our outstanding indebtedness to Deerfield. In February and March 2013, Deerfield exercised all of the Deerfield Warrants resulting in a \$7.5 million reduction in the amount owed to Deerfield. See Note 6. “Commitments and Contingencies” for further discussion.

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

In September and October 2012, Series B Warrants to purchase 5,761,765 shares of common stock were exercised at a price of \$0.85 per share. The remaining Series B Warrants to purchase 755,883 shares of common stock expired in October 2012.

In January and March 2013, Series A Warrants to purchase 1,109,010 shares of common stock were exercised resulting in gross proceeds of approximately \$1,275,000. The remaining Series A Warrants to purchase 5,408,638 shares of common stock will expire in April 2018.

The key assumptions used to value the Series A Warrants were as follows:

Assumption	September 30, 2013		December 31, 2012	
Expected price volatility	95	%	80	%
Expected term (in years)	4.53		5.27	
Risk-free interest rate	1.21	%	0.78	%
Dividend yield	0.00	%	0.00	%
Weighted-average fair value of warrants	\$ 0.42		\$ 0.69	

## **9. Stockholders' Equity**

### ***Common Stock***

In April 2013, 144,499 shares of common stock were issued to Oxford Capital Financing upon the cashless net exercise of 287,356 warrants in accordance with the terms of the warrants.

In January and March 2013, Series A Warrants to purchase 1,109,010 shares of common stock were exercised resulting in gross proceeds of approximately \$1,275,000.

On February 6, 2013, the Facility Agreement with Deerfield was amended to provide that the exercise price of the Deerfield Warrants could be satisfied through a reduction in the principal amount of our outstanding indebtedness to Deerfield. In February and March 2013, Deerfield exercised the 6,000,000 Deerfield Warrants resulting in a \$7.5 million reduction in the amount owed to Deerfield.

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

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

In September 2012, we entered into a stock purchase and option agreement with an affiliate of Braeburn pursuant to which we sold 3,400,000 shares of our common stock for an aggregate purchase price of \$4.25 million, or \$1.25 per share, and agreed to an exclusive option period for execution of the proposed license agreement. The \$1.7 million premium, or \$0.50 per share, has been allocated to the fair value of the option agreement and was recorded as license revenue in 2012.

In April 2012, we entered into subscription agreements with certain institutional investors for the purchase and sale, in a registered direct offering, of (i) 6,517,648 shares of our common stock, (ii) 6,517,648 Series A Warrants and (iii) 6,517,648 Series B Warrants for gross proceeds of \$5,540,000 (the "Offering"). The Offering closed in April 2012. As a result of the Offering, and pursuant to the terms of the Deerfield Warrants, the exercise price of the Deerfield Warrants was adjusted to \$1.25 per share. We recorded the gross proceeds from the Offering, net of (i) issuance costs of \$0.5 million and (ii) the fair value of the Series A and Series B Warrants of \$2.9 million as common stock paid-in in the Consolidated Balance Sheets. See Note 8, "Warrant Liability" for further discussion.

## **10. Subsequent Events**

On November 12, 2013, we entered into the Third Amendment to the Agreement and a stock purchase agreement (the "SPA") with Braeburn primarily to modify the amount and timing of the approval and sales milestone payments under the Agreement and to provide for a \$5,000,000 equity investment by Braeburn in our company.

The Third Amendment provides for a reduction in the milestone payable to us upon approval by the FDA of the Probuphine NDA from \$45 million to \$15 million and an increase in the total amount of potential sales milestones payable under the Agreement from \$130 million to \$165 million. Braeburn also agreed to assume responsibility for all expenses relating to the Probuphine regulatory process. The Third Amendment also contains a provision entitling us to receive a low single digit royalty on sales by Braeburn of other mid to long-term continuous delivery treatments for opioid dependence, up to a maximum of \$50 million. We will have the additional right to elect to participate in a low single digit royalty on sales by Braeburn of other products in the addiction market in exchange for a similar reduction in our royalties on Probuphine.

