

TITAN PHARMACEUTICALS INC  
Form 10-Q  
November 13, 2014

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, D.C. 20549**

**FORM 10-Q**

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

**For the quarterly period ended September 30, 2014.**

**or**

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

**For the Transition Period From                      to**

**Commission file number 000-27436**



Edgar Filing: TITAN PHARMACEUTICALS INC - Form 10-Q

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

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

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

There were 109,997,533 shares of the Registrant’s Common Stock issued and outstanding on November 7, 2014.

**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 September 30, 2014 and December 31, 2013</u>	3
<u>Condensed Statements of Operations and Comprehensive Income (Loss) for the three and nine months ended September 30, 2014 and 2013</u>	4
<u>Condensed Statements of Cash Flows for the nine months ended September 30, 2014 and 2013</u>	5
<u>Notes to Condensed Financial Statements</u>	6
Item 2. <u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	14
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	17
Item 4. <u>Controls and Procedures</u>	17

**Part II. Other Information**

Item 1A. <u>Risk Factors</u>	17
Item 5. <u>Exhibits</u>	17
<b><u>SIGNATURES</u></b>	20

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

	September 30, 2014 (unaudited)	December 31, 2013 (Note 1)
Assets		
Current assets:		
Cash	\$ 7,450	\$ 11,798
Receivables	4,143	4,818
Prepaid expenses and other current assets	266	204
Total current assets	11,859	16,820
Property and equipment, net	1,357	1,603
Total assets	\$ 13,216	\$ 18,423
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 4,362	\$ 5,118
Accrued clinical trials expenses	173	118
Other accrued liabilities	343	293
Deferred contract revenue	2,583	5,317
Total current liabilities	7,461	10,846
Warrant liabilities	1,504	1,817
Total liabilities	8,965	12,663
Commitments and contingencies		
Stockholders' equity:		
Common stock, at amounts paid-in	284,449	284,485
Additional paid-in capital	22,149	21,692
Accumulated deficit	(302,347 )	(300,417 )
Total stockholders' equity	4,251	5,760
Total liabilities and stockholders' equity	\$ 13,216	\$ 18,423

See Notes to Condensed Financial Statements



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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Revenues:				
License revenue	\$ 911	\$ 2,198	\$ 2,734	\$ 8,146
Royalty revenue	—	—	—	1,424
Total revenue	911	2,198	2,734	9,570
Operating expenses:				
Research and development	782	1,679	2,480	7,380
General and administrative	867	647	2,476	2,439
Total operating expenses	1,649	2,326	4,956	9,819
Loss from operations	(738 )	(128 )	(2,222 )	(249 )
Other income (expense):				
Interest expense, net	—	—	—	(1,568 )
Other income (expense), net	(7 )	(7 )	(21 )	10,431
Non-cash gain (loss) on changes in the fair value of warrants	1,461	(1,010 )	313	1,306
Other income (expense), net	1,454	(1,017 )	292	10,169
Net income (loss) and comprehensive income (loss)	\$ 716	\$ (1,145 )	\$ (1,930 )	\$ 9,920
Basic net income (loss) per common share	\$ 0.01	\$ (0.01 )	\$ (0.02 )	\$ 0.12
Diluted net income (loss) per common share	\$ (0.01 )	\$ (0.00 )	\$ (0.03 )	\$ 0.11
Weighted average shares used in computing basic net income (loss) per common share	88,998	82,544	88,975	81,125
Weighted average shares used in computing diluted net income (loss) per common share	89,368	82,544	89,284	81,832

See Notes to Condensed Financial Statements

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

	Nine Months Ended September 30,	
	2014	2013
Cash flows from operating activities:		
Net income (loss)	\$(1,930 )	\$9,920
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and amortization	265	19
Non-cash gain on settlement of long-term debt	—	(1,860 )
Non-cash gain on termination of royalty purchase agreement	—	(8,962 )
Non-cash gain on changes in fair value of warrants	(313 )	(1,306 )
Stock-based compensation	457	656
Changes in operating assets and liabilities:		
Receivables	675	56
Prepaid expenses and other assets	(63 )	425
Accounts payable and other accrued liabilities	(650 )	1,504
Deferred contract revenue	(2,734 )	(8,147 )
Net cash used in operating activities	(4,293 )	(7,695 )
Cash flows from investing activities:		
Purchases of furniture and equipment	(18 )	(297 )
Net cash used in investing activities	(18 )	(297 )
Cash flows from financing activities:		
Proceeds from issuing common stock from the exercise of stock options	—	113
Proceeds from the exercise of warrants, net of issuance costs	—	1,275
Issuance of common stock from the vesting of restricted shares	(37 )	—
Payments on long-term debt	—	(2,500 )
Net cash used in financing activities	(37 )	(1,112 )
Net decrease in cash	(4,348 )	(9,104 )
Cash at beginning of period	11,798	18,102
Cash at end of period	\$7,450	\$8,998

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 conditions for which steady state delivery of a drug provides an efficacy 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 and nine month periods ended September 30, 2014 are not necessarily indicative of the results that may be expected for the year ending December 31, 2014, or any future interim periods.

