

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended March 31, 2017.

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
(State or other jurisdiction of
incorporation or organization)

94-3171940
(I.R.S. Employer
Identification No.)

**400 Oyster Point Blvd., Suite 505,
South San Francisco, California**
(Address of principal executive offices)

94080
(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 (§232.405 of this chapter) 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, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/> (Do not check if a smaller reporting company)		
Smaller reporting company	<input type="checkbox"/>	Emerging growth company	<input type="checkbox"/>

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

Class	Outstanding at May 5, 2017
Common Stock, Par value \$0.001	21,203,744

Titan Pharmaceuticals, Inc.

Index to Form 10-Q

<u>Part I. Financial Information</u>		
Item 1.	Financial Statements (unaudited)	3
	Condensed Balance Sheets as of March 31, 2017 and December 31, 2016	3
	Condensed Statements of Operations and Comprehensive Loss for the three months ended March 31, 2017 and 2016	4
	Condensed Statements of Cash Flows for the three months ended March 31, 2017 and 2016	5
	Notes to Condensed Financial Statements	6
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	13
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	15
Item 4.	Controls and Procedures	15
<u>Part II. Other Information</u>		
Item 1A.	Risk Factors	17
Item 6.	Exhibits	17
SIGNATURES		20

Part I. Financial Information

Item 1. Financial Statements

TITAN PHARMACEUTICALS, INC.

CONDENSED BALANCE SHEETS
(in thousands)

	March 31, 2017	December 31, 2016
	(unaudited)	(Note 1)
Assets		
Current assets:		
Cash and cash equivalents	\$ 10,870	\$ 14,006
Receivables	1,009	3,587
Prepaid expenses and other current assets	433	237
Total current assets	<u>12,312</u>	<u>17,830</u>
Property and equipment, net	762	837
Total assets	<u>\$ 13,074</u>	<u>\$ 18,667</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,537	\$ 3,015
Accrued clinical trials expenses	189	1,387
Other accrued liabilities	544	455
Total current liabilities	<u>2,270</u>	<u>4,857</u>
Warrant liabilities	197	619
Total liabilities	<u>2,467</u>	<u>5,476</u>
Commitments and contingencies		
Stockholders' equity:		
Common stock, at amounts paid-in	297,855	297,855
Additional paid-in capital	24,721	24,300
Accumulated deficit	(311,969)	(308,964)
Total stockholders' equity	<u>10,607</u>	<u>13,191</u>
Total liabilities and stockholders' equity	<u>\$ 13,074</u>	<u>\$ 18,667</u>

See Notes to Condensed Financial Statements

TITAN PHARMACEUTICALS, INC.

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

	Three Months Ended	
	March 31,	
	2017	2016
Revenues:		
License revenue	\$ 40	\$ —
Total revenue	<u>40</u>	<u>—</u>
Operating expenses:		
Research and development	2,126	700
General and administrative	1,351	1,131
Total operating expenses	<u>3,477</u>	<u>1,831</u>
Loss from operations	(3,437)	(1,831)
Other income (expense):		
Other income (expense), net	10	(19)
Non-cash gain on changes in the fair value of warrants	422	4
Other income (expense), net	<u>432</u>	<u>(15)</u>
Net loss and comprehensive loss	<u>\$ (3,005)</u>	<u>\$ (1,846)</u>
Basic net loss per common share	<u>\$ (0.14)</u>	<u>\$ (0.09)</u>
Diluted net loss per common share	<u>\$ (0.16)</u>	<u>\$ (0.09)</u>
Weighted average shares used in computing basic net loss per common share	<u>21,199</u>	<u>20,060</u>
Weighted average shares used in computing diluted net loss per common share	<u>21,376</u>	<u>20,400</u>

See Notes to Condensed Financial Statements

TITAN PHARMACEUTICALS, INC.