Pursuant to the SPA, we agreed to issue 6,250,000 shares of our common stock to Braeburn for an aggregate purchase price of \$5,000,000, or \$.80 per share, the closing price on the day before execution of the agreements. The Third Amendment will be effective upon the closing of the SPA

## Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

*The following discussion contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Such statements include, but are not limited to, any statements relating to our product development programs and any other statements that are not historical facts. Such statements involve risks and uncertainties that could negatively affect our business, operating results, financial condition and stock price. Factors that could cause actual results to differ materially from management's current expectations include those risks and uncertainties relating to the regulatory approval process, the development, testing, production and marketing of our drug candidates, patent and intellectual property matters and strategic agreements and relationships. We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations or any changes in events, conditions or circumstances on which any such statement is based, except as required by law.*

*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 for the treatment of serious medical disorders. Our product development programs focus primarily on important pharmaceutical markets with significant unmet medical needs and commercial potential. We are directly developing our product candidates and also utilize corporate, academic and government partnerships as appropriate. Such collaborations have helped to fund product development and have enabled us to retain significant economic interest in our products.

Our principal asset is Probuphine®, the first slow release implant formulation of buprenorphine in development for the treatment of opioid dependence. It is designed to maintain a stable, around the clock blood level of the medicine in patients for six months following a single treatment. Upon completion of the Phase 3 clinical studies of Probuphine, we participated in a pre- NDA meeting with the FDA, and subsequently prepared and submitted the NDA in October 2012. On April 30, 2013, the FDA issued a complete response letter to our NDA stating that it cannot approve the application in its present form and outlining the FDA's request for additional clinical data demonstrating adequate clinical benefit to patients from this treatment, data from human factors testing of the training program, as well as recommendations regarding product labeling, Risk Evaluation and Mitigation Strategy ("REMS") and non-clinical safety data. We are committed to addressing these issues and have been working diligently with our partners at Braeburn along with a team of proven, expert clinical and regulatory advisors with experience in assisting companies through similar regulatory processes, and pursuing a broad range of avenues to advance Probuphine. We have submitted briefing materials in support of a meeting with the FDA, the goal for which will be to discuss the key issues identified in the CRL and to outline important safety and efficacy data that we believe can help in addressing the questions from the FDA.

In December 2012, we entered into the Agreement that grants Braeburn exclusive commercialization rights to Probuphine® in the United States and Canada. We received a non-refundable up-front license fee of \$15.75 million (approximately \$15.0 million, net of expenses). The Agreement entitled us to receive a \$45 million milestone payment upon the approval of the NDA by the FDA, up to \$130 million upon achievement of specified sales milestones, up to \$35 million in regulatory milestones in the event of future NDA submissions and approvals for additional indications, including chronic pain, and tiered royalties on net sales of Probuphine ranging from the mid-teens to the low twenties.

On May 28, 2013, we entered into the Amendment to the Agreement with Braeburn primarily to modify certain of the termination provisions of the Agreement. The Amendment gives Braeburn the right to terminate the Agreement in the event that (A) after May 28, 2013, based on written or oral communications from or with the FDA, Braeburn reasonably determines either that the FDA will require significant development to be performed before approval of the Probuphine NDA can be given, such as, but not limited to, one or more additional controlled clinical studies with a clinical efficacy endpoint, or substantial post-approval commitments that may materially impact the products financial returns or that the FDA will require one or more changes in the proposed label, which change(s) Braeburn reasonably determines will materially reduce the authorized prescribed patient base, or (B) the NDA has not been approved by the FDA on or before June 30, 2014. The Amendment also provides that we will share in legal and consulting expenses in excess of a specified amount prior to approval of the NDA.

On July 2, 2013, we entered into the Second Amendment to the Agreement primarily to establish and provide the parameters for a committee comprised of representatives of Titan and Braeburn responsible for and with the authority to make all decisions regarding the development and implementation of a strategic plan to seek approval from the FDA of Probuphine® for subdermal use in the maintenance treatment of adult patients with opioid dependence, including development of the strategy for all written and oral communications with the FDA. The Second Amendment also makes Braeburn the primary contact for FDA communications regarding the Probuphine NDA.