The balance sheet at December 31, 2013 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, 2013, 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. At September 30, 2014, we had cash of approximately \$7.5 million. On October 8, 2014, we completed a financing transaction with net proceeds of approximately \$9.6 million, and these funds, together with the cash on hand at September 30, 2014, are sufficient to support our planned operations into the fourth quarter of 2016.

In the last several months our activities have focused on the Phase 3 clinical study of Probuphine which began patient enrollment in July 2014, and is expected to be fully enrolled before the end of this year with study completion anticipated by the middle of 2015. The clinical study is a randomized, double blind, double dummy design that is expected to enroll approximately 180 patients into two parallel treatment arms and is expected to provide key information necessary to address the Complete Response Letter (“CRL”) issued by the U.S. Food and Drug Administration (“FDA”) in April 2013. Resubmission of the New Drug Application (NDA) is expected in 2015 following completion of this study, with potential approval of Probuphine by the FDA in the first half of 2016. This study and subsequent NDA resubmission is funded primarily by Braeburn Pharmaceuticals Sprl (“Braeburn”) and Titan personnel will provide ongoing support for the conduct of the study as well as preparation of the NDA. We have also commenced development activities relating to a ProNeura technology platform based implant utilizing the compound ropinirole for the treatment of Parkinson’s disease. Our goal is to complete non-clinical studies with the ropinirole implant in support of filing an Investigational New Drug (IND) application with the FDA which should enable us to commence a ‘proof of concept’ clinical study in 2016 following potential approval of Probuphine.

### ***Revenue Recognition***

We generate revenue principally from collaborative research and development arrangements, technology licenses, royalties 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:

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.

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 collectibility is reasonably assured. We no longer recognize royalty income related to the Fanapt royalty payments received from Novartis unless Fanapt sales exceed certain thresholds (see Note 7, “Royalty Liability” for further discussion).

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.

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

Research and development expenses include internal and external costs. Internal costs include salaries and employment related expenses, facility costs, administrative expenses and allocations of corporate costs. External expenses consist of costs associated with outsourced clinical research organization activities, sponsored research studies, product registration, patent application and prosecution, and investigator sponsored trials. We also record accruals for estimated ongoing clinical trial costs. Clinical trial costs represent costs incurred by clinical research organizations (“CROs”) and clinical sites. These costs are recorded as a component of research and development expenses. Under our agreements, progress payments are typically made to investigators, clinical sites and CROs. We analyze the progress of the clinical trials, including levels of patient enrollment, invoices received and contracted costs when evaluating the adequacy of accrued liabilities. Significant judgments and estimates must be made and used in determining the accrued balance in any accounting period. Actual results could differ from those estimates under different assumptions. Revisions are charged to expense in the period in which the facts that give rise to the revision become known.

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

In 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, 2016, 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 probably 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. We are currently evaluating the impact of our pending adoption of ASU 2014-12 on our financial statements and the method by which we will adopt the standard.

In August 2014, the FASB issued ASU No. 2014-15 (Subtopic 205-40) — Presentation of Financial Statements—Going Concern: Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern (“ASU 2014-15”) which provides guidance about management’s responsibility to evaluate whether or not there is substantial doubt about the Company’s ability to continue as a going concern and to provide related footnote disclosure. ASU 2014-15 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2016. Early application is permitted. We are currently evaluating the impact of our pending adoption of ASU 2014-15 on our financial statements and the method by which we will adopt the standard.

### ***Subsequent Events***

We have evaluated events that have occurred after September 30, 2014 and through the date that the financial statements are issued.

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

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

Level 1 – quoted prices in active markets for identical assets or liabilities

Level 2 – quoted prices for similar assets and liabilities in active markets or inputs that are observable;

Level 3 – inputs that are unobservable (for example cash flow modeling inputs based on assumptions).

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

As a result of the fair value adjustment of the warrant liabilities, we recorded a non-cash gain on a decrease in the fair value of \$1.5 million and \$0.3 million for the three and nine months ended September 30, 2014, respectively, in our Condensed Statements of Operations and Comprehensive Income (Loss). See Note 8, "Warrant Liability" for further discussion on the calculation of the fair value of the warrant liabilities.

