

TITAN PHARMACEUTICALS INC

Form 10-Q

May 15, 2013

[Table of Contents](#)

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

**FORM 10-Q**

x **Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**  
For the quarterly period ended March 31, 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)

Edgar Filing: TITAN PHARMACEUTICALS INC - Form 10-Q

**Delaware**  
(State or Other Jurisdiction of

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

**Incorporation or Organization)**

**Identification No.)**

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

(Address of Principal Executive Offices, Including Zip Code)

**(650) 244-4990**

(Registrant's Telephone Number, Including Area Code)

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, 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 May 8, 2013.

**Table of Contents**

**Titan Pharmaceuticals, Inc.**

**Index to Form 10-Q**

**Part I. Financial Information**

|  |  |    |
|--|--|----|
| Item 1.                                  | <u>Financial Statements</u>  | 3  |
|  | <u>Condensed Balance Sheets as of March 31, 2013 and December 31, 2012</u>   | 3  |
|  | <u>Condensed Statements of Operations and Comprehensive Income (Loss) for the three months ended March 31, 2013 and 2012</u> | 4  |
|  | <u>Condensed Statements of Cash Flows for the three months ended March 31, 2013 and 2012</u>                                 | 5  |
|  | <u>Notes to Condensed Financial Statements</u>   | 6  |
| Item 2.                                  | <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>                                 | 14 |
| Item 3.                                  | <u>Quantitative and Qualitative Disclosures About Market Risk</u>  | 17 |
| Item 4.                                  | <u>Controls and Procedures</u>   | 17 |
| <b><u>Part II. Other Information</u></b> |  | 17 |
| Item 1A.                                 | <u>Risk Factors</u>  | 17 |
| Item 5.                                  | <u>Exhibits</u>  | 18 |
| <b><u>SIGNATURES</u></b>                 |  | 20 |

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

(in thousands)

|   | March 31,<br>2013<br>(unaudited) | December 31,<br>2012<br>(Note 1) |
|---|----------------------------------|----------------------------------|
| <b>Assets</b>                               |                                  |                                  |
| Current assets:                             |                                  |                                  |
| Cash  | \$ 17,606                        | \$ 18,102                        |
| Receivables                                 | 4,094                            | 4,646                            |
| Prepaid expenses and other current assets   | 265                              | 687                              |
| Total current assets                        | 21,965                           | 23,435                           |
| Property and equipment, net                 | 1,567                            | 1,392                            |
| Total assets                                | \$ 23,532                        | \$ 24,827                        |
| <b>Liabilities and Stockholders Deficit</b> |                                  |                                  |
| Current liabilities                         |                                  |                                  |
| Accounts payable                            | \$ 5,039                         | \$ 3,767                         |
| Accrued clinical trials expenses            | 1,390                            | 532                              |
| Other accrued liabilities                   | 427                              | 219                              |
| Deferred contract revenue                   | 10,625                           | 14,375                           |
| Current portion of long-term debt           | 2,500                            | 2,500                            |
| Total current liabilities                   | 19,981                           | 21,393                           |
| Warrant liability                           | 6,599                            | 8,240                            |
| Royalty liability                           |                                  | 8,962                            |
| Long-term debt, net of discount             |                                  | 9,360                            |
| Total liabilities                           | 26,580                           | 47,955                           |
| Commitments and contingencies               |                                  |                                  |
| Stockholders deficit                        |                                  |                                  |
| Common stock, at amounts paid-in            | 279,560                          | 265,986                          |
| Additional paid-in capital                  | 21,519                           | 21,014                           |
| Accumulated deficit                         | (304,127)                        | (310,128)                        |
| Total stockholders deficit                  | (3,048)                          | (23,128)                         |
| Total liabilities and stockholders deficit  | \$ 23,532                        | \$ 24,827                        |