On November 12, 2013, we entered into the SPA pursuant to which Braeburn agreed to make a \$5 million equity investment in our company and the Third Amendment primarily to modify the amount and timing of the approval and sales milestone payments payable under the Agreement. Under the Third Amendment, we are entitled to receive a \$15 million payment upon FDA approval of the NDA, up to \$165 million in sales milestones and \$35 in regulatory milestones. In addition, we are entitled to receive a low single digit royalty on sales by Braeburn, if any, of other continuous delivery treatments for opioid dependence as defined in the Third Amendment and can elect to receive a low single digit royalty on sales by Braeburn, if any, of other products in the addiction market in exchange for a similar reduction in the Company's royalties on Probuphine. The Third Amendment will become effective upon the closing of the sale of shares under the SPA.

Probuphine is the first product to utilize ProNeura<sup>®</sup>, our novel, proprietary, continuous drug delivery technology. Our ProNeura technology has the potential to be used in developing products for the treatment of other chronic conditions, such as Parkinson's disease, where maintaining stable, around the clock blood levels of a drug can benefit the patient and improve medical outcomes.

Under a sublicense agreement with Novartis, we are entitled to royalty revenue of 8-10% of net sales of Fanapt<sup>®</sup> (iloperidone), an atypical antipsychotic compound being marketed in the U.S. by Novartis for the treatment of schizophrenia, based on a licensed U.S. patent that expires in October 2016 (excluding the potential of a six month pediatric extension). We have entered into several agreements with Deerfield, a healthcare investment fund, which entitle Deerfield to most of the future royalty revenues related to Fanapt in exchange for cash and debt considerations, the proceeds from which we have been using to advance the development of Probuphine and for general corporate purposes. In April 2013, we made the final principal payment of \$2.5 million to Deerfield, and have repaid the Deerfield loan in full. We have retained a portion of the royalty revenue from the net sales of Fanapt in excess of specified annual threshold levels; however, based on sales levels to date, it is unlikely that we will receive any revenue from Fanapt in the next several years, if ever.

### ***Recent Accounting Pronouncements***

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

### ***Results of Operations for the Three and Nine months Ended September 30, 2013 and September 30, 2012***

License revenues of approximately \$2.2 million and \$8.1 million, respectively, for the three and nine months ended September 30, 2013 reflect the amortization of the upfront license fee received from Braeburn in December 2012. Royalty revenues during the nine months ended September 30, 2013 and the three and nine months ended September 30, 2012 reflect royalties paid on sales of Fanapt, all of which were paid to Deerfield in accordance with our royalty sales agreement. We no longer recognize Fanapt royalty revenues since all of such royalties are paid to third parties. We generated no grant revenue during the three and nine months ended September 30, 2013 compared with \$42,000 of NIH grant revenue during the nine months ended September 30, 2012 relating to our Probuphine program.

Research and development expenses for the three month period ended September 30, 2013 were approximately \$1.7 million, compared to approximately \$3.0 million for the comparable period in 2012, a decrease of approximately \$1.3 million, or 43%. Research and development expenses for the nine month period ended September 30, 2013 were approximately \$7.4 million, compared to approximately \$8.0 million for the comparable period in 2012, a decrease of approximately \$0.6 million, or 8%. The decrease in research and development costs during the three and nine month periods ended September 30, 2013 was primarily associated with a decrease in external research and development expenses related the review of the NDA for our Probuphine product with the FDA. 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, 2013, external research and development expenses relating to our Probuphine product development program were approximately \$0.7 million and \$3.3 million, respectively. Other research and development expenses include internal operating costs such as clinical research and development personnel-related expenses, clinical trials related travel expenses, and allocation of facility and corporate costs. As a result of the risks and uncertainties inherently associated with pharmaceutical research and development activities described elsewhere in this report, we are unable to estimate the specific timing and future costs of our clinical development programs or the timing of material cash inflows, if any, from our product candidates.

General and administrative expenses for the three month period ended September 30, 2013 were approximately \$0.6 million, compared to approximately \$0.9 million for the comparable period in 2012, a decrease of approximately \$0.3 million, or 33%. General and administrative expenses for the nine month period ended September 30, 2013 were approximately \$2.4 million, compared to approximately \$3.8 million for the comparable period in 2012, a decrease of approximately \$1.4 million, or 37%. The decrease in general and administrative expenses during the three month period ended September 30, 2013 was primarily related to decreases in non-cash stock compensation costs of approximately \$0.2 million and legal fees of approximately \$0.1 million. The decrease in general and administrative expenses during the nine month period ended September 30, 2013 was primarily related to decreases in non-cash stock compensation and employee related costs of approximately \$1.1 million and consulting and professional fees of approximately \$0.3 million.