(in thousands)	Warrant Liability
Total warrant liability at December 31, 2013	\$ 1,817
Adjustment to record warrants at fair value	(313 )
Total warrant liability at September 30, 2014	\$ 1,504

## 2. Stock Plans

The following table summarizes the stock-based compensation expense recorded for awards under the stock option plans for the three and nine month periods ended September 30, 2014 and 2013:

(in thousands, except per share amounts)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Research and development	\$ 33	\$ 11	\$ 206	\$ 367
General and administrative	38	10	251	289
Total stock-based compensation expenses	\$ 71	\$ 21	\$ 457	\$ 656

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

We use the Black-Scholes-Merton option-pricing model with the following assumptions to estimate the stock-based compensation expense for the three and nine month periods ended September 30, 2014 and 2013:

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2014		2013		2014		2013	
Weighted-average risk-free interest rate	1.7	%	0.9	%	2.0	%	0.9	%
Expected dividend payments	—		—		—		—	
Expected holding period (years) <sup>1</sup>	4.21		3.8		6.5		4.0	
Weighted-average volatility factor <sup>2</sup>	1.66		1.05		1.66		1.48	
Estimated forfeiture rates <sup>3</sup>	31	%	32	%	31	%	32	%

(1) Expected holding periods are based on the simplified method provided in Staff Accounting Bulletin No. 107 for “plain vanilla options.”

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

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

No options were granted during the three month periods ended September 30, 2014 and 2013.

The following table summarizes option activity for the nine month period ended September 30, 2014:

(in thousands, except per share amounts)	Options	Weighted Average Exercise Price	Weighted Average Remaining Option Term	Aggregate Intrinsic Value
Outstanding at January 1, 2014	6,732	\$ 1.31	5.75	\$ —
Granted	275	0.66		
Exercised	—	—		
Expired or cancelled	(410 )	2.12		

Edgar Filing: TITAN PHARMACEUTICALS INC - Form 10-Q

Forfeited	(27 )	1.66			
Outstanding at September 30, 2014	6,570	\$ 1.23	5.36	\$	—
Exercisable at September 30, 2014	6,495	\$ 1.24	5.31	\$	—

The following table summarizes restricted stock activity for the nine month period ended September 30, 2014:

(in thousands, except per share amounts)	Restricted Stock	Weighted Average Exercise Price	Weighted Average Remaining Term	Aggregate Intrinsic Value
Outstanding at January 1, 2014	—	\$ —	—	\$ —
Granted	617	—		
Released	(259 )	—		
Expired or cancelled	—	—		
Forfeited	—	—		
Outstanding at September 30, 2014	358	\$ —	9.37	\$ 199
Exercisable at September 30, 2014	—	\$ —	—	\$ —

No shares of restricted stock were awarded to employees, directors and consultants during the three month periods ended September 30, 2014 and 2013.

As of September 30, 2014, there was approximately \$92,000 of total unrecognized compensation expense related to non-vested options and restricted stock. This expense is expected to be recognized over a weighted-average period of 0.4 years.

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

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

The following table sets forth the reconciliation of the numerator and denominator used in the computation of basic and diluted net income (loss) per common share for the three and nine months ended September 30, 2014 and 2013:

(in thousands, except per share amounts)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Numerator:				
Net income (loss) used for basic earnings per share	\$ 716	\$ (1,145 )	\$ (1,930 )	\$ 9,920
Less change in fair value of warrant liability	1,461	(1,010 )	313	1,306
Net (loss) income used for diluted earnings per share	\$ (745 )	\$ (135 )	\$ (2,243 )	\$ 8,614
Denominator:				
Basic weighted-average outstanding common shares	88,998	82,544	88,975	81,125
Effect of dilutive potential common shares resulting from options	370	—	309	624
Effect of dilutive potential common shares resulting from warrants	—	—	—	83
Weighted-average shares outstanding—diluted	89,368	82,544	89,284	81,832
Net income (loss) per common share:				
Basic	\$ 0.01	\$ (0.01 )	\$ (0.02 )	\$ 0.12
Diluted	\$ (0.01 )	\$ (0.00 )	\$ (0.03 )	\$ 0.11

The table below presents common shares underlying stock options and warrants that are excluded from the calculation of the weighted average number of common shares outstanding used for the calculation of diluted net income (loss) per common share. These are excluded from the calculation due to their anti-dilutive effect for the three and nine months ended September 30, 2014 and 2013:

	Three Months Ended September 30,	Nine Months Ended September 30,
--	----------------------------------	---------------------------------

Edgar Filing: TITAN PHARMACEUTICALS INC - Form 10-Q

(in thousands)	2014	2013	2014	2013
Weighted-average anti-dilutive common shares resulting from options	6,362	6,767	6,514	2,141
Weighted-average anti-dilutive common shares resulting from warrants	3,694	5,016	3,828	234
	10,056	11,783	10,342	2,375

**4. Comprehensive Income (Loss)**

Comprehensive income and loss for the periods presented is comprised solely of our net income and loss. We had no items of other comprehensive income (loss) during the three and nine-month periods ended September 30, 2014 and 2013. Comprehensive income for the three-month period ended September 30, 2014 was \$0.7 million and comprehensive loss for the nine-month period ended September 30, 2014 was \$1.9 million. Comprehensive loss for the three-month period ended September 30, 2013 was \$1.1 million and comprehensive income for the nine-month period ended September 30, 2013 was \$9.9 million.