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

	Three months Ended	
	March 31,	
	2017	2016
Cash flows from operating activities:		
Net loss	\$ (3,005)	\$ (1,846)
Adjustments to reconcile loss to net cash used in operating activities:		
Depreciation and amortization	101	93
Non-cash gain on changes in fair value of warrants	(422)	(4)
Stock-based compensation	421	332
Changes in operating assets and liabilities:		
Receivables	2,578	(644)
Prepaid expenses and other assets	(196)	(196)
Accounts payable and other accrued liabilities	(2,587)	227
Net cash used in operating activities	<u>(3,110)</u>	<u>(2,038)</u>
Cash flows from investing activities:		
Purchases of furniture and equipment	(26)	(57)
Net cash used in investing activities	<u>(26)</u>	<u>(57)</u>
Net decrease in cash and cash equivalents	<u>(3,136)</u>	<u>(2,095)</u>
Cash and cash equivalents at beginning of period	14,006	7,857
Cash and cash equivalents at end of period	<u>\$ 10,870</u>	<u>\$ 5,762</u>

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 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.

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, 2017 are not necessarily indicative of the results that may be expected for the year ending December 31, 2017, or any future interim periods.

The balance sheet at December 31, 2016 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, 2016, 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 May 2016, the U.S. Food and Drug Administration (“FDA”) approved our Probuphine New Drug Application (“NDA”) and pursuant to our license agreement with Braeburn Pharmaceuticals, Inc. (“Braeburn”), as amended to date, we received a \$15 million milestone payment and subsequently transferred the NDA to Braeburn.

At March 31, 2017, we had cash and cash equivalents of approximately \$10.9 million, which we believe are sufficient to fund our planned operations through the second quarter of 2018. We will require additional funds, either through payments from Braeburn under the license agreement or through other financing arrangements, to advance our current ProNeura development programs beyond the planned activities for the next 12 months and to complete the regulatory approval process necessary to commercialize any products we might develop.

Going concern assessment

In accordance with Accounting Standard Update, or ASU No. 2014-15, we assessed going concern uncertainty in our financial statements to determine if we have sufficient cash and cash equivalents on hand and working capital to operate for a period of at least one year from the date the financial statements are issued or available to be issued, which is referred to as the “look-forward period” as defined by ASU No. 2014-15. As part of this assessment, based on conditions that are known and reasonably knowable to us, we considered various scenarios, forecasts, projections, estimates and made certain key assumptions, including the timing and nature of projected cash expenditures or programs, and our ability to delay or curtail expenditures or programs, if necessary, among other factors. Based on this assessment, as necessary or applicable, we made certain assumptions around implementing curtailments or delays in the nature and timing of programs and expenditures to the extent we deem probable those implementations can be achieved and we have the proper authority to execute them within the look-forward period in accordance with ASU No. 2014-15.

Based upon the above assessment, we believe our cash and cash equivalents of approximately \$10.9 million at March 31, 2017 are sufficient to fund our planned operations through the second quarter of 2018. We will require additional funds, either through payments from Braeburn under the license agreement or through other financing arrangements, to advance our current ProNeura development programs beyond the planned activities for the next 12 months and to complete the regulatory approval process necessary to commercialize any 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.
- 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 contract research organization, or 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 August 2016, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments*, addressing eight specific cash flow issues in an effort to reduce diversity in practice. The amended guidance is effective for fiscal years beginning after December 31, 2017, and for interim periods within those years. Early adoption is permitted. We do not expect the amended guidance to have a material impact on our statements of cash flows.

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.

Subsequent Events

We have evaluated events that have occurred after March 31, 2017 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 non-cash gains on decreases in the fair value of approximately \$422,000 and approximately \$4,000 for the three month periods ended March 31, 2017 and 2016 in our Condensed Statements of Operations and Comprehensive Loss. See Note 6, “Warrant Liability” for further discussion on the calculation of the fair value of the warrant liability.

<u>(in thousands)</u>	<u>Warrant liability</u>
Total warrant liability at December 31, 2016	\$ 619
Adjustment to record warrants at fair value	(422)
Total warrant liability at March 31, 2017	<u>\$ 197</u>

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, 2017 and 2016:

<u>(in thousands, except per share amounts)</u>	<u>Three Months Ended</u>	
	<u>March 31,</u>	
	<u>2017</u>	<u>2016</u>
Research and development	\$ 117	\$ 132
General and administrative	304	200
Total stock-based compensation expenses	<u>\$ 421</u>	<u>\$ 332</u>

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

We use the Black-Scholes-Merton option-pricing model with the following assumptions to estimate the stock-based compensation expense for the three month period ended March 31, 2017 and 2016:

	<u>Three Months Ended</u>	
	<u>March 31,</u>	
	<u>2017</u>	<u>2016</u>
Weighted-average risk-free interest rate	2.16%	1.53%
Expected dividend payments	—	—
Expected holding period (years) ¹	6.6	6.5
Weighted-average volatility factor ²	0.88	0.92
Estimated forfeiture rates for options granted ³	28%	29%

- (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 436,000 and approximately 168,000 common shares were granted during the three month periods ended March 31, 2017 and 2016, respectively.