See Notes to Condensed Financial Statements



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

|   | <b>Three Months Ended<br/>March 31,</b> |                   |
|---|---|-------------------|
|   | <b>2013</b>                             | <b>2012</b>       |
| <b>Revenues:</b>  |   |                   |
| License revenue   | \$ 3,750                                | \$                |
| Royalty revenue   | 1,424                                   | 1,228             |
| Grant revenue   |   | 42                |
| <b>Total revenue</b>  | <b>5,174</b>                            | <b>1,270</b>      |
| <b>Operating expenses:</b>  |   |                   |
| Research and development  | 3,912                                   | 3,069             |
| General and administrative  | 1,091                                   | 1,733             |
| <b>Total operating expenses</b>   | <b>5,003</b>                            | <b>4,802</b>      |
| Income (loss) from operations   | 171                                     | (3,532)           |
| <b>Other income (expense):</b>  |   |                   |
| Interest expense, net   | (1,569)                                 | (1,563)           |
| Other income (expense)  | 10,444                                  | (52)              |
| Non-cash loss on changes in the fair value of warrants                                      | (3,045)                                 | (16)              |
| <b>Other income (expense), net</b>  | <b>5,830</b>                            | <b>(1,631)</b>    |
| <b>Net income (loss) and comprehensive income (loss)</b>                                    | <b>\$ 6,001</b>                         | <b>\$ (5,163)</b> |
| <b>Basic net income (loss) per common share</b>   | <b>\$ 0.08</b>                          | <b>\$ (0.09)</b>  |
| <b>Diluted net income (loss) per common share</b>   | <b>\$ 0.07</b>                          | <b>\$ (0.09)</b>  |
| <b>Weighted average shares used in computing basic net income (loss) per common share</b>   | <b>78,256</b>                           | <b>59,387</b>     |
| <b>Weighted average shares used in computing diluted net income (loss) per common share</b> | <b>86,762</b>                           | <b>59,387</b>     |

See Notes to Condensed Financial Statements

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

|  | <b>Three Months Ended<br/>March 31,</b> |                 |
|--|---|-----------------|
|  | <b>2013</b>                             | <b>2012</b>     |
| <b>Cash flows from operating activities:</b>   |   |                 |
| Net income (loss)  | \$ 6,001                                | \$ (5,163)      |
| Adjustments to reconcile net income (loss) to net cash used in operating activities: |   |                 |
| Depreciation and amortization  | 5                                       | 5               |
| Non-cash gain on settlement of long-term debt  | (1,860)                                 |                 |
| Non-cash gain on termination of royalty repurchase agreement                         | (8,962)                                 |                 |
| Interest on royalty liability  |   | 167             |
| Non-cash loss on changes in fair value of warrants                                   | 3,045                                   | 16              |
| Stock-based compensation   | 505                                     | 1,552           |
| Changes in operating assets and liabilities:   |   |                 |
| Receivables  | 552                                     | 189             |
| Prepaid expenses and other assets  | 422                                     | (62)            |
| Accounts payable and other accrued liabilities                                       | 2,338                                   | 764             |
| Deferred contract revenue  | (3,750)                                 |                 |
| <b>Net cash used in operating activities</b>   | <b>(1,704)</b>                          | <b>(2,532)</b>  |
| <b>Cash flows from investing activities:</b>   |   |                 |
| Purchases of furniture and equipment   | (180)                                   | (522)           |
| <b>Net cash used in investing activities</b>   | <b>(180)</b>                            | <b>(522)</b>    |
| <b>Cash flows from financing activities:</b>   |   |                 |
| Proceeds from the issuance of common stock from the exercise of stock options        | 113                                     |                 |
| Proceeds from the exercise of warrants, net of issuance costs                        | 1,275                                   |                 |
| Payments on long-term debt   |   | (44)            |
| <b>Net cash provided by (used in) financing activities</b>                           | <b>1,388</b>                            | <b>(44)</b>     |
| <b>Net decrease in cash</b>  | <b>(496)</b>                            | <b>(3,098)</b>  |
| Cash at beginning of period  | 18,102                                  | 5,406           |
| <b>Cash at end of period</b>   | <b>\$ 17,606</b>                        | <b>\$ 2,308</b> |

See Notes to Condensed Financial Statements

---

**Table of Contents**

**TITAN PHARMACEUTICALS, INC.**

**NOTES TO CONDENSED FINANCIAL STATEMENTS**

**(unaudited)**

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

***The Company***

We are a biopharmaceutical company developing proprietary therapeutics 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<sup>®</sup>, the first slow release implant formulation of buprenorphine, 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 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, 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. generally accepted accounting principles for complete financial statements. These unaudited condensed financial statements should be read in conjunction with the audited financial statements and footnotes thereto included in the Titan Pharmaceuticals, Inc. Annual Report on Form 10-K 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. 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.