## 5. Braeburn License

In December 2012, we entered into the Agreement with Braeburn granting Braeburn exclusive commercialization rights to Probuphine in the United States and its territories, including Puerto Rico, and Canada. As part of the Agreement, we received a non-refundable up-front license fee of \$15.75 million (approximately \$15.0 million, net of expenses), and would have received \$45.0 million upon approval by the FDA of the NDA as well as up to an additional \$130.0 million upon achievement of specified sales milestones and up to \$35.0 million in regulatory milestones for additional indications, including chronic pain. We would have received tiered royalties on net sales of Probuphine ranging from the mid-teens to the low twenties.

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

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

On November 12, 2013, we entered into the stock purchase agreement pursuant to which Braeburn made a \$5 million equity investment in our company and the Third Amendment primarily to modify the amount and timing of the approval and sales milestone payments payable under the Agreement. Under the Third Amendment, we are entitled to receive a \$15 million payment upon FDA approval of the NDA, up to \$165 million in sales milestones and \$35 million in regulatory milestones. We are entitled to receive a tiered royalty in the mid-teens to low twenties on all net sales of Probuphine. In addition, we are entitled to receive a low single digit royalty on sales by Braeburn, if any, of other continuous delivery treatments for opioid dependence as defined in the Third Amendment and can elect to receive a low single digit royalty on sales by Braeburn, if any, of other products in the addiction market in exchange for a similar reduction in our royalties on Probuphine.

## 6. Commitments and Contingencies

### *Financing Agreements*

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

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

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

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

In 1997, we entered into an exclusive license agreement with Sanofi-Aventis SA (formerly Hoechst Marion Roussel, Inc.). The agreement gave us a worldwide license to the patent rights and know-how related to the antipsychotic agent Fanapt (iloperidone), including the ability to develop, use, sublicense, manufacture and sell products and processes claimed in the patent rights. Upon commercialization of the product, the license agreement provides that we will pay royalties based on net sales. Net sales of Fanapt by Novartis during the three-month periods ended September 30, 2014 and 2013 were approximately \$17.2 million and \$20.0 million, respectively, and we were obligated to pay royalties of approximately \$2.6 million and \$3.1 million to Sanofi-Aventis on September 30, 2014 and December 31, 2013, respectively, which were included in Receivables and Accounts Payable on the Condensed Balance Sheets.

### ***Legal Proceedings***

There are no ongoing legal proceedings against our company.

### **7. Royalty Liability**

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

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

Under the November 14, 2011 amended and restated royalty agreement, in exchange for an additional \$5.0 million royalty liability, Deerfield is entitled to our portion of the royalties on Fanapt (5.5% to 7.5% of net sales, net of the 2.5% previously agreed to have been provided to Deerfield) up to specified threshold levels of net sales of Fanapt and 40% of the royalties above the threshold level. We retain 60% of the royalties on net sales of Fanapt above the threshold levels. The \$5.0 million received was recorded as a royalty liability in accordance with the appropriate accounting guidance as the related agreement included a provision which allowed us to repurchase the royalty rights from Deerfield through a payment of a lump sum. Interest on this royalty obligation was recognized using the interest method based on the estimated future royalties expected to be paid under the royalty agreement.

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

### **8. Warrant Liability**

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

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

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

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

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

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

Assumption	September 30, 2014		December 31, 2013	
Expected price volatility	115	%	90	%
Expected term (in years)	3.53		4.27	
Risk-free interest rate	1.26	%	1.40	%
Dividend yield	0.00	%	0.00	%
Weighted-average fair value of warrants \$	0.28		\$ 0.34	

## 9. Stockholders' Equity

### *Common Stock*

In November 2013, we entered into a stock purchase agreement with Braeburn pursuant to which we sold 6,250,000 shares of our common stock for an aggregate purchase price of \$5.0 million, or \$0.80 per share.

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

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

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

## 10. Subsequent Events

On October 8, 2014, we completed an underwritten public offering of 21,000,000 units at an offering price of \$0.50 per unit, with each unit consisting of one share of common stock and 0.75 of a warrant, each full warrant to purchase one share of common stock at an exercise price of \$0.60 per share. Net proceeds were approximately \$9.6 million after deducting underwriting discounts, commissions and other related expenses.

Proceeds from this offering will be used to support ongoing Probuphine® development and ex-U.S. partnering efforts, for pre-clinical development of other ProNeura technology-based products, including for the treatment of Parkinson's disease, and for working capital and other general corporate purposes.

The warrants will be exercisable beginning on the later of (i) one year and one day from the date of issuance and (ii) the date our stockholders approve either an increase in the number of our authorized shares of common stock or a reverse stock split, in either case in an amount sufficient to permit the exercise in full of the warrants, and will expire on the fifth anniversary of the date they first become exercisable.