The following table summarizes option activity for the three month period ended March 31, 2017:

(in thousands, except per share amounts)	Options	Weighted Average Exercise Price	Weighted Average Remaining Option Term	Aggregate Intrinsic Value
Outstanding at January 1, 2017	2,002	\$ 5.67	5.68	\$ 203
Granted	436	3.89		
Exercised	—	—		
Expired or cancelled	(14)	17.21		
Forfeited	—	—		
Outstanding at March 31, 2017	<u>2,424</u>	<u>\$ 5.29</u>	<u>6.27</u>	<u>\$ 8</u>
Exercisable at March 31, 2017	<u>1,823</u>	<u>\$ 5.60</u>	<u>5.21</u>	<u>\$ 8</u>

No shares of restricted stock were awarded to employees, directors and consultants during the three month periods ended March 31, 2017 and 2016.

As of March 31, 2017, there was approximately \$1,302,000 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 1.3 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, 2017 and 2016:

(in thousands, except per share amounts)	Three months ended March 31,	
	2017	2016
Numerator:		
Net loss used for basic earnings per share	\$ (3,005)	\$ (1,846)
Less change in fair value of warrant liability	(422)	(4)
Net loss used for diluted earnings per share	<u>\$ (3,427)</u>	<u>\$ (1,850)</u>
Denominator:		
Basic weighted-average outstanding common shares	21,199	20,060
Effect of dilutive potential common shares resulting from options	45	18
Effect of dilutive potential common shares resulting from warrants	132	322
Weighted-average shares outstanding—diluted	<u>21,376</u>	<u>20,400</u>
Net loss per common share:		
Basic	\$ (0.14)	\$ (0.09)
Diluted	\$ (0.16)	\$ (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 loss per common share. These are excluded from the calculation due to their anti-dilutive effect for the three months ended March 31, 2017 and 2016:

(in thousands)	Three months ended March 31,	
	2017	2016
Weighted-average anti-dilutive common shares resulting from options	1,913	1,667
Weighted-average anti-dilutive common shares resulting from warrants	246	316
	<u>2,159</u>	<u>1,983</u>

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, 2017 and 2016. Comprehensive loss for the three-month period ended March 31, 2017 and 2016 was \$3.0 million and \$1.8 million, respectively.

5. Braeburn License

We are party to a license agreement with 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 a \$15.0 million milestone payment upon FDA approval of the Probuphine NDA in 2016. We receive royalties on net sales of Probuphine ranging in percentage from the mid-teens to the low twenties. Upon receipt of approval, our obligation was fulfilled and we recognized 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, up to an aggregate of \$50 million, 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. 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 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 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.

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

Assumption	March 31, 2017
Expected price volatility	49%
Expected term (in years)	1.02
Risk-free interest rate	1.04%
Dividend yield	0.00%
Weighted-average fair value of warrants	\$ 0.20