The accompanying financial statements have been prepared assuming we will continue as a going concern. We believe that our working capital at March 31, 2013 is sufficient to fund our planned operations through April 2014, inclusive of estimated expenses for preparation of our response to the Complete Response Letter regarding the Probuphine New Drug Application ( NDA ) that we received from the U.S. Food and Drug Administration ( FDA ). Under circumstances specified in the license agreement, our licensee, Braeburn Pharmaceuticals Sprl ( Braeburn ), has the right to either terminate the agreement or reduce the amount of the \$50 million milestone payment payable to us in the event the FDA ultimately approves Probuphine. If Braeburn were to terminate the agreement, we would not have sufficient funds available to us to complete the FDA approval process and commercialize Probuphine without raising additional capital and, as a result, our business and prospects will be materially adversely impacted. Furthermore, in the absence of such milestone payment, we may be unable to continue our current Parkinson s disease development program and will not be able to initiate any additional programs without obtaining additional financing, either through the sale of debt or equity securities. 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 activities.

***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.



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

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, the amount of revenue allocable to the delivered

---

## **Table of Contents**

technology is deferred. Non-refundable upfront fees with stand-alone value that are not dependent on future performance under these agreements are recognized as revenue when received, and are deferred if we have continuing performance obligations and have no evidence of fair value of those obligations. Cost reimbursements for research and development spending are recognized when the related costs are incurred and when collectability is reasonably assured. Payments received related to substantive, performance-based at-risk milestones are recognized as revenue upon achievement of the clinical success or regulatory event specified in the underlying contracts, which represent the culmination of the earnings process. Amounts received in advance are recorded as deferred revenue until the technology is transferred, costs are incurred, or a milestone is reached.

Technology license agreements typically consist of non-refundable upfront license fees, annual minimum access fees and/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<sup>®</sup> by Novartis 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 another third party. As we have no performance obligations under the license agreements, we have recorded the royalties earned, net of royalties we are obligated to pay, as revenue in our consolidated statement of operations.

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

Research and development expenses include internal and external costs. Internal costs include salaries and employment related expenses, facility costs, administrative expenses and allocations of corporate costs. External expenses consist of costs associated with outsourced clinical research organization (CRO) 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 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***

There have been no recent accounting pronouncements or changes in accounting pronouncements during the three months ended March 31, 2013, as compared to the recent accounting pronouncements described in our Annual Report on Form 10-K, that are of significance, or potential significance to us.

### ***Subsequent Events***

We have evaluated events that have occurred after March 31, 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 requires 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:

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

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 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.

**Table of Contents**

For the three months ended March 31, 2013, as a result of the fair value adjustment of the warrant liability, we recorded a non-cash loss on an increase in the fair value of \$3.0 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 liability.

| (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 March 31, 2013 | 3,045             |
| <br>Total warrant liability at March 31, 2013                                   | <br>\$ 6,599      |

**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, 2013 and 2012:

| (in thousands, except per share amounts)    | Three Months Ended<br>March 31, |              |
|---|---------------------------------|--------------|
|   | 2013                            | 2012         |
| Research and development                    | \$ 304                          | \$ 616       |
| General and administrative                  | 201                             | 936          |
| <br>Total share-based compensation expenses | <br>\$ 505                      | <br>\$ 1,552 |

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, 2013 and 2012:

|   | Three Months Ended<br>March 31, |       |
|---|---------------------------------|-------|
|   | 2013                            | 2012  |
| Weighted-average risk-free interest rate                                      | 0.64%                           | 0.94% |
| Expected dividend payments  |                                 |       |
| Expected holding period (years) <sup>1</sup>                                  | 4.4                             | 5.1   |
| Weighted-average volatility factor <sup>2</sup>                               | 1.83                            | 1.74  |
| Estimated forfeiture rates for options granted to management <sup>3</sup>     | 23%                             | 23%   |
| Estimated forfeiture rates for options granted to non-management <sup>3</sup> | 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, 2013. Based upon the above methodology, the weighted-average fair value of options and awards granted during the three-month period ended March 31, 2012 was \$1.09.