As a result of anti-dilution provisions contained in the outstanding Series A warrants, the exercise price of such warrants was reduced from \$1.15 to \$0.89 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. 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 conditions for which steady state delivery of a drug provides an efficacy or safety benefit.

Our principal asset is Probuphine®, the first slow release implant formulation of buprenorphine in development for the long term maintenance treatment of opioid dependence. It is designed to maintain a stable, around the clock blood level of the medicine in patients for six months following a single treatment. Upon completion of the Phase 3 clinical studies of Probuphine, we participated in a pre-NDA meeting with the FDA, and subsequently prepared and submitted the NDA in October 2012. On April 30, 2013, the FDA issued a CRL to our NDA stating that it cannot approve the application in its present form and outlining the FDA’s request for additional clinical data demonstrating adequate clinical benefit to patients from this treatment, data from human factors testing of the training program for insertion and removal of the implants, as well as recommendations regarding product labeling, Risk Evaluation and Mitigation Strategy (“REMS”) and non-clinical safety data.

Following a meeting with the FDA in November 2013 and subsequent communications, the FDA provided clear guidance on a path forward, which along with other steps included conducting an additional clinical study. This study, which is being funded and managed by Braeburn, is a randomized, double blind, double dummy design that is expected to enroll approximately 180 patients into two parallel treatment arms. The study population is clinically stable patients who are receiving maintenance treatment with an approved sublingual formulation containing buprenorphine at a daily dose of 8mg or less. Patients will be randomized to receive either four Probuphine implants, or to continue the daily sublingual buprenorphine therapy. The patients are expected to be treated for six months, and the primary analysis will be a non-inferiority comparison of responders in the two arms. Patient enrollment in this 180 patient clinical study began in July 2014 and full patient enrollment is expected before the end of 2014, with study completion by the middle of 2015, followed by resubmission of the NDA later in the year. Probuphine development continues under Priority Review at the FDA and we could expect a PDUFA date for completion of the FDA review of the NDA in the first half of 2016.

Pursuant to the 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 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 low single digit royalties on sales by Braeburn, if any, of other future products in the addiction market.

Probuphine is the first product to utilize ProNeura™, our novel, proprietary, continuous drug delivery technology. Our ProNeura technology has the potential to be used in developing products for the treatment of other chronic conditions, such as Parkinson's disease (PD), where maintaining stable, around the clock blood levels of a dopamine agonist may benefit the patient and improve medical outcomes. We have commenced initial work on an implant formulation with ropinirole, a dopamine agonist approved for the treatment of PD. We are now optimizing the implant formulation, and having completed the recent financing we expect to proceed with the non-clinical studies of the ropinirole implant in support of filing an Investigational New Drug (IND) application with the FDA which should enable us to commence a 'proof of concept' clinical study in 2016 following potential approval of Probuphine.

We are also currently evaluating drugs and disease settings for opportunities to develop this drug delivery technology for other potential treatment applications in situations where conventional treatment is limited by variability in blood drug levels and poor patient compliance. We currently have very limited financial resources to pursue these additional research and development programs beyond an initial stage and are dependent on our ability to secure the requisite financing, either through payments from Braeburn under the Agreement in the event the Probuphine NDA is ultimately approved or through other arrangements.

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 and Nine Months Ended September 30, 2014 and September 30, 2013***

License revenues of approximately \$0.9 million and \$2.7 million for the three and nine month periods ended September 30, 2014, respectively, and approximately \$2.2 million and \$8.1 million for the three and nine month periods ended September 30, 2013, respectively, reflect the amortization of the upfront license fee received from Braeburn in December 2012. We recognized no net royalty revenues during the three and nine month periods ended September 30, 2014 compared to \$1.4 million during the nine months ended September 30, 2013 reflecting royalties paid on sales of Fanapt, all of which were paid to Deerfield in accordance with our royalty sales agreement. Beginning April 2013, we no longer recognize Fanapt royalty revenues since all of such royalties are paid to third parties.

Research and development expenses for the three month period ended September 30, 2014 were approximately \$0.8 million, compared to approximately \$1.7 million for the comparable period in 2013, a decrease of approximately \$0.9 million, or 53%. Research and development expenses for the nine month period ended September 30, 2014 were approximately \$2.5 million, compared to approximately \$7.4 million for the comparable period in 2013, a decrease of approximately \$4.9 million, or 70%. The decrease in research and development costs was primarily associated with a decrease in external research and development expenses related to the completion of the Probuphine product development program and preparation and review of the NDA submission with the FDA. During the nine months ended September 30, 2014, external research and development expenses relating to our Probuphine product development program were approximately \$116,000. Other research and development expenses include internal operating costs such as clinical research and development personnel-related expenses, clinical trials related travel expenses, and allocation of facility and corporate costs. As a result of the risks and uncertainties inherently associated with pharmaceutical research and development activities described elsewhere in this report, we are unable to estimate the specific timing and future costs of our clinical development programs or the timing of material cash inflows, if any, from our product candidates.