Net other expense for the three month period ended September 30, 2013 was approximately \$1.0 million, compared to net other expense of approximately \$5.4 million in the comparable period in 2012. Net other income for the nine month period ended September 30, 2013 was approximately \$10.2 million compared to net other expense of approximately \$7.0 million in the comparable period in 2012. The decrease in net other expense during the three month period ended September 30, 2013, was primarily related to an approximately \$1.0 million non-cash loss related to increases in the fair value of outstanding warrants compared to an approximately \$3.7 million non-cash loss related to decreases in the fair value of outstanding warrants during the comparable period in 2012 and a decrease in interest expense of approximately \$1.6 million related to the Deerfield loans. The increase in net other income during the nine month period ended September 30, 2013, was primarily related to approximately \$9.0 million of other income generated by the termination of our royalty repurchase agreement with Deerfield, an approximately \$1.9 million gain resulting from the \$7.5 million settlement of our indebtedness to Deerfield as a result of Deerfield's exercise of all of the Deerfield Warrants, a decrease in interest expense of approximately \$3.5 million related to the Deerfield loans and approximately \$3.0 million related to non-cash gains on changes in the fair value of warrants. This was offset in part by approximately \$0.5 million of other expense related to unamortized transaction fees related to the initial Deerfield debt transaction.

Our net loss for the three month period ended September 30, 2013 was approximately \$1.1 million, or approximately \$0.01 per share, compared to our net loss of approximately \$8.0 million, or approximately \$0.12 per share, for the comparable period in 2012. Net income for the nine month period ended September 30, 2013 was approximately \$9.9 million, or approximately \$0.12 per share, compared to a net loss of approximately \$14.9 million, or approximately \$0.23 per share, for the comparable period in 2012.

### ***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, 2013, we had working capital of approximately \$1.6 million compared to working capital of approximately \$2.0 million at December 31, 2012.

Our operating activities used approximately \$7.7 million during the nine-months ended September 30, 2013. This consisted primarily of the net income for the period of approximately \$9.9 million and non-cash charges of approximately \$0.7 million related to share-based compensation expenses. This was offset in part by approximately \$1.9 million related to a non-cash gain on the settlement of long-term debt, approximately \$9.0 million related to a non-cash gain on the termination of our royalty repurchase agreement with Deerfield, approximately \$1.3 million related to non-cash gains resulting from changes in the fair value of warrants and \$6.2 million related to net changes in other operating assets and liabilities. Uses of cash in operating activities were primarily to fund product development programs and administrative expenses. Our license agreement with Sanofi-Aventis requires us to pay royalties on future product sales.

Net cash used by investing activities of approximately \$0.3 million during the nine months ended September 30, 2013 consisted primarily of approximately \$0.3 million related to purchases of equipment.

Our financing activities used approximately \$1.1 million during the nine-months ended September 30, 2013. This consisted primarily of approximately \$2.5 million related to payments on our long-term debt. This was offset in part by approximately \$1.3 million in proceeds from the exercise of warrants and approximately \$0.1 million in proceeds from the exercise of stock options.

At December 31, 2012, we had \$10.0 million principal amount of outstanding indebtedness to Deerfield under the terms of an amended Facility Agreement that was payable in four equal annual installments of \$2.5 million commencing April 2013. In February 2013, we amended the terms of the Deerfield Warrants to permit payment of the

exercise price through the reduction of the outstanding loan. In February and March 2013, Deerfield exercised all of the Deerfield Warrants resulting in a \$7.5 million reduction of our outstanding indebtedness. In April 2013, we made the last \$2.5 million installment payment and our debt obligation to Deerfield was satisfied in full.

