

TITAN PHARMACEUTICALS INC
Form 10-Q
May 10, 2016

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, 2016.

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 001-13341

Titan Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

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

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

(Address of Principal Executive Offices, Including Zip Code)

(650) 244-4990

(Registrant's Telephone Number, Including Area Code)

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, 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 20,084,760 shares of the Registrant's Common Stock issued and outstanding on May 6, 2016.

Titan Pharmaceuticals, Inc.

Index to Form 10-Q

Part I. Financial Information

Item 1. <u>Financial Statements (unaudited)</u>	3
<u>Condensed Balance Sheets as of March 31, 2016 and December 31, 2015</u>	3
<u>Condensed Statements of Operations and Comprehensive Income (Loss) for the three months ended March 31, 2016 and 2015</u>	4
<u>Condensed Statements of Cash Flows for the three months ended March 31, 2016 and 2015</u>	5
<u>Notes to Condensed Financial Statements</u>	6
Item 2. <u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	13
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	16
Item 4. <u>Controls and Procedures</u>	16

Part II. Other Information

Item 1A. <u>Risk Factors</u>	17
Item 6. <u>Exhibits</u>	17
<u>SIGNATURES</u>	21

Part I. Financial Information**Item 1. Financial Statements****TITAN PHARMACEUTICALS, INC.****CONDENSED BALANCE SHEETS****(in thousands)**

	March 31, 2016 (unaudited)	December 31, 2015 (Note 1)
Assets		
Current assets:		
Cash	\$ 5,762	\$ 7,857
Receivables	4,857	4,213
Prepaid expenses and other current assets	370	174
Total current assets	10,989	12,244
Property and equipment, net	1,007	1,043
Total assets	\$ 11,996	\$ 13,287
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 4,258	\$ 4,158
Accrued clinical trials expenses	379	341
Other accrued liabilities	443	354
Total current liabilities	5,080	4,853
Warrant liabilities	1,440	1,444
Total liabilities	6,520	6,297
Commitments and contingencies		
Stockholders' equity:		
Common stock, at amounts paid-in	297,828	297,828
Additional paid-in capital	23,593	23,261
Accumulated deficit	(315,945)	(314,099)
Total stockholders' equity	5,476	6,990
Total liabilities and stockholders' equity	\$ 11,996	\$ 13,287

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 March 31,	
	2016	2015
Revenues:		
License revenue	\$—	\$ 911
Total revenue	—	911
Operating expenses:		
Research and development	700	1,431
General and administrative	1,131	1,095
Total operating expenses	1,831	2,526
Loss from operations	(1,831)	(1,615)
Other expense:		
Other expense, net	(19)	(3)
Non-cash gain (loss) on changes in the fair value of warrants	4	(3,279)
Other expense, net	(15)	(3,282)
Net loss and comprehensive loss	\$(1,846)	\$(4,897)
Basic net loss per common share	\$(0.09)	\$(0.24)
Diluted net loss per common share	\$(0.09)	\$(0.24)
Weighted average shares used in computing basic net loss per common share	20,060	20,031
Weighted average shares used in computing diluted net loss per common share	20,400	20,056

See Notes to Condensed Financial Statements

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

	Three months Ended March 31,	
	2016	2015
Cash flows from operating activities:		
Net loss	\$ (1,846)	\$ (4,897)
Adjustments to reconcile loss to net cash used in operating activities:		
Depreciation and amortization	93	89
Non-cash (gain) loss on changes in fair value of warrants	(4)	3,279
Stock-based compensation	332	491
Changes in operating assets and liabilities:		
Receivables	(644)	485
Prepaid expenses and other assets	(196)	(151)
Accounts payable and other accrued liabilities	227	(411)
Deferred contract revenue	—	(911)
Net cash used in operating activities	(2,038)	(2,026)
Cash flows from investing activities:		
Purchases of furniture and equipment	(57)	(7)
Net cash used in investing activities	(57)	(7)
Cash flows from financing activities:		
Issuance of common stock due to the vesting of restricted shares	—	(14)
Net cash used by financing activities	—	(14)
Net decrease in cash and cash equivalents	(2,095)	(2,047)
Cash at beginning of period	7,857	15,470
Cash at end of period	\$ 5,762	\$ 13,423