General and administrative expenses for the three month period ended September 30, 2014 were approximately \$0.9 million, compared to approximately \$0.6 million for the comparable period in 2013, an increase of approximately \$0.3 million, or 50%. General and administrative expenses for the nine month periods ended September 30, 2014 were approximately \$2.5 million, compared to approximately \$2.4 million for the comparable period in 2013, an increase of approximately \$0.1 million, or 4%. The increase in general and administrative expenses during the three month period ended September 30, 2014 was primarily related to increases in legal and consulting fees, Board fees, depreciation expense and non-cash stock compensation and employee related costs. The increase in general and administrative expenses during the nine month period ended September 30, 2014 was primarily related to an increase in depreciation

expense which was offset in part by decreases in non-cash stock compensation and employee related costs and facilities related expenses.

Net other income for the three month period ended September 30, 2014 was approximately \$1.5 million which was primarily related to non-cash gains on changes in the fair value of warrants compared to net other expense of approximately \$1.0 million in the comparable period in 2013 which was primarily related to non-cash losses on changes in the fair value of warrants. Net other income for the nine month period ended September 30, 2014 was approximately \$0.3 million which was primarily related to non-cash gains on changes in the fair value of warrants. Net other income during the comparable period in 2013 was approximately \$10.2 million, consisting primarily of approximately \$9.0 million in other income generated by the termination of Titan's royalty repurchase agreement with Deerfield, an approximately \$1.9 million gain resulting from the settlement of indebtedness to Deerfield as a result of the exercise of all of the Deerfield Warrants and non-cash gains on changes in the fair value of warrants of approximately \$1.3 million. These amounts were offset in part by interest expense of approximately \$1.6 million related to the Deerfield loans and approximately \$0.5 million in other expenses related to unamortized transaction fees related to the initial Deerfield debt transaction.

Our net income for the three month period ended September 30, 2014 was approximately \$0.7 million, or approximately \$0.01 per share, compared to our net loss of approximately \$1.1 million, or approximately \$0.01 per share, for the comparable period in 2013. Our net loss for the nine month period ended September 30, 2014 was approximately \$1.9 million, or approximately \$0.02 per share, compared to our net income of approximately \$9.9 million, or approximately \$0.12 per share, for the comparable period in 2013.

### ***Liquidity and Capital Resources***

We have funded our operations since inception primarily through the sale of our securities and the issuance of debt, as well as with proceeds from warrant and option exercises, corporate licensing and collaborative agreements, and government-sponsored research grants. At September 30, 2014, we had working capital of approximately \$4.4 million compared to working capital of approximately \$6.0 million at December 31, 2013.

Our operating activities used approximately \$4.3 million during the nine-months ended September 30, 2014. This consisted primarily of the net loss for the period of approximately \$1.9 million, approximately \$2.8 million related to net changes in other operating assets and liabilities and approximately \$0.3 million related to non-cash gains resulting from changes in the fair value of warrants. This was offset in part by, non-cash charges of approximately \$0.5 million related to share-based compensation expenses, and approximately \$0.3 million related to depreciation and amortization. Uses of cash in operating activities were primarily to fund product development programs and administrative expenses. Our license agreement with Sanofi-Aventis requires us to pay royalties on future product sales.

Net cash used in investing activities of approximately \$18,000 during the nine-months ended September 30, 2014 was primarily related to purchases of equipment.

Net cash used in financing activities of approximately \$37,000 during the nine-months ended September 30, 2014 was primarily related to the issuance of restricted stock.

In March 2011, we entered into several agreements with entities affiliated with Deerfield pursuant to which Deerfield agreed to provide \$20.0 million in funding to us. Pursuant to the terms of The Facility Agreement, we issued Deerfield 8.5% promissory notes in the aggregate principal amount of \$20.0 million. We paid Deerfield a facility fee of \$0.5 million and issued them the Deerfield Warrants to purchase 6,000,000 shares of our common stock. Under the Royalty Agreement, in exchange for \$3.0 million that was recorded as royalty liability, we agreed to pay Deerfield 2.5% of the aggregate royalties on net sales of Fanapt, subsequent to the funding date, constituting a portion of the royalty revenue we receive from Novartis. The agreements with Deerfield also provided us with the option to repurchase the royalty rights for \$40.0 million.

In November 2011, we entered into several agreements with Deerfield pursuant to which we agreed to pay them a substantial portion of the remaining future royalties on the sales of Fanapt in exchange for \$5.0 million in cash that was recorded as royalty liability, a \$10.0 million reduction in the principal amount owed to Deerfield under the existing facility agreement and a revised principal repayment schedule of \$2.5 million per year for four years commencing in April 2013 to retire the remaining long-term debt of \$10.0 million. Deerfield is entitled to the balance of our portion of the royalties on Fanapt (5.5% to 7.5% of net sales, net of the 2.5% we previously agreed to pay to Deerfield) up to specified threshold levels of net sales of Fanapt and 40% of the royalties above the threshold level.