In April 2012, we sold, in a registered direct offering, (i) 6,517,648 shares of our common stock, (ii) six-year Series A Warrants to purchase 6,517,648 shares of common stock and (iii) six-month Series B Warrants to purchase 6,517,648 shares of common stock for net proceeds of approximately \$5.0 million. Prior to their expiration, Series B Warrants to purchase 5,761,765 shares of our common stock were exercised resulting in gross proceeds to us of approximately \$4.9 million. In January and March 2013, Series A Warrants to purchase 1,109,010 shares of common stock were exercised resulting in gross proceeds of approximately \$1,275,000.

On September 12, 2012, we entered into a stock purchase and option agreement with an affiliate of Braeburn pursuant to which we sold 3,400,000 shares of our common stock for an aggregate purchase price of \$4.25 million, or \$1.25 per share, and agreed to an exclusive option period for execution of the proposed license agreement

Effective December 14, 2012, we entered into the Agreement with Braeburn pursuant to which we granted Braeburn an exclusive right and license to commercialize Probuphine® in the Territory. We retained all of the rights to Probuphine® outside the Territory. In consideration of the rights granted to Braeburn under the license agreement, Braeburn paid to us an upfront, non-refundable license fee of \$15.75 million (approximately \$15.0 million, net of expenses).

We believe that our working capital at September 30, 2013, together with the \$5.0 million in proceeds from the sale of common stock under the SPA, is sufficient to fund our planned operations into January 2015, inclusive of estimated expenses for preparation of our response to the CRL regarding the Probuphine NDA that we received from the FDA. We have a meeting scheduled with the FDA to review and respond to issues raised in the CRL, the goal of which is to achieve clarity on next steps and determine the appropriate timing of the submission of our response to the CRL, which should help determine the nature, timing and extent of our requirements for additional capital. If Braeburn were to terminate the license agreement, we would not have sufficient funds available to us to complete the FDA regulatory process and, in the event of ultimate approval, commercialize Probuphine without raising additional capital. If we are unable to complete a debt or equity offering, or otherwise obtain sufficient financing in such event, our business and prospects would be materially adversely impacted. Furthermore, in the event of termination or any substantial reduction in the milestone payment payable to us if the FDA ultimately approves Probuphine, we may be unable to continue our current Parkinson's disease development program and would not be able to initiate any additional programs without obtaining additional financing, either through the sale of debt or equity securities.

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

Our market risk disclosures set forth in our Annual Report on Form 10-K/A for the year ended December 31, 2012 have not changed materially.

### **Item 4. Controls and Procedures**

#### ***Disclosure Controls and Procedures***

Our President, being our principal executive and financial officer, has evaluated the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934 as of September 30, 2013, the end of the period covered by this report, and has concluded that our disclosure controls and procedures were effective to ensure that the information required to be disclosed by us in reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC, and that such information is accumulated and communicated to our principal executive and principal financial officer as appropriate to allow timely decisions regarding required disclosure.

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

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934) during the three months ended September 30, 2013 that have materially affected, or are reasonably likely to materially affect, Titan's internal control over financial reporting.

**PART II****Item 1A. Risk Factors**

In addition to the other information set forth in this report, you should carefully consider the factors discussed in Part I, “Item 1A. Risk Factors” in our Annual Report on Form 10-K/A for the year ended December 31, 2012, which could materially affect our business, financial condition or future results. The risks described in our Annual Report on Form 10-K/A are not the only risks facing our Company. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results.