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 specialty pharmaceutical company developing proprietary therapeutics for the treatment of serious medical disorders. Our product development programs utilize our proprietary long-term drug delivery platform, ProNeura®, and focus primarily on innovative treatments for select chronic diseases for which steady state delivery of a drug provides an efficacy and/or safety benefit. We are directly developing our product candidates and also utilize corporate, academic and government partnerships as appropriate. We operate in only one business segment, the development of pharmaceutical products. All share and per share amounts give retroactive effect to a 1 for 5.5 reverse stock split effected in September 2015. See Note 7 “Stockholders’ Equity – Reverse Stock Split.”

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 month period ended March 31, 2016 are not necessarily indicative of the results that may be expected for the year ending December 31, 2016, or any future interim periods.

The balance sheet at December 31, 2015 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 for the year ended December 31, 2015, 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.

In February 2016, the U.S. Food and Drug Administration (“FDA”) extended the agency action date for the Probuphine New Drug Application (“NDA”) by three months to May 27, 2016. At March 31, 2016, we had cash of approximately \$5.8 million, which we believe is sufficient to fund our planned operations through the end of 2016. We are entitled to a milestone payment from Braeburn Pharmaceuticals of \$15 million upon the potential approval of Probuphine. Accordingly, any substantial additional delay by the FDA could adversely impact our ability to continue our product development programs for Parkinson’s disease and hypothyroidism without obtaining additional financing, which is unlikely to be available on acceptable terms during this ongoing review process. If we are unable to complete a debt or equity offering, or otherwise obtain sufficient financing in the event of further delays, the progress of our development programs will be curtailed and our business and prospects could be materially adversely impacted. Furthermore, in order to advance our current ProNeura development programs to later stage clinical studies, we will require additional funds, either through payments from Braeburn under the license agreement in the event the Probuphine NDA is ultimately approved or through other financing arrangements, to complete the clinical studies and regulatory approval process necessary to commercialize any additional products we might develop.

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.

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. We no longer recognize royalty income related to the Fanapt® royalty payments received from Vanda Pharmaceuticals, Inc. (“Vanda”). See Note 6 “Commitments and Contingencies – Royalty Payments.”

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.

- 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 collections are reasonably expected. Payments received related to substantive, performance-based “at-risk” milestones are recognized as revenue upon achievement of the clinical success or regulatory event specified in the underlying contracts, which

represent the culmination of the earnings process. Amounts received in advance are recorded as deferred revenue until the technology is transferred, costs are incurred, or a milestone is reached.

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

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers* (“ASU 2014-09”), which supersedes nearly all existing revenue recognition guidance under U.S. GAAP. The core principle of ASU 2014-09 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration to which an entity expects to be entitled for those goods or services. ASU 2014-09 defines a five step process to achieve this core principle and, in doing so, more judgment and estimates may be required within the revenue recognition process than are required under existing U.S. GAAP.

The standard is effective for annual periods beginning after December 15, 2017, and interim periods therein, using either of the following transition methods: (i) a full retrospective approach reflecting the application of the standard in each prior reporting period with the option to elect certain practical expedients, or (ii) a retrospective approach with the cumulative effect of initially adopting ASU 2014-09 recognized at the date of adoption (which includes additional footnote disclosures). We are currently evaluating the impact of our pending adoption of ASU 2014-09 on our financial statements and have not yet determined the method by which we will adopt the standard.