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 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 based on the ProNeura platform, was approved by the FDA in May 2016 for the maintenance treatment of opioid dependence in patients who are stable on low to moderate doses of daily sublingual buprenorphine treatment. We have licensed development and commercialization rights of Probuphine for the U.S. and Canadian markets to Braeburn and pursuant to the license agreement as amended to date, we received a \$15 million milestone payment upon FDA approval of the Probuphine NDA, and are entitled to receive royalties on net sales of Probuphine ranging in percentage from the mid-teens to the low twenties based on a tiered structure. The agreement also provides for up to an additional \$165 million in sales milestones and \$35 million in regulatory milestones on Probuphine. Additionally, in certain circumstances the agreement entitles us to a low single digit royalty, up to an aggregate of \$50 million, on net sales by Braeburn, if any, of other future competing products in the addiction market, e.g. a monthly depot injection. Braeburn commenced commercialization activities in support of the Probuphine product launch shortly after FDA approval. During the second half of 2016, Braeburn was engaged in training qualified health care providers in the implant insertion and removal procedures, physician outreach, payment and reimbursement discussions with third party payors and sales and marketing efforts associated with the launch including hiring personnel for a field sales force. In January 2017, Braeburn indicated that more than 2,500 health care providers from all 50 states and Puerto Rico were certified to provide Probuphine to their patients, and more than 70 payors, including private insurers, the Centers for Medicare & Medicaid Services (CMS) and Veterans Administration programs covered Probuphine. Also, the permanent J-code for Probuphine as the first six-month buprenorphine implant for the maintenance treatment of opioid addiction became effective on January 1, 2017, and we were informed that it should be incorporated into the reimbursement processing systems of most third party payor plans by early to mid-second quarter 2017. With a field sales force and medical support staff of more than 60 in place by early first quarter 2017, Braeburn commenced a full commercial launch focused on more than 80 key treatment centers throughout the U.S. to establish 'sites of excellence' for the long-term maintenance treatment with Probuphine. As with the launch of any new method of medical treatment in the current reimbursement environment, progress is slow during the initial several months while the challenges of the third party payor system are addressed. Braeburn has devoted substantial resources to support the patient and the physician community to facilitate this process of getting prior approvals from third party payors for treatment with Probuphine. While they have indicated good progress with some payors, it remains a challenge with some and recently Braeburn expanded its distribution channels and processing capacity by adding a second specialty pharmacy company to increase coverage across the country. During the first quarter, the number of patients seeking treatment with Probuphine showed a steady growth from month to month, and at the same time the number of health care providers that have prescribed Probuphine has been increasing from week to week. While revenues to Titan from Probuphine have to date been limited, the patient and physician trends are encouraging and we believe Braeburn is establishing a strong foundation for future success. We have been advised that most patients completing the first six month treatment with Probuphine during the quarter opted for treatment continuation. We believe we will benefit from the trend of opioid addiction treatment's move towards extended release formulations, a trend evidenced by the development efforts of the major suppliers of daily dosed buprenorphine products aimed at adding extended release formulations to their product pipeline. However, in light of the difficulties encountered to date, we cannot predict either the timing or the degree to which Probuphine will be accepted by the medical community.

We have continued to make progress in the efforts to advance potential commercialization of Probuphine outside of the U.S. and Canada. To obtain regulatory clarity for product approval in Europe, we met in December 2016 with the U.K. and German regulatory agencies, and based on feedback from these meetings we submitted an application to the European Medicines Agency, or EMA, seeking eligibility for Probuphine to follow the centralized review and approval process for its Marketing Authorization Application or MAA. In early March 2017, we received confirmation from the EMA that Probuphine is eligible for a centralized review and approval process. We were recently informed by the EMA that a pediatric indication waiver has been granted. While we are still early in this process, it is our estimate that an MAA could be filed in the fourth quarter of 2017. We have also been granted Small Manufacturing Entity, or SME, status in Europe, which provides for some monetary benefits during the application process and commercialization. We have continued the interactions regarding potential partnerships for Probuphine in Europe and elsewhere, and this regulatory clarity has helped in advancing the dialogue.



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.

The non-clinical development work related to the ropinirole implant, including the toxicology studies, was completed in the fourth quarter of 2016 and the IND was submitted to the FDA in January 2017. In late February 2017, in a telephone conversation, we received comments from the FDA following its initial review of the IND requesting additional information related to final test results for the ropinirole implant and the applicator, as well as the name of the Principal Investigator, and we were asked to hold the initiation of the clinical study. We received the FDA's written comments in late March giving details of the requested information. We are working as quickly as possible to provide the FDA with the additional information and expect to have during June all the data needed for the FDA submission. We hope to be able to commence the clinical study in early third quarter, although there is no assurance that the FDA will clear the IND within that timeframe, if at all.

During 2016 we identified refinements to the T3 implant formulation, however, due to shortage of the active pharmaceutical ingredient, or API, further investigation had to be temporarily suspended during the fourth quarter of 2016. In early 2017, we obtained the requisite supply of the API and have commenced work towards the optimization of the T3 implant. We intend to have further discussions this quarter with experts on the clinical development pathway, and the timing of further development activities will be dependent on those discussions and the availability of additional financial resources.