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

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

In November 2013, we entered into (i) a stock purchase agreement pursuant to which Braeburn made a \$5.0 million equity investment in our company and (ii) the Third Amendment primarily to modify the amount and timing of the approval and sales milestone payments payable under the Agreement.

In October 2014, we completed an underwritten public offering of 21,000,000 units at an offering price of \$0.50 per unit, with each unit consisting of one share of common stock and 0.75 of a warrant, each full warrant to purchase one share of common stock at an exercise price of \$0.60 per share (the "Public Offering"). Net proceeds were approximately \$9.6 million after deducting underwriting discounts, commissions and other related expenses.

At September 30, 2014, we had cash of approximately \$7.5 million, which together with the proceeds of the Public Offering, we believe is sufficient to support our planned operations into the fourth quarter of 2016.

Although Braeburn has commenced the clinical study and is proceeding with plans for completing the clinical study expeditiously, under our December 2012 license agreement with Braeburn, as amended, Braeburn currently has the technical right to terminate the Agreement. If Braeburn were to exercise its right to terminate the Agreement, we would not have sufficient funds available to us to complete the FDA regulatory process and, in the event of ultimate approval, commercialize Probuphine without raising additional capital. If we are unable to complete a debt or equity offering, or otherwise obtain sufficient financing in such event, our business and prospects would be materially adversely impacted. Furthermore, while the proceeds of the Public Offering will enable us to advance our current ProNeura development program for Parkinson's disease to later stage clinical studies and to pursue the initial stages of other research and development, 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, 2013 have not changed materially.

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

#### *Disclosure Controls and Procedures*

Our President, being our principal executive and financial officer, has evaluated the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934 as of September 30, 2014, the end of the period covered by this report, and has concluded that our disclosure controls and procedures were effective to ensure that the information required to be disclosed by us in reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC, and that such information is accumulated and communicated to our principal executive and principal financial officer as appropriate to allow timely decisions regarding required disclosure.

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

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934) during the three months ended September 30, 2014 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, 2013 and in our registration statement on Form S-1 (File No. 333-198476), which could materially affect our business, financial

condition or future results. The risks described in such filings are not the only risks facing our Company. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results.

## Item 5. Exhibits

### No. Description

- 1.1 Form of Underwriting Agreement<sup>26</sup>
- 3.1 Amended and Restated Certificate of Incorporation of the Registrant, as amended<sup>9</sup>
- 3.2 By-laws of the Registrant<sup>1</sup>
- 3.3 Certificate of Designations of Junior Participating Preferred Stock of Titan Pharmaceuticals, Inc.<sup>15</sup>
- 4.1 Registration Rights Agreement dated as of December 17, 2007<sup>2</sup>
- 4.2 Registration Rights Agreement dated as of December 8, 2009<sup>9</sup>
- 4.3 Warrant to Purchase Common Stock dated December 23, 2009 issued to Oxford Finance Corporation<sup>9</sup>
- 4.4 Form of Warrant<sup>13</sup>
- 4.5 Registration Rights Agreement, dated as of March 15, 2011<sup>13</sup>
- 4.6 Form of Series A Warrant<sup>18</sup>
- 4.7 Form of Class A Warrant<sup>26</sup>
- 4.8 Form of Underwriter's Warrant<sup>26</sup>
- 10.1 1998 Stock Option Plan<sup>3</sup>
- 10.2 2001 Non-Qualified Employee Stock Option Plan<sup>4</sup>