In June 2014, the FASB issued ASU No. 2014-12, *Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could Be Achieved after the Requisite Service Period* (“ASU 2014-12”). The standard provides guidance that a performance target that affects vesting of a share-based payment and that could be achieved after the requisite service condition is a performance condition. As a result, the target is not reflected in the estimation of the award’s grant date fair value. Compensation cost for such award would be recognized over the required service period, if it is probable that the performance condition will be achieved. ASU 2014-12 is effective for annual reporting periods beginning after December 15, 2015. Early adoption is permitted. The guidance should be applied on a prospective basis to awards that are granted or modified on or after the effective date. Companies also have the option to apply the amendments on a modified retrospective basis for performance targets outstanding on or after the beginning of the first annual period presented as of the adoption date. The adoption of this ASU did not have a significant impact on our financial statements.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*, which supersedes the existing guidance for lease accounting, *Leases (Topic 840)*. ASU 2016-02 requires lessees to recognize leases on their balance sheets, and leaves lessor accounting largely unchanged. The amendments in this ASU are effective for fiscal years beginning after December 15, 2018 and interim periods within those fiscal years. Early application is permitted for all entities. ASU 2016-02 requires a modified retrospective approach for all leases existing at, or entered into after, the date of initial application, with an option to elect to use certain transition relief. We are currently evaluating the impact of our pending adoption of ASU 2016-02 on our financial statements.

Subsequent Events

We have evaluated events that have occurred after March 31, 2016 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 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, we recorded a non-cash gain on a decrease in the fair value of approximately \$4,000 for the three months ended March 31, 2016 and a non-cash loss on an increase in the fair value of approximately \$3.3 million for the three months ended March 31, 2015 in our Condensed Statements of Operations and Comprehensive Income (Loss). See Note 6, "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, 2015	\$ 1,444
Adjustment to record warrants at fair value	(4)
Total warrant liability at March 31, 2016	\$ 1,440

2. Stock Plans

The following table summarizes the stock-based compensation expense recorded for awards under the stock option plans for the three month periods ended March 31, 2016 and 2015:

	Three Months Ended March 31,	
(in thousands, except per share amounts)	2016	2015
Research and development	\$ 132	\$ 203
General and administrative	200	288
Total stock-based compensation expenses	\$ 332	\$ 491

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.

Edgar Filing: TITAN PHARMACEUTICALS INC - Form 10-Q

We use the Black-Scholes-Merton option-pricing model with the following assumptions to estimate the stock-based compensation expense for the three month period ended March 31, 2016 and 2015:

	Three Months Ended March 31, 2016 2015	
Weighted-average risk-free interest rate	1.53 %	1.8 %
Expected dividend payments	—	—
Expected holding period (years) ¹	6.5	6.4
Weighted-average volatility factor ²	0.92	1.61
Estimated forfeiture rates for options granted ³	29 %	30 %

(1) Expected holding period is based on historical experience of similar awards, giving consideration to the contractual terms of the stock-based awards, vesting schedules and the expectations of future employee behavior.

(2) Weighted average volatility is based on the historical volatility of our common stock.

(3) Estimated forfeiture rates are based on historical data.

Options to purchase approximately 168,000 and approximately 250,000 common shares were granted during the three month periods ended March 31, 2016 and 2015, respectively.

The following table summarizes option activity for the three month period ended March 31, 2016:

(in thousands, except per share amounts)	Options	Weighted Average Exercise Price	Weighted Average Remaining Option Term	Aggregate Intrinsic Value
Outstanding at January 1, 2016	1,883	\$ 5.83	5.14	\$ 388
Granted	168	5.10		
Exercised	—	—		
Expired or cancelled	(17)	7.70		
Forfeited	—	—		
Outstanding at March 31, 2016	2,034	\$ 5.75	6.38	\$ 642
Exercisable at March 31, 2016	1,532	\$ 5.97	5.27	\$ 642

No shares of restricted stock were awarded to employees, directors and consultants during the three month periods ended March 31, 2016 and 2015.