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, 2017 and March 31, 2016

License revenues were approximately \$40,000 during the three months ended March 31, 2017 compared with no license revenue during the three months ended March 31, 2016. License revenue for the 2017 period reflects the recognition of royalties earned on net sales of our Probuphine product by Braeburn.

Research and development expenses for the three month period ended March 31, 2017 were approximately \$2.1 million, compared to approximately \$0.7 million for the comparable period in 2016, an increase of approximately \$1.4 million, or 200%. The increase in research and development costs was primarily associated with increases in external research and development expenses related to the support of our Probuphine and ProNeura product development programs and other research and development expenses. During the three month period ended March 31, 2017, external research and development expenses relating to our product development programs were approximately \$1.1 million compared to approximately \$0.6 million for the comparable period in 2016. 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, 2017 were approximately \$1.4 million compared to approximately \$1.1 million for the comparable period in 2016, an increase of approximately \$0.3 million, or 27%. The increase in general and administrative expenses was primarily related to increases in non-cash stock-based compensation and employee-related costs of approximately \$0.1 million and professional fees of approximately \$0.1 million.

Net other income for the three month period ended March 31, 2017 was approximately \$0.4 million compared to net other expense of approximately \$15,000 for the comparable period in 2016. Net other income for the three month period ended March 31, 2017 consisted primarily of non-cash gains on changes in the fair value of warrants and interest income.

Our net loss for the three month period ended March 31, 2017 was approximately \$3.0 million, or approximately \$0.14 per share, compared to approximately \$1.8 million, or approximately \$0.09 per share, for the comparable period in 2016.

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, 2017, we had working capital of approximately \$10.0 million compared to working capital of approximately \$13.0 million at December 31, 2016.

Our operating activities used approximately \$3.1 million during the three months ended March 31, 2017. This consisted primarily of the net loss for the period of approximately \$3.0 million, \$0.4 million related to non-cash gains on changes in the fair value of warrants and \$0.2 million related to net changes in other operating assets and liabilities. This was offset, in part, by non-cash charges of approximately \$0.4 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 \$26,000 during the three months ended March 31, 2017, which was primarily related to purchases of equipment.

We had no financing activities during the three months ended March 31, 2017.

At March 31, 2017, we had cash and cash equivalents of approximately \$10.9 million, which we believe are sufficient to fund our planned operations through the second quarter of 2018. We will require additional funds, either through payments from Braeburn under the license agreement or through other financing arrangements, to advance our current ProNeura development programs beyond the planned activities for the next 12 months and to complete the regulatory approval process necessary to commercialize any 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, 2016 have not changed materially.

Item 4. Controls and Procedures

Disclosure Controls and Procedures

Our President and Chief Executive Officer, 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, 2017, 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, 2017 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, 2016, 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 ⁷
3.1(2)	Certificate of Amendment to the Restated Certificate of Incorporation dated September 24, 2015 ¹⁸
3.2	By-laws of the Registrant ¹
3.3	Certificate of Designations of Junior Participating Preferred Stock of Titan Pharmaceuticals, Inc. ¹⁰
4.1	Form of Series A Warrant ¹¹
4.2	Form of Class A Warrant ¹⁷
4.3	Form of Underwriter Warrant ¹⁷
10.1	2001 Non-Qualified Employee Stock Option Plan ²
10.2	2002 Stock Option Plan ³
10.3	Lease for the Registrant’s facilities, amended as of October 1, 2004 ⁴
10.4	Amendments to lease for Registrant’s facilities dated May 21, 2007 and March 12, 2009 ⁷
10.5*	License Agreement between the Registrant and Sanofi-Aventis SA effective as of December 31, 1996 ⁵
10.6*	Sublicense Agreement between the Registrant and Novartis Pharma AG dated November 20, 1997 ⁶
10.7	Amendment to lease for Registrant’s facilities dated June 15, 2010 ⁸
10.8	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 ⁹
10.9	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 ⁹
10.10	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 ⁹