**Item 5. Exhibits**

No.	Description
3.1	Amended and Restated Certificate of Incorporation of the Registrant, as amended <sup>9</sup>
3.2	By-laws of the Registrant <sup>1</sup>
3.3	Certificate of Designations of Junior Participating Preferred Stock of Titan Pharmaceuticals, Inc. <sup>15</sup>
4.1	Registration Rights Agreement dated as of December 17, 2007 <sup>2</sup>
4.2	Registration Rights Agreement dated as of December 8, 2009 <sup>9</sup>
4.3	Warrant to Purchase Common Stock dated December 23, 2009 issued to Oxford Finance Corporation <sup>9</sup>
4.4	Form of Warrant <sup>13</sup>
4.5	Registration Rights Agreement, dated as of March 15, 2011 <sup>13</sup>
4.6	Form of Series A Warrant <sup>17</sup>
4.7	Rights Agreement, dated as of May 28, 2013, between Titan Pharmaceuticals, Inc. and Continental Stock Transfer & Trust Company, as Rights Agent <sup>21</sup>
10.1	1998 Stock Option Plan <sup>3</sup>
10.2	2001 Non-Qualified Employee Stock Option Plan <sup>4</sup>
10.3	2002 Stock Option Plan <sup>5</sup>
10.4	Employment Agreement between the Registrant and Sunil Bhonsle, dated May 16, 2009, as amended by agreements dated February 17, 2010, December 30, 2011 and December 31, 2012 <sup>9, 16, 18</sup>
10.5	Employment Agreement between the Registrant and Marc Rubin, dated May 16, 2009, as amended by agreements dated February 17, 2010, December 30, 2011 and December 31, 2012 <sup>9, 16, 18</sup>
10.6	Lease for the Registrant’s facilities, amended as of October 1, 2004 <sup>4</sup>

Edgar Filing: TITAN PHARMACEUTICALS INC - Form 10-Q

- 10.7 Amendments to lease for Registrant's facilities dated May 21, 2007 and March 12, 2009<sup>9</sup>
- 10.8\* License Agreement between the Registrant and Sanofi-Aventis SA effective as of December 31, 1996<sup>7</sup>
- 10.9\* Sublicense Agreement between the Registrant and Novartis Pharma AG dated November 20, 1997<sup>8</sup>
- 10.10 Loan and Security Agreement between the Registrant and Oxford Finance Corporation dated December 18, 2009<sup>9</sup>
- 10.11 Stock Purchase Agreement between the Registrant and certain investors dated December 8, 2009<sup>9</sup>
- 10.12 Amendment to Employment Agreement dated June 15, 2010 between the Registrant and Marc Rubin<sup>10</sup>
- 10.13 Amendment to Employment Agreement dated June 15, 2010 between the Registrant and Sunil Bhonsle<sup>10</sup>
- 10.14 Amendment to lease for Registrant's facilities dated June 15, 2010<sup>1</sup>
- 10.15 Amended and Restated Loan and Security Agreement between the Registrant and Oxford Finance Corporation dated September 27, 2010<sup>12</sup>

No.	Description
10.16	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 <sup>13</sup>
10.17	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 <sup>13</sup>
10.18	Royalty Purchase Agreement, dated November 14, 2011, by and among the Company, Deerfield Private Design Fund II, L.P., Deerfield Special Situations Fund, L.P. and Horizon Sante TTNP SARL <sup>14</sup>
10.19	Amended and Restated Royalty Agreement, dated November 14, 2011 by and among the Company, Deerfield Private Design Fund II, L.P., Deerfield Special Situations Fund, L.P. and Horizon Sante TTNP SARL <sup>14</sup>
10.20	Amended and Restated Royalty Repurchase Agreement, dated November 14, 2011, by and among the Company, Deerfield Private Design Fund II, L.P., and Horizon Sante TTNP SARL <sup>14</sup>
10.21	Cash Management Agreement, dated November 14, 2011, by and among the Company, Deerfield Private Design Fund II, L.P., Deerfield Special Situations Fund, L.P. and Horizon Sante TTNP SARL <sup>14</sup>
10.22	Paying Agent Agreement, dated November 14, 2011, by and among the Company, Deerfield Management Company, L.P. and U.S. Bank National Association <sup>14</sup>
10.23	Agreement, dated as of November 14, 2011, by and among the Company, Deerfield Private Design Fund II, L.P., Deerfield Private Design International II, L.P., Deerfield Special Situations Fund, L.P., and Deerfield Special Situations Fund International Limited <sup>14</sup>
10.24	Form of Subscription Agreement dated April 9, 2012 <sup>17</sup>
10.25*	License Agreement by and between Titan Pharmaceuticals, Inc. and Braeburn Pharmaceuticals Sprl, dated December 14, 2012 <sup>19</sup>
10.26*	Amendment dated May 28, 2013 to License Agreement dated December 14, 2012 between Titan Pharmaceuticals, Inc. and Braeburn Pharmaceuticals Sprl <sup>21</sup>
10.27	Amendment dated July 2, 2013 to License Agreement dated December 14, 2012 between Titan Pharmaceuticals, Inc. and Braeburn Pharmaceuticals Sprl <sup>22</sup>
10.28**	Amendment dated November 12, 2013 to License Agreement dated December 14, 2012 between Titan Pharmaceuticals, Inc. and Braeburn Pharmaceuticals Sprl <sup>23</sup>
10.29	Stock Purchase Agreement dated November 12, 2013 Titan Pharmaceuticals, Inc. and Braeburn Pharmaceuticals Sprl <sup>23</sup>