As of March 31, 2016, there was approximately \$1,245,000 of total unrecognized compensation expense related to non-vested stock options. This expense is expected to be recognized over a weighted-average period of approximately 1.6 years.

3. Net Loss Per Share

Basic net loss per share excludes the effect of dilution and is computed by dividing net loss by the weighted-average number of shares outstanding for the period. Diluted net 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 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.

The following table sets forth the reconciliation of the numerator and denominator used in the computation of basic and diluted net loss per common share for the three months ended March 31, 2016 and 2015:

(in thousands, except per share amounts)	Three months ended March	
	2016	2015
Numerator:		
Net loss used for basic earnings per share	\$ (1,846)	\$ (4,897)
Less change in fair value of warrant liability	(4)	—
Net loss used for diluted earnings per share	\$ (1,850)	\$ (4,897)
Denominator:		
Basic weighted-average outstanding common shares	20,060	20,031
Effect of dilutive potential common shares resulting from options	18	25
Effect of dilutive potential common shares resulting from warrants	322	—
Weighted-average shares outstanding—diluted	20,400	20,056
Net loss per common share:		
Basic	\$ (0.09)	\$ (0.24)
Diluted	\$ (0.09)	\$ (0.24)

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 loss per common share. These are excluded from the calculation due to their anti-dilutive effect for the three months ended March 31, 2016 and 2015:

(in thousands)	Three months ended	
	March 31,	
	2016	2015
Weighted-average anti-dilutive common shares resulting from options	1,667	1,241
Weighted-average anti-dilutive common shares resulting from warrants	316	597
	1,983	1,838

4. Comprehensive Loss

Comprehensive 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, 2016 and 2015. Comprehensive loss for the three-month period ended March 31, 2016 and 2015 was \$1.8 million and \$4.9 million, respectively.

5. Braeburn License

We are party to a license agreement with Braeburn Pharmaceuticals, Inc. (“Braeburn”) pursuant to which we have granted Braeburn the exclusive commercialization rights to Probuphine in the United States and its territories and Canada. Under the agreement (as amended to date, the “Agreement”), we received a non-refundable license fee of \$15.75 million (approximately \$15.0 million net of expenses) in December 2012 and are entitled to receive a \$15.0 million milestone payment upon FDA approval of the Probuphine NDA and royalties on net sales of Probuphine ranging in percentage from the mid-teens to the low twenties. Upon receipt of such approval, our obligation will be fulfilled and we will recognize the full amount of the milestone payment in accordance with the milestone method of revenue recognition. The Agreement also provides for up to \$165 million in sales milestones and \$35 million in regulatory milestones. In addition, we are entitled to receive a low single digit royalty on sales by Braeburn, if any, of other competing continuous delivery treatments for opioid dependence as defined in the Agreement, and can also 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 our royalties on Probuphine. Following FDA approval, we will be reimbursed by Braeburn for any developments services and activities undertaken by us at Braeburn’s request.

6. Warrant Liability

We currently have outstanding warrants to purchase an aggregate of 983,395 shares of common stock (“Series A Warrants”). The Series A Warrants are exercisable at \$4.89 per share, which gives effect to an anti-dilution adjustment as a result of the October 2014 public offering, and expire in April 2018. The Series A 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 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.

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

Assumption	March 31, 2016	
Expected price volatility	80	%
Expected term (in years)	2.02	
Risk-free interest rate	0.73	%
Dividend yield	0.00	%
Weighted-average fair value of warrants	\$ 1.46	

In October 2014, we completed an underwritten public offering (the “2014 Offering”) of units consisting of one share of common stock and 0.75 of a warrant (“Class A Warrant”). The Class A Warrants entitle the holders thereof to purchase an aggregate of 2,863,643 shares of our common stock at an initial exercise price of \$3.30 per share of common stock.