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

The following table summarizes option activity for the three-month period ended March 31, 2013:

| (in thousands, except per share amounts) | Options | Weighted<br>Average<br>Exercise<br>Price | Weighted<br>Average<br>Remaining<br>Option<br>Term | Aggregate<br>Intrinsic<br>Value |
|--|---------|--|--|---------------------------------|
| Outstanding at January 1, 2013           | 6,842   | \$ 1.33                                  | 6.65   | \$ 722                          |
| Granted                                  |         |  |  |                                 |
| Exercised                                | (75)    | 1.50                                     |  |                                 |
| Expired or canceled                      |         |  |  |                                 |
| Forfeited                                |         |  |  |                                 |
| Outstanding at March 31, 2013            | 6,767   | \$ 1.32                                  | 6.47   | \$ 3,386                        |
| Exercisable at March 31, 2013            | 6,639   | \$ 1.32                                  | 6.47   | \$ 3,323                        |

**Table of Contents**

As of March 31, 2013 there was approximately \$0.1 million of total unrecognized compensation expense related to non-vested stock options. This expense is expected to be recognized over a weighted-average period of 0.3 years.

No shares of restricted stock were awarded to employees, directors and consultants during the three-month period ended March 31, 2013.

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

Basic net income (loss) per common share is computed by dividing net income (loss) by the weighted average number of common shares outstanding for the period. Diluted net income (loss) per common share gives effect to all potentially dilutive common shares outstanding for the period. The potentially dilutive securities include stock options and warrants, which are calculated using the treasury stock method which is calculated using the if-converted method.

Diluted net loss per common share used the same weighted average number of common shares outstanding for the three months ended March 31, 2012, as calculated for the basic net loss per common share as the inclusion of any potential dilutive securities would be anti-dilutive. In addition, certain potential dilutive securities were excluded from the dilution calculation for the three months ended March 31, 2013, and 2012, as their inclusion would have been anti-dilutive.

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 months ended March 31, 2013, and 2012:

| <b>(in thousands, except per share amounts)</b>                    | <b>Three months ended March 31,</b> |                  |
|--|-------------------------------------|------------------|
|  | <b>2013</b>                         | <b>2012</b>      |
| <b>Numerator:</b>  |                                     |                  |
| Net income (loss) used for basic and diluted calculation           | \$ 6,001                            | \$ (5,163)       |
| <b>Denominator:</b>  |                                     |                  |
| Basic weighted-average outstanding common shares                   | 78,256                              | 59,387           |
| Effect of dilutive potential common shares resulting from options  | 2,237                               |                  |
| Effect of dilutive potential common shares resulting from warrants | 6,269                               |                  |
| <b>Weighted-average shares outstanding diluted</b>                 | <b>\$ 86,762</b>                    | <b>\$ 59,387</b> |
| <b>Net income (loss) per common share:</b>                         |                                     |                  |
| Basic  | \$ 0.08                             | \$ (0.09)        |
| Diluted  | \$ 0.07                             | \$ (0.09)        |

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 months ended March 31, 2013 and 2012:

| <b>(in thousands)</b>  | <b>Three months ended March 31,</b> |             |
|--|-------------------------------------|-------------|
|  | <b>2013</b>                         | <b>2012</b> |
| Weighted-average anti-dilutive common shares resulting from options  | 491                                 | 2,455       |
| Weighted-average anti-dilutive common shares resulting from warrants | 7                                   | 1,605       |
|  | 498                                 | 4,060       |

**4. Comprehensive Income and 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-month periods ended March 31, 2013 and 2012. Comprehensive income for the three-month periods ended March 31, 2013 was \$6.0 million. Comprehensive loss for the three-month periods ended March 31, 2012 was \$5.2 million.



---

**Table of Contents****5. Braeburn License**

In December 2012, we entered into a license agreement with Braeburn granting Braeburn exclusive commercialization rights to Probuphine in the United States and Canada. 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), and will receive a \$50.0 million milestone payment upon approval by the FDA of the NDA. We will be eligible to receive up to \$130.0 million upon achievement of specified sales milestones and up to \$35.0 million in regulatory milestones for additional indications, including chronic pain. We will receive tiered royalties on net sales of Probuphine ranging from the mid-teens to the low twenties. In addition, Apple Tree Partners IV, Braeburn's parent company, has allocated in excess of \$75.0 million to launch, commercialize and continue the development of Probuphine.