- 10.11 Paying Agent Agreement, dated November 14, 2011, by and among the Company, Deerfield Management Company, L.P. and U.S. Bank National Association ⁹
- 10.12 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 ⁹
- 10.13* License Agreement by and between Titan Pharmaceuticals, Inc. and Braeburn Pharmaceuticals Sprl, dated December 14, 2012 ¹²
- 10.14 Amendment dated May 28, 2013 to License Agreement by and between Titan Pharmaceuticals, Inc. and Braeburn Pharmaceuticals Sprl ¹³
- 10.15 Second Amendment dated July 2, 2013 to License Agreement by and between Titan Pharmaceuticals, Inc. and Braeburn Pharmaceuticals Sprl ¹⁴
- 10.16 Third Amendment dated November 12, 2013 to License Agreement by and between Titan Pharmaceuticals, Inc. and Braeburn Pharmaceuticals Sprl ¹⁵
- 10.17 Stock Purchase Agreement dated November 12, 2013 by and between Titan Pharmaceuticals, Inc. and Braeburn Pharmaceuticals Sprl ¹⁵
- 10.18 2014 Incentive Plan ¹⁶
- 10.19 Titan Pharmaceuticals, Inc. Amended and Restated 2015 Omnibus Equity Incentive Plan ¹⁹
- 10.20 Controlled Equity OfferingSM Sales Agreement, dated September 1, 2016, between the Company and Cantor Fitzgerald & Co. ²⁰
- 10.21 Employment Agreement between the Company and Sunil Bhonsle dated September 29, 2016 ²¹
- 10.22 Employment Agreement between the Company and Marc Rubin dated September 29, 2016 ²¹
- 14.1 Code of Business Conduct and Ethics ¹⁷
- 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 Annual Report on Form 10-K for the year ended December 31, 2001.

- (3) Incorporated by reference from the Registrant's Annual Report on Form 10-K for the year ended December 31, 2002.
- (4) Incorporated by reference from the Registrant's Annual Report on Form 10-K for the year ended December 31, 2005.
- (5) Incorporated by reference from the Registrant's Annual Report on Form 10-KSB for the year ended December 31, 1996.
- (6) Incorporated by reference from the Registrant's Registration Statement on Form S-3 (File No. 333-42367).
- (7) Incorporated by reference from the Registrant's Registration Statement on Form 10.
- (8) Incorporated by reference from the Registrant's Quarterly Report on Form 10-Q for the period ended June 30, 2010.
- (9) Incorporated by reference from the Registrant's Current Report on Form 8-K filed on November 17, 2011.
- (10) Incorporated by reference from the Registrant's Current Report on Form 8-K filed on December 21, 2011.
- (11) Incorporated by reference from the Registrant's Current Report on Form 8-K filed on April 10, 2013.
- (12) Incorporated by reference from the Registrant's Current Report on Form 8-K/A filed on February 28, 2013.
- (13) Incorporated by reference from the Registrant's Current Report on Form 8-K dated May 29, 2013.
- (14) Incorporated by reference from the Registrant's Current Report on Form 8-K dated July 5, 2013.
- (15) Incorporated by reference from the Registrant's Current Report on Form 8-K dated November 13, 2013.
- (16) Incorporated by reference from the Registrant's Annual Report on Form 10-K for the year ended December 31, 2013.
- (17) Incorporated by reference from the Registrant's Annual Report on Form 10-K for the year ended December 31, 2012.
- (18) Incorporated by reference from the Registrant's Current Report on Form 8-K dated September 28, 2015.
- (19) Incorporated by reference from the Registrant's Current Report on Form 8-K dated August 3, 2016.
- (20) Incorporated by reference from the Registrant's Current Report on Form 8-K dated September 1, 2016.
- (21) Incorporated by reference from the Registrant's Current Report on Form 8-K dated October 3, 2016.

* 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, 2017

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

CERTIFICATION

I, Sunil Bhonsle, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Titan Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the registrant is made known to me by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under my supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 10, 2017

/s/ Sunil Bhonsle

Name: Sunil Bhonsle

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

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002**

In connection with this quarterly report on Form 10-Q of Titan Pharmaceuticals, Inc. (the "Company") for the period ended March 31, 2017, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer of the Company hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 10, 2017

/s/ Sunil Bhonsle

Name: Sunil Bhonsle

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