We agreed to hold a stockholders meeting no later than August 31, 2015 in order to seek stockholder approval for an amendment to our certificate of incorporation to either (i) increase the number of shares of common stock we are authorized to issue or (ii) effect a reverse split of the common stock, in either case in an amount sufficient to permit the exercise in full of the Class A Warrants in accordance with their terms. Failure to effect an increase in our authorized shares of common stock or effect a reverse split of our common stock prior to October 9, 2015 would have required us to pay liquidated damages in the aggregate amount of \$2,500,000. In September 2015, we effected a 1-for-5.5 reverse split of our common stock (the “Reverse Split”), which was within the range approved by our stockholders at the annual meeting held on August 24, 2015.

We also agreed to issue to the underwriter of the 2014 Offering warrants to purchase 114,546 shares of common stock (the “Underwriter Warrants”). The Underwriter Warrants have an exercise price per share of \$3.30 and may be exercised on a cashless basis. The Underwriter Warrants are not redeemable by us. The Underwriter Warrants are substantially the same form as the Class A Warrants included in the units except that they do not include certain liquidated damages rights contained in the Class A Warrants and will expire on the fifth anniversary of the date of effectiveness of the registration statement.

At the time these warrants were issued, we did not have adequate authorized and unissued common shares to be able to satisfy the exercise of these warrants. 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 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 September 29, 2015, we effected the Reverse Split, which will permit the exercise in full of the Class A Warrants in accordance with their terms and, accordingly, the associated warrant liability was reclassified to stockholders’ equity.

7. Stockholders’ Equity

Reverse Stock Split

On September 29, 2015, pursuant to prior shareholder authorization, our Board effected the Reverse Split of the outstanding shares of our common stock at a ratio of one (1) share for every five and one-half (5.5) shares outstanding, so that every five and one-half (5.5) outstanding shares of common stock before the Reverse Split represents one (1) share of common stock after the Reverse Split. Pursuant to their respective terms, the number of shares underlying our outstanding options and warrants was reduced by the Reverse Split ratio.

All share and per share amounts in the accompanying financial statements have been restated for all periods presented to give retroactive effect to the Reverse Split. The shares of common stock retained a par value of \$0.001 per share.

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 (the “Exchange Act”). 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 specialty pharmaceutical company developing proprietary therapeutics for the treatment of serious medical disorders. Our product development programs utilize our proprietary long-term drug delivery platform, ProNeura®, and focus primarily on innovative treatments for select chronic diseases for which steady state delivery of a drug provides an efficacy and/or safety benefit.

Probuphine®, our first product candidate to utilize ProNeura, is currently under NDA review by the FDA, with an action date of May 27, 2016. Pursuant to our license agreement with Braeburn, as amended to date, we are entitled to receive a \$15 million milestone payment upon FDA approval of the Probuphine NDA and royalties on net sales of Probuphine ranging in percentage from the mid-teens to the low twenties. The agreement also provides for up to \$165 million in sales milestones and \$35 million in regulatory milestones and entitles us to royalty rates in the low single digit on sales by Braeburn, if any, of other future competing products in the addiction market.

We believe that our ProNeura long term drug delivery platform has the potential to be used in the treatment of other chronic conditions where maintaining stable, around the clock blood levels of a medication may benefit the patient and improve medical outcomes. We have two products in early development using the ProNeura platform, an implant designed to provide long-term delivery of ropinirole, a dopamine agonist approved as a daily dosed oral formulation for the treatment of Parkinson's disease and an implant designed to provide long-term delivery of T3, a synthetic thyroid hormone approved as a daily dosed oral formulation for the treatment of hypothyroidism. In December 2015 we submitted briefing material to the FDA on the development plans for the ropinirole implant in support of the pre-Investigational New Drug ("IND") meeting request, and in late January we received feedback from the FDA on our product development plans. We have commenced preparation for the required non-clinical studies with the ropinirole implant, and following the potential approval of Probuphine, our goal is to complete the non-clinical development plan required in support of an IND application during this year, submit the IND in the fourth quarter of 2016 and enable commencement of a 'proof of concept' clinical study shortly thereafter. Early stage development of the T3 implant continues and we are currently conducting non-clinical studies to help optimize the formulation. We expect to finalize the initial development plans for the T3 implant and request a pre-IND meeting with the FDA by the fourth quarter of 2016 and hope to commence a proof of concept clinical study in the second half of 2017. Our goal is to further expand the product pipeline, and we are currently evaluating other drugs and disease settings for opportunities to use the ProNeura platform in potential treatment applications where conventional treatment is limited by variability in blood drug levels and poor patient compliance.