We have evaluated the revenue components of this license 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 estimate the revenue recognition period for the up-front payment to be approximately 12 months from the date of this agreement. Accordingly, we will recognize revenue for the up-front payment ratably from December 14, 2012, the date of the agreement, through December 14, 2013 at an amount equal to approximately \$1.25 million per month. As of March 31, 2013, we have recognized approximately \$4.4 million in license revenue and recorded deferred revenues of \$10.6 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 license agreement, we will receive a \$50.0 million milestone payment from Braeburn within 10 days following the achievement of FDA approval of the product NDA. 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 the \$50.0 million 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 license 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 license agreement.

**6. Commitments and Contingencies*****Financing Agreements***

On March 15, 2011, we entered into several agreements pursuant to which Deerfield agreed to provide \$20.0 million in funding to us. Funding occurred on April 5, 2011 and we used approximately \$7.6 million of proceeds from the Deerfield funding to repay an outstanding loan from Oxford Financing Corporation in full, including required final payments aggregating \$480,000. Pursuant to the terms of a facility agreement, we issued Deerfield promissory notes in the aggregate principal amount of \$20.0 million. The long-term debt bears interest at 8.5% per annum, payable quarterly, and was originally repayable over five years, with 10% of the principal amount due on the first anniversary, 15% due on the second anniversary, and 25% due on each of the next three anniversaries. We paid Deerfield a facility fee of \$0.5 million. The long-term debt is secured by our assets and has a provision for pre-payment. Deerfield has the right to have the long-term debt repaid at 110% of the principal amount in the event we complete a major transaction, which includes, but is not limited to, a merger or sale of our company or the sale of Probuphine. In connection with the facility agreement, we issued Deerfield six-year warrants to purchase 6,000,000 shares of our common stock at an exercise price of \$1.57 per share (Deerfield Warrants) (See Note 8, Warrant Liabilities for further discussion). As a result of our April 2012 subscription agreements, 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 in exchange for \$3.0 million (see Note 7, Royalty Liability for further discussion).





---

**Table of Contents**

We recorded the promissory notes with an aggregate principal amount of \$20.0 million at its face value less a note discount consisting of (i) \$3.0 million cash discount, (ii) a \$500,000 loan fee, and (iii) the \$5.5 million fair value of the associated warrants. The note discount totaling \$9.0 million is being amortized using the interest method. The effective annual interest rate on the note was 33% based on the note discount amortization, stated interest rate and note term.

On November 14, 2011, we entered into several agreements with Deerfield pursuant to which we agreed to pay a substantial portion of the remaining future royalties on the sales of Fanapt to Deerfield in exchange for \$5.0 million in cash that was recorded as royalty liability (see Note 7, *Royalty Liability* for further discussion), a \$10.0 million reduction in the principal amount owed to Deerfield under the existing facility agreement and a revised principal repayment schedule of \$2.5 million per year for four years commencing in April 2013 to retire the remaining long-term debt of \$10.0 million. We evaluated the November 2011 principal reduction and other amendments to the \$20.0 million facility agreement and determined that the modifications should be accounted for as a troubled debt restructuring on a prospective basis. As a result, we will recognize the difference between the carrying value of the long-term debt and the total required future principal and interest payments as interest expense over the remaining term using the interest method.

On February 6, 2013, the facility agreement dated as of March 11, 2011 with Deerfield was amended to provide that the exercise price of the Deerfield Warrants may be satisfied through a reduction in the principal amount of our outstanding indebtedness to Deerfield. In February and March 2013, Deerfield exercised an aggregate of 6,000,000 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. This resulted in a gain of \$1.9 million which was recorded in Other Income.

***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, 2013 and 2012 were approximately \$17.8 million and \$15.4 million, respectively, and we are obligated to pay royalties of approximately \$2.7 million and \$1.8 million to Sanofi-Aventis on March 31, 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 the Company.

**7. Royalty Liability**

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

The \$3.0 million received under the March 2011 royalty agreement was recorded as a royalty liability in accordance with the appropriate accounting guidance as the related agreement includes a provision which allows us to repurchase the royalty rights from Deerfield through a payment of a lump sum. Interest on the royalty liability is being recognized using the interest method based on the estimated future royalties expected to be paid under the royalty agreement. The current effective annual interest rate is 51.0%.