- 10.3 2002 Stock Option Plan <sup>5</sup>
- 10.4 Employment Agreement between the Registrant and Sunil Bhonsle, dated May 16, 2009, as amended by agreements dated February 17, 2010, December 30, 2011 and December 31, 2012 <sup>9, 16, 19</sup>
- 10.5 Employment Agreement between the Registrant and Marc Rubin, dated May 16, 2009, as amended by agreements dated February 17, 2010, December 30, 2011 and December 31, 2012 <sup>9, 16, 19</sup>
- 10.6 Lease for the Registrant's facilities, amended as of October 1, 2004<sup>6</sup>
- 10.7 Amendments to lease for Registrant's facilities dated May 21, 2007 and March 12, 2009<sup>9</sup>
- 10.8\* License Agreement between the Registrant and Sanofi-Aventis SA effective as of December 31, 1996 <sup>7</sup>
- 10.9\* Sublicense Agreement between the Registrant and Novartis Pharma AG dated November 20, 1997 <sup>8</sup>
- 10.10 Loan and Security Agreement between the Registrant and Oxford Finance Corporation dated December 18, 2009 <sup>9</sup>
- 10.11 Stock Purchase Agreement between the Registrant and certain investors dated December 8, 2009 <sup>9</sup>
- 10.12 Amendment to Employment Agreement dated June 15, 2010 between the Registrant and Marc Rubin <sup>10</sup>
- 10.13 Amendment to Employment Agreement dated June 15, 2010 between the Registrant and Sunil Bhonsle <sup>10</sup>
- 10.14 Amendment to lease for Registrant's facilities dated June 15, 2010<sup>11</sup>
- 10.15 Amended and Restated Loan and Security Agreement between the Registrant and Oxford Finance Corporation dated September 27, 2010 <sup>12</sup>
- 10.16 Facility Agreement, dated as of March 15, 2011, by and among the Company, Deerfield Private Design Fund II, L.P., Deerfield Private Design International II, L.P., Deerfield Special Situations Fund, L.P., and Deerfield Special Situations Fund International Limited <sup>13</sup>
- 10.17 Security Agreement, dated as of March 15, 2011, by and among the Company, Deerfield Private Design Fund II, L.P., Deerfield Private Design International II, L.P., Deerfield Special Situations Fund, L.P., and Deerfield Special Situations Fund International Limited <sup>13</sup>
- 10.18 Royalty Purchase Agreement, dated November 14, 2011, by and among the Company, Deerfield Private Design Fund II, L.P., Deerfield Special Situations Fund, L.P. and Horizon Sante TTNP SARL <sup>14</sup>
- 10.19 Amended and Restated Royalty Agreement, dated November 14, 2011 by and among the Company, Deerfield Private Design Fund II, L.P., Deerfield Special Situations Fund, L.P. and Horizon Sante TTNP SARL <sup>14</sup>
- 10.20 Amended and Restated Royalty Repurchase Agreement, dated November 14, 2011, by and among the Company, Deerfield Private Design Fund II, L.P., and Horizon Sante TTNP SARL <sup>14</sup>

- 10.21 Cash Management Agreement, dated November 14, 2011, by and among the Company, Deerfield Private Design Fund II, L.P., Deerfield Special Situations Fund, L.P. and Horizon Sante TTNP SARL <sup>14</sup>
- 10.22 Paying Agent Agreement, dated November 14, 2011, by and among the Company, Deerfield Management Company, L.P. and U.S. Bank National Association <sup>14</sup>
- 10.23 Agreement, dated as of November 14, 2011, by and among the Company, Deerfield Private Design Fund II, L.P., Deerfield Private Design International II, L.P., Deerfield Special Situations Fund, L.P., and Deerfield Special Situations Fund International Limited <sup>14</sup>
- 10.24 Form of Subscription Agreement dated April 9, 2012 <sup>18</sup>
- 10.25\* License Agreement by and between Titan Pharmaceuticals, Inc. and Braeburn Pharmaceuticals Sprl, dated December 14, 2012 <sup>20</sup>
- 10.26 Amendment dated May 28, 2013 to License Agreement by and between Titan Pharmaceuticals, Inc. and Braeburn Pharmaceuticals Sprl <sup>21</sup>

18

- 10.27 Second Amendment dated July 2, 2013 to License Agreement by and between Titan Pharmaceuticals, Inc. and Braeburn Pharmaceuticals Sprl<sup>22</sup>
- 10.28 Third Amendment dated November 12, 2013 to License Agreement by and between Titan Pharmaceuticals, Inc. and Braeburn Pharmaceuticals Sprl<sup>23</sup>
- 10.29 Stock Purchase Agreement dated November 12, 2013 by and between Titan Pharmaceuticals, Inc. and Braeburn Pharmaceuticals Sprl<sup>23</sup>
- 10.30 2014 Incentive Plan<sup>24</sup>
- 14.1 Code of Business Conduct and Ethics<sup>25</sup>
- 31.1 Certification of the Principal Executive and Financial Officer pursuant to Rule 13(a)-14(a) of the Securities Exchange Act of 1934
- 32.1 Certification of the Principal Executive and Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
- 101.INS XBRL Instance Document
- 101.SCH XBRL Taxonomy Extension Schema Document
- 101.CAL XBRL Taxonomy Extension Calculation Linkbase Document
- 101.DEF XBRL Taxonomy Extension Definition Linkbase Document
- 101.LAB XBRL Taxonomy Extension Label Linkbase Document
- 101.PRE XBRL Taxonomy Extension Presentation Linkbase Document

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

Edgar Filing: TITAN PHARMACEUTICALS INC - Form 10-Q

- 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 Annual Report on Form 10-K for the year ended December 31, 2012.
- (26) Incorporated by reference from the Registrant's Registration Statement on Form S-1/A (File No. 333-198476).
- \* 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: November 13, 2014 By: /s/ SUNIL BHONSLE  
Name: **Sunil Bhonsle**  
Title: **President (Principal Executive and Principal Financial Officer)**