We operate in only one business segment, the development of pharmaceutical products.

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 months Ended March 31, 2016 and March 31, 2015

We had no license revenue during the three months ended March 31, 2016 compared to license revenue of approximately \$0.9 million for the three months ended March 31, 2015. License revenue for the 2015 period reflects the amortization of the upfront license fee received from Braeburn in December 2012.

Research and development expenses for the three month period ended March 31, 2016 were approximately \$0.7 million, compared to approximately \$1.4 million for the comparable period in 2015, a decrease of approximately \$0.7 million, or 50%. The decrease in research and development costs was primarily associated with the reimbursement of expenses by our development partner, Braeburn. This was partially offset by increases in external research and development expenses related to the support of our Probuphine and ProNeura product development programs, employee related expenses and other research and development expenses. During the three month period ended March 31, 2016, external research and development expenses relating to our product development programs were approximately \$0.6 million compared to approximately \$0.4 million for the comparable period in 2015. 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 periods ended March 31, 2016 and 2015 were approximately \$1.1 million.

Net other expense for the three month period ended March 31, 2016 was approximately \$15,000 compared to approximately \$3.3 million for the comparable period in 2015. Net other expense consisted primarily of non-cash gains and losses on changes in the fair value of warrants, tax expenses and interest income.

Our net loss for the three month period ended March 31, 2016 was approximately \$1.8 million, or approximately \$0.09 per share, compared to approximately \$4.9 million, or approximately \$0.24 per share, for the comparable period in 2015.

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 March 31, 2016, we had working capital of approximately \$5.9 million compared to working capital of approximately \$7.4 million at December 31, 2015.

Our operating activities used approximately \$2.0 million during the three months ended March 31, 2016. This consisted primarily of the net loss for the period of approximately \$1.8 million and \$0.6 million related to net changes in other operating assets and liabilities. This was offset, in part, by non-cash charges of approximately \$0.3 million related to stock-based compensation and approximately \$0.1 million related to depreciation and amortization. Uses of cash in operating activities were primarily to fund product development programs and administrative expenses.

Our investing activities used approximately \$57,000 during the three months ended March 31, 2016, which was primarily related to purchases of equipment.

We had no financing activities during the three months ended March 31, 2016.

In February 2016, the U.S. Food and Drug Administration (“FDA”) extended the agency action date for the Probuphine New Drug Application (“NDA”) by three months to May 27, 2016. At March 31, 2016, we had cash of approximately \$5.8 million, which we believe is sufficient to fund our planned operations through the end of 2016. We are entitled to a milestone payment from Braeburn Pharmaceuticals of \$15 million upon the potential approval of Probuphine. Accordingly, any substantial additional delay by the FDA could adversely impact our ability to continue our product development programs for Parkinson’s disease and hypothyroidism without obtaining additional financing, which is unlikely to be available on acceptable terms during this ongoing review process. If we are unable to complete a debt or equity offering, or otherwise obtain sufficient financing in the event of further delays, the progress of our development programs will be curtailed and our business and prospects could be materially adversely impacted. Furthermore, in order to advance our current ProNeura development programs to later stage clinical studies, we will require additional funds, either through payments from Braeburn under the license agreement in the event the Probuphine NDA is ultimately approved or through other financing arrangements, to complete the clinical studies and regulatory approval process necessary to commercialize any additional products we might develop.