Under the November 14, 2011 amended and restated royalty agreement, in exchange for an additional \$5.0 million royalty liability, Deerfield is entitled to the balance of our portion of the royalties on Fanapt (5.5% to 7.5% of net sales, net of the 2.5% previously agreed to have been provided to Deerfield) up to specified threshold levels of net sales of Fanapt and 40% of the royalties above the threshold level. We retain 60% of the royalties on net sales of Fanapt above the threshold levels, subject to an agreement that half of any such retained royalties will go towards repayment of our outstanding debt to Deerfield. Funding occurred on November 25, 2011. The proceeds of this transaction are being used to advance the development of Probuphine and for general corporate purposes.

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



**Table of Contents**

On March 28, 2013, we amended the agreements with Deerfield terminating our option to repurchase the royalty rights. As a result, we have recognized a gain on the extinguishment of the royalty liability of \$9.0 million 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 Deerfield 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 subscription agreements, 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 were immediately exercisable and 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 Consolidated Statement 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 dated as of March 11, 2011 with Deerfield was amended to provide that the exercise price of the Deerfield Warrants may be satisfied through a reduction in the principal amount of our outstanding indebtedness to Deerfield. In February and March 2013, Deerfield exercised an aggregate of 6,000,000 warrants resulting in a reduction of our outstanding indebtedness to Deerfield of \$7.5 million (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 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 Series B Warrants to purchase 6,517,648 shares of common stock at an exercise price of \$0.85 per share. The Series A 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 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                              | March 31,<br>2013 | December 31,<br>2012 |
|---|-------------------|----------------------|
| Expected price volatility               | 85%               | 80%                  |
| Expected term (in years)                | 5.03              | 5.27                 |
| Risk-free interest rate                 | 0.78%             | 0.78%                |
| Dividend yield                          | 0.00%             | 0.00%                |
| Weighted-average fair value of warrants | \$ 1.22           | \$ 0.69              |

**9. Stockholders Deficit****Common Stock**

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.

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

On February 6, 2013, the facility agreement dated as of March 11, 2011 with Deerfield was amended to provide that the exercise price of the Deerfield Warrants may be satisfied through a reduction in the principal amount of our outstanding indebtedness to Deerfield. In February and March 2013, Deerfield exercised an aggregate of 6,000,000 warrants resulting in a reduction of our outstanding indebtedness to Deerfield of \$7.5 million.

## **Table of Contents**

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 (See Note 8, Warrant Liabilities for further discussion) was adjusted to \$1.25 per share. We recorded the gross proceeds from the Offering, net of (i) issuance costs of \$0.5 million and (ii) the fair value of the Warrants of \$2.9 million (see Note 8, Warrant Liabilities), as common stock paid-in in the Consolidated Balance Sheets.

## **10. Subsequent Events**

### ***Financing***

On April 1, 2013, we made the final principal payment of \$2.5 million under the facility agreement dated as of March 11, 2011 with Deerfield.

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 and human factors testing of the training program, as well as recommendations regarding product labeling and Risk Evaluation and Mitigation Strategy (REMS). We are committed to addressing these issues and we intend to discuss with the FDA the scope of the CRL comments to obtain clarification and determine next steps.

**Table of Contents****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, 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-New Drug Application (NDA) meeting with the Food and Drug Administration (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 and human factors testing of the training program, as well as recommendations regarding product labeling and Risk Evaluation and Mitigation Strategy (REMS). We are committed to addressing these issues and we intend to discuss with the FDA the scope of the CRL comments to obtain clarification and determine next steps.

In December 2012, we entered into a license 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) and are entitled to receive a \$50 million milestone payment upon the approval of the NDA by the FDA. Additionally, we will be eligible to receive up to \$130 million upon achievement of specified sales milestones and up to \$35 million in regulatory milestones in the event of future NDA submissions and approvals for additional indications, including chronic pain. We are entitled to receive tiered royalties on net sales of Probuphine ranging from the mid-teens to the low twenties.

Probuphine is the first product to utilize ProNeura, 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® (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 as of now have fully repaid the Deerfield loan. 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**

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

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.