14.1

Code of Business Conduct and Ethics<sup>20</sup>

31.1

Certification of the Principal Executive and Financial Officer pursuant to Rule 13(a)-14(a) of the Securities Exchange Act of 1934

32.1

Certification of the Principal Executive and Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

101.INS\*\*\*

XBRL Instance Document

101.SCH\*\*\*

XBRL Taxonomy Extension Schema Document

101.CAL\*\*\*

XBRL Taxonomy Extension Calculation Linkbase Document

101.DEF\*\*\*

XBRL Taxonomy Extension Definition Linkbase Document

101.LAB\*\*\*

XBRL Taxonomy Extension Label Linkbase Document

101.PRE\*\*\*

XBRL Taxonomy Extension Presentation Linkbase Document

---

- (1) Incorporated by reference from the Registrant's Registration Statement on Form SB-2 (File No. 33-99386).
- (2) Incorporated by reference from the Registrant's Current Report on Form 8-K dated December 27, 2007.
- (3) Incorporated by reference from the Registrant's definitive Proxy Statement filed on July 28, 2000.
- (4) Incorporated by reference from the Registrant's Annual Report on Form 10-K for the year ended December 31, 2001.
- (5) Incorporated by reference from the Registrant's Annual Report on Form 10-K for the year ended December 31, 2002.
- (6) Incorporated by reference from the Registrant's Annual Report on Form 10-K for the year ended December 31, 2005.
- (7) Incorporated by reference from the Registrant's Annual Report on Form 10-KSB for the year ended December 31, 1996.
- (8) Incorporated by reference from the Registrant's Registration Statement on Form S-3 (File No. 333-42367).

- (9) Incorporated by reference from the Registrant's Registration Statement on Form 10.
- (10) Incorporated by reference from the Registrant's Annual Report on Form 10-K for the year ended December 31, 2003.
- (11) Incorporated by reference from the Registrant's Quarterly Report on Form 10-Q for the period ended June 30, 2010.
- (12) Incorporated by reference from the Registrant's Quarterly Report on Form 10-Q for the period ended September 30, 2010.
- (13) Incorporated by reference from the Registrant's Current Report on Form 8-K filed on March 18, 2011.
- (14) Incorporated by reference from the Registrant's Current Report on Form 8-K filed on November 17, 2011.
- (15) Incorporated by reference from the Registrant's Current Report on Form 8-K filed on December 21, 2011.
- (16) Incorporated by reference from the Registrant's Current Report on Form 8-K filed on January 4, 2012.
- (17) Incorporated by reference from the Registrant's Current Report on Form 8-K filed on April 10, 2013.
- (18) Incorporated by reference from the Registrant's Current Report on Form 8-K filed on January 2, 2013.
- (19) Incorporated by reference from the Registrant's Current Report on Form 8-K/A filed on February 28, 2013.
- (20) Incorporated by reference from the Registrant's Annual Report on Form 10-K for the year ended December 31, 2012.
- (21) Incorporated by reference from the Registrant's Current Report on Form 8-K filed on May 29, 2013.
- (22) Incorporated by reference from the Registrant's Current Report on Form 8-K filed on July 5, 2013.
- (23) Incorporated by reference from the Registrant's Current Report on Form 8-K filed on November 13, 2013.
- \* Confidential treatment has been granted with respect to portions of this exhibit.
- \*\* Confidential treatment has been requested 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.

**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, 2013	By:	/s/ Sunil Bhonsle
	Name:	<b>Sunil Bhonsle</b>
	Title:	<b>President (Principal Executive and Principal Financial Officer)</b>