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, 2015 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 Exchange Act as of March 31, 2016, the end of the period covered by this report, and has concluded that our disclosure controls and procedures were effective to ensure that the information required to be disclosed by us in reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC, and that such information is accumulated and communicated to our principal executive and principal financial officer as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the three months ended March 31, 2016 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 for the year ended December 31, 2015, 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.

Item 6. Exhibits

No.	Description
------------	--------------------

- | | |
|--------|--|
| 3.1(1) | Amended and Restated Certificate of Incorporation of the Registrant, as amended ⁹ |
| 3.1(2) | Certificate of Amendment to the Restated Certificate of Incorporation dated September 24, 2015 ²⁷ |
| 3.2 | By-laws of the Registrant ¹ |
| 3.3 | Certificate of Designations of Junior Participating Preferred Stock of Titan Pharmaceuticals, Inc. ¹⁵ |
| 4.1 | Registration Rights Agreement dated as of December 17, 2007 ² |
| 4.2 | Registration Rights Agreement dated as of December 8, 2009 ⁹ |
| 4.3 | Warrant to Purchase Common Stock dated December 23, 2009 issued to Oxford Finance Corporation ⁹ |
| 4.4 | Form of Warrant ¹³ |
| 4.5 | Registration Rights Agreement, dated as of March 15, 2011 ¹³ |
| 4.6 | Form of Series A Warrant ¹⁸ |
| 4.6 | Form of Class A Warrant ²⁶ |

- 4.6 Form of Underwriter Warrant ²⁶
- 10.1 1998 Stock Option Plan ³
- 10.2 2001 Non-Qualified Employee Stock Option Plan ⁴
- 10.3 2002 Stock Option Plan ⁵
- 10.4 Employment Agreement between the Registrant and Sunil Bhonsle, dated May 16, 2009, as amended by agreements dated February 17, 2010, December 30, 2011 and December 31, 2012 ^{9, 16, 19}
- 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 ^{9, 16, 19}
- 10.6 Lease for the Registrant's facilities, amended as of October 1, 2004⁶
- 10.7 Amendments to lease for Registrant's facilities dated May 21, 2007 and March 12, 2009⁹
- 10.8* License Agreement between the Registrant and Sanofi-Aventis SA effective as of December 31, 1996 ⁷

- 10.9* Sublicense Agreement between the Registrant and Novartis Pharma AG dated November 20, 1997 ⁸
- 10.10 Loan and Security Agreement between the Registrant and Oxford Finance Corporation dated December 18, 2009 ⁹
- 10.11 Stock Purchase Agreement between the Registrant and certain investors dated December 8, 2009 ⁹
- 10.12 Amendment to Employment Agreement dated June 15, 2010 between the Registrant and Marc Rubin ¹⁰
- 10.13 Amendment to Employment Agreement dated June 15, 2010 between the Registrant and Sunil Bhonsle ¹⁰
- 10.14 Amendment to lease for Registrant's facilities dated June 15, 2010¹¹
- 10.15 Amended and Restated Loan and Security Agreement between the Registrant and Oxford Finance Corporation dated September 27, 2010 ¹²
- 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, as amended on February 6, 2013 ^{13, 27}
- 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 ¹³
- 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 ¹⁴
- 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 ¹⁴
- 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 ¹⁴
- 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 ¹⁴
- 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 ¹⁴
- 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 ¹⁴
- 10.24 Form of Subscription Agreement dated April 9, 2012 ¹⁸
- 10.25*

Edgar Filing: TITAN PHARMACEUTICALS INC - Form 10-Q

License Agreement by and between Titan Pharmaceuticals, Inc. and Braeburn Pharmaceuticals Sprl,
dated December 14, 2012 ²⁰