---

**Table of Contents*****Results of Operations for the Three Months Ended March 31, 2013 and March 31, 2012***

Our net income for the three-month period ended March 31, 2013 was approximately \$6.0 million, or approximately \$0.08 per share, compared to our net loss of approximately \$5.2 million, or approximately \$0.09 per share, for the comparable period in 2012.

We generated licensing revenue of approximately \$3.8 million during the three-month period ended March 31, 2013. The licensing revenue resulted from the amortization of the non-refundable up-front license fee of \$15.75 million (approximately \$15.0 million, net of expenses) related to our licensing agreement with Braeburn. There were no revenues from licensing agreements in the comparable period of 2012. We generated royalty revenues during the three-month period ended March 31, 2013 of approximately \$1.4 million, compared to approximately \$1.2 million for the comparable period in 2012. We generated no grant revenues during the three-month period ended March 31, 2013, compared to approximately \$42,000 for the comparable period in 2012. Royalty revenues during the three-month periods ended March 31, 2013 and 2012 consisted of royalties on sales of Fanapt. The royalty revenues for the three-month period ended March 31, 2013 will be paid to Deerfield in accordance with the terms of the agreements entered into during 2011. Grant revenues during the three-month period ended March 31, 2012 consisted of proceeds from the NIH grants related to our ProNeura program.

Research and development expenses for the three-month period ended March 31, 2013 were approximately \$3.9 million, compared to approximately \$3.1 million for the comparable period in 2012, an increase of \$0.8 million, or 26%. The increase in research and development costs during the three-month period ended March 31, 2013 was primarily associated with an increase in external research and development expenses related to the review of the NDA for our Probuphine product with the FDA, including preparation for the advisory committee meeting. External research and development expenses include direct expenses such as clinical research organization charges, investigator and review board fees, patient expense reimbursements, regulatory expenses associated with NDA preparation and review and contract manufacturing expenses. In the first quarter of 2013, our external research and development expenses relating to our Probuphine product development program were approximately \$1.7 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, 2013 were approximately \$1.1 million, compared to approximately \$1.7 million for the comparable period in 2012, a decrease of \$0.6 million, or 35%. The decrease in general and administrative expenses during the three-month period ended March 31, 2013 was primarily related to decreases in non-cash stock compensation of approximately \$0.7 million. This was offset in part by fees paid to members of our board of directors of approximately \$0.1 million.

Net other income for the three-month period ended March 31, 2013 was approximately \$5.8 million compared to net other expense of approximately \$1.6 million in the comparable period in 2012. The increase in net other income during the three-month period ended March 31, 2013 resulted from approximately \$9.0 million of other income generated by the termination of our royalty repurchase agreement with Deerfield and 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 6,000,000 warrants. This was offset in part by approximately \$3.0 million related to non-cash losses on changes in the fair value of warrants and approximately \$0.5 million of other expense related to unamortized transaction fees related to the initial Deerfield debt transaction.

***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, 2013, we had approximately \$17.6 million of cash compared to approximately \$18.1 million at December 31, 2012. At March 31, 2013, we had working capital of approximately \$12.6 million, excluding \$10.6 million of deferred revenue, compared to working capital of approximately \$16.4 million, excluding \$14.4 million of deferred revenue, at December 31, 2012. Deferred revenue was excluded from the calculation of working capital because it will not be settled with the use of cash.

Our operating activities used approximately \$1.7 million during the three-months ended March 31, 2013. This consisted primarily of the net income for the period of approximately \$6.0 million, approximately \$3.0 million related to non-cash losses resulting from changes in the fair value of warrants and non-cash charges of approximately \$0.5 million related to share-based compensation expenses. This was offset in part by approximately \$0.4 million related to net changes in other operating assets and liabilities, \$1.9 million related to a non-cash gain on the settlement of long-term debt and \$9.0 million related to a non-cash gain on the termination of our royalty repurchase agreement with Deerfield. Uses of cash in operating activities were primarily to fund product development programs and administrative expenses. Our license agreement with Sanofi-Aventis requires us to pay royalties on future product sales. In addition, in order to maintain license and other rights while products are under development, we must comply with customary licensee obligations, including the payment of patent-related costs, annual minimum

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

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 \$3,000.