- 10.26 Amendment dated May 28, 2013 to License Agreement by and between Titan Pharmaceuticals, Inc. and
Braeburn Pharmaceuticals Sprl ²¹
- 10.27 Second Amendment dated July 2, 2013 to License Agreement by and between Titan Pharmaceuticals, Inc. and
Braeburn Pharmaceuticals Sprl ²²

18

- 10.28 Third Amendment dated November 12, 2013 to License Agreement by and between Titan Pharmaceuticals, Inc. and Braeburn Pharmaceuticals Sprl ²³
- 10.29 Stock Purchase Agreement dated November 12, 2013 by and between Titan Pharmaceuticals, Inc. and Braeburn Pharmaceuticals Sprl ²³
- 10.30 2014 Incentive Plan ²⁴
- 10.31 2015 Titan Pharmaceuticals, Inc. Omnibus Equity Incentive Plan ²⁵
- 14.1 Code of Business Conduct and Ethics ²⁶
- 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.

Edgar Filing: TITAN PHARMACEUTICALS INC - Form 10-Q

(6) Incorporated by reference from the Registrant's Annual Report on Form 10-K for the year ended December 31, 2005.

(7) Incorporated by reference from the Registrant's Annual Report on Form 10-KSB for the year ended December 31, 1996.

(8) Incorporated by reference from the Registrant's Registration Statement on Form S-3 (File No. 333-42367).

(9) Incorporated by reference from the Registrant's Registration Statement on Form 10.

(10) Incorporated by reference from the Registrant's Annual Report on Form 10-K for the year ended December 31, 2003.

(11) Incorporated by reference from the Registrant's Quarterly Report on Form 10-Q for the period ended June 30, 2010.

⁽¹²⁾ Incorporated by reference from the Registrant's Quarterly Report on Form 10-Q for the period ended September 30, 2010.

⁽¹³⁾ Incorporated by reference from the Registrant's Current Report on Form 8-K filed on March 18, 2011.

⁽¹⁴⁾ Incorporated by reference from the Registrant's Current Report on Form 8-K filed on November 17, 2011.

⁽¹⁵⁾ Incorporated by reference from the Registrant's Current Report on Form 8-K filed on December 21, 2011.

⁽¹⁶⁾ Incorporated by reference from the Registrant's Current Report on Form 8-K filed on January 4, 2012.

⁽¹⁷⁾ Incorporated by reference from the Registrant's Annual Report on Form 10-K for the year ended December 31, 2011.

⁽¹⁸⁾ Incorporated by reference from the Registrant's Current Report on Form 8-K filed on April 10, 2013.

⁽¹⁹⁾ Incorporated by reference from the Registrant's Current Report on Form 8-K filed on January 2, 2013.

⁽²⁰⁾ Incorporated by reference from the Registrant's Current Report on Form 8-K/A filed on February 28, 2013.

⁽²¹⁾ Incorporated by reference from the Registrant's Current Report on Form 8-K dated May 29, 2013.

⁽²²⁾ Incorporated by reference from the Registrant's Current Report on Form 8-K dated July 5, 2013.

⁽²³⁾ Incorporated by reference from the Registrant's Current Report on Form 8-K dated November 13, 2013.

⁽²⁴⁾ Incorporated by reference from the Registrant's Annual Report on Form 10-K for the year ended December 31, 2013.

⁽²⁵⁾ Incorporated by reference from the Registrant's Current Report on Form 8-K dated August 25, 2015.

⁽²⁶⁾ Incorporated by reference from the Registrant's Annual Report on Form 10-K for the year ended December 31, 2012.

(27) Incorporated by reference from the Registrant's Current Report on Form 8-K dated September 28, 2015.

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

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 10,
2016

By: /s/ Sunil Bhonsle

Name: **Sunil Bhonsle**

Title: **President and Chief Executive Officer
(Principal Executive and Principal Financial Officer)**