---

**Table of Contents**

Our investing activities used approximately \$0.2 million during the three-months ended March 31, 2013 primarily related to purchases of equipment.

Our financing activities provided approximately \$1.4 million during the three-months ended March 31, 2013. This consisted primarily of approximately \$1.3 million in proceeds from the exercise of warrants and approximately \$0.1 million in proceeds from the exercise of stock options.

On March 15, 2011, we entered into several agreements with entities affiliated with Deerfield pursuant to which Deerfield agreed to provide \$20.0 million in funding to us. Pursuant to the terms of a facility agreement, we issued Deerfield 8.5% promissory notes in the aggregate principal amount of \$20.0 million, paid them a facility fee of \$0.5 million and issued them warrants to purchase 6,000,000 shares of our common stock (the Deerfield Warrants). Under a royalty agreement, in exchange for \$3.0 million that was recorded as royalty liability, we agreed to pay Deerfield 2.5% of the aggregate royalties on net sales of Fanapt, subsequent to the funding date, constituting a portion of the royalty revenue we receive from Novartis.

On November 14, 2011, we entered into several agreements with Deerfield pursuant to which we agreed to pay them a substantial portion of the remaining future royalties on the sales of Fanapt in exchange for \$5.0 million in cash that was recorded as royalty liability, a \$10.0 million reduction in the principal amount owed to Deerfield under the existing facility agreement and a revised principal repayment schedule of \$2.5 million per year for four years commencing in April 2013 to retire the remaining long-term debt of \$10.0 million. Deerfield is entitled to the balance of our portion of the royalties on Fanapt (5.5% to 7.5% of net sales, net of the 2.5% we previously agreed to pay to Deerfield) up to specified threshold levels of net sales of Fanapt and 40% of the royalties above the threshold level. We retain 60% of the royalties on net sales of Fanapt above the threshold levels, subject to an agreement that half of any such retained royalties will go towards repayment of our outstanding debt to Deerfield. The agreements with Deerfield also provided us with the option to repurchase the royalty rights for \$40.0 million.

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 and, accordingly, upon our payment of the \$2.5 million installment in April 2013, our debt obligation to Deerfield was satisfied in full. In March 2013, we amended the agreements with Deerfield to terminate our option to repurchase the royalty rights.

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

On December 13, 2012, we entered into a license 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 March 31, 2013 is sufficient to fund our planned operations through April 2014 inclusive of estimated expenses for preparation of our response to the Complete Response Letter regarding the Probuphine NDA that was received from the FDA. Under circumstances specified in the license agreement, if additional clinical studies are required prior to FDA approval of Probuphine that would require expenditures in excess of certain amounts, Braeburn has the right to either terminate the agreement or reduce the amount of the \$50 million milestone payment payable to us in the event the FDA ultimately approves Probuphine. If Braeburn were to terminate the agreement, we would not have sufficient funds available to us to complete the FDA approval process and commercialize Probuphine without raising additional capital, and, as a result, our business and prospects will be materially adversely impacted. Furthermore, in the absence of such milestone payment, we may be unable to continue our current Parkinson's disease development program and will not be able to initiate any additional programs without obtaining additional financing, either through the sale of debt or equity securities. If we are unable to complete a

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

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 activities.

**Table of Contents**

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

Our market risk disclosures set forth in our Annual Report on Form 10-K 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 March 31, 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 March 31, 2013 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**

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 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 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.

**Table of Contents****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>  |
| 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, 200 <del>4</del>  |
| 10.7  | Amendments to lease for Registrant's facilities dated May 21, 2007 and March 12, 200 <del>9</del>   |
| 10.8* | 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, 201 <del>0</del>  |
| 10.15 | Amended and Restated Loan and Security Agreement between the Registrant and Oxford Finance Corporation dated September 27, 2010 <sup>12</sup>   |
| 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>   |



**Table of Contents**

| No.       | Description   |
|-----------|---|
| 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 Spri, dated December 14, 2012 <sup>19</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.

\* Confidential treatment has been granted with respect to portions of this exhibit.

\*\* Pursuant to Rule 406T of Regulation S-T, the interactive files on Exhibit 101.1 hereto are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and otherwise are not subject to liability under those sections.





**Table of Contents**

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

**TITAN PHARMACEUTICALS, INC.**

Dated: May 15, 2013

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