TITAN PHARMACEUTICALS INC
Form 10-Q
November 16, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2015.

or

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

For the Transition Period From to

Commission file number 001-13341

Titan Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

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

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

(Address of Principal Executive Offices, Including Zip Code)

(650) 244-4990

(Registrant's Telephone Number, Including Area Code)

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

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

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

Large accelerated filer ¨ Accelerated filer ¨

Non-accelerated filer ¨ (Do not check if a smaller reporting company) Smaller reporting company x

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

There were 20,059,656 shares of the Registrant's Common Stock issued and outstanding on November 10, 2015.

Titan Pharmaceuticals, Inc.

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Part I. Financial Information

Item 1. Financial Statements

TITAN PHARMACEUTICALS, INC.

CONDENSED BALANCE SHEETS

(in thousands)

	September 30, 2015 (unaudited)	**December 31, 2014** (Note 1)
Assets		
Current assets:		
Cash	$ 9,690	$ 15,470
Receivables	3,898	3,968
Prepaid expenses and other current assets	262	145
Total current assets	13,850	19,583
Property and equipment, net	1,059	1,268
Total assets	$ 14,909	$ 20,851
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,038	$ 4,408
Accrued clinical trials expenses	206	254
Other accrued liabilities	350	329
Deferred contract revenue	—	1,671
Total current liabilities	4,594	6,662
Warrant liabilities	1,398	5,578
Total liabilities	5,992	12,240
Commitments and contingencies		
Stockholders' equity:		
Common stock, at amounts paid-in	297,828	289,196
Additional paid-in capital	22,894	22,235
Accumulated deficit	(311,805)	(302,820)
Total stockholders' equity	8,917	8,611

Total liabilities and stockholders' equity	$ 14,909	$ 20,851

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,	
	2015	2014	2015	2014
Revenues:				
License revenue	$ —	$ 911	$ 1,671	$ 2,734
Total revenue	—	911	1,671	2,734
Operating expenses:				
Research and development	1,010	782	3,540	2,480
General and administrative	792	867	2,640	2,476
Total operating expenses	1,802	1,649	6,180	4,956
Loss from operations	(1,802)	(738)	(4,509)	(2,222)
Other income (expense):				
Other expense, net	(3)	(7)	(10)	(21)
Non-cash gain (loss) on changes in the fair value of warrants	(2)	1,461	(4,466)	313
Other income (expense), net	(5)	1,454	(4,476)	292
Net income (loss) and comprehensive income (loss)	$ (1,807)	$ 716	$ (8,985)	$ (1,930)
Basic net income (loss) per common share	$ (0.09)	$ 0.04	$ (0.45)	$ (0.12)
Diluted net loss per common share	$ (0.09)	$ (0.05)	$ (0.45)	$ (0.14)
Weighted average shares used in computing basic net income (loss) per common share	20,060	16,182	20,050	16,177
Weighted average shares used in computing diluted net loss per common share	20,060	16,249	20,050	16,233

See Notes to Condensed Financial Statements

TITAN PHARMACEUTICALS, INC.

CONDENSED STATEMENTS OF CASH FLOWS

(in thousands)

(unaudited)

	Nine Months Ended September 30,	
	2015	2014
Cash flows from operating activities:		
Net loss	$(8,985)	$(1,930)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	265	265
Non-cash (gain) loss on changes in fair value of warrants	4,466	(313)
Stock-based compensation	659	457
Changes in operating assets and liabilities:		
Receivables	70	675
Prepaid expenses and other assets	(117)	(63)
Accounts payable and other accrued liabilities	(397)	(650)
Deferred contract revenue	(1,671)	(2,734)
Net cash used in operating activities	(5,710)	(4,293)
Cash flows from investing activities:		
Purchases of furniture and equipment	(56)	(18)
Net cash used in investing activities	(56)	(18)
Cash flows from financing activities:		
Issuance of common stock from the vesting of restricted shares	(14)	(37)
Net cash used by financing activities	(14)	(37)
Net decrease in cash and cash equivalents	(5,780)	(4,348)
Cash at beginning of period	15,470	11,798
Cash at end of period	$9,690	$7,450
Schedule of non-cash transactions		
Fair value of warrants at the time of reclassification to equity	$8,646	$—

See Notes to Condensed Financial Statements

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TITAN PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

(unaudited)

1. Organization and Summary of Significant Accounting Policies

The Company

We are a specialty pharmaceutical company developing proprietary therapeutics for the treatment of serious medical disorders. Our product development programs utilize our proprietary long-term drug delivery platform, ProNeura®, and focus primarily on innovative treatments for select chronic diseases for which steady state delivery of a drug provides an efficacy and/or safety benefit. We are directly developing our product candidates and also utilize corporate, academic and government partnerships as appropriate. We operate in only one business segment, the development of pharmaceutical products.

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, 2015 are not necessarily indicative of the results that may be expected for the year ending December 31, 2015, or any future interim periods.

The balance sheet at December 31, 2014 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, 2014, 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, 2015, we had cash of approximately $9.7 million, which we believe is sufficient to fund our planned operations into the fourth quarter of 2016.

Although Braeburn has completed the PRO-814 clinical study and the resubmitted Probuphine NDA has been accepted for review by the FDA with an action date of February 27, 2016, under our December 2012 license agreement with Braeburn Pharmaceuticals, as amended (the “Agreement”), Braeburn currently has the technical right to terminate the Agreement. If Braeburn were to exercise its right to terminate the Agreement following the FDA action date, we would need to raise additional capital to have sufficient funds available to us to complete the FDA regulatory process and, in the event of ultimate approval, commercialize Probuphine. If we are unable to complete a debt or equity offering, or otherwise obtain sufficient financing in such event, our business and prospects would be materially adversely impacted. Furthermore, in order to advance our current ProNeura development program for Parkinson’s disease to later stage clinical studies, we will require additional funds, either through payments from Braeburn under the Agreement in the event the Probuphine NDA is ultimately approved or through other financing arrangements, to complete the clinical studies and regulatory approval process necessary to commercialize any additional products we might develop.

Revenue Recognition

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

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

- Technology license agreements typically consist of non-refundable upfront license fees, annual minimum access fees or royalty payments. Non-refundable upfront license fees and annual minimum payments received with separable stand-alone values are recognized when the technology is transferred or accessed, provided that the technology transferred or accessed is not dependent on the outcome of our continuing research and development efforts.

- Royalties earned are based on third-party sales of licensed products and are recorded in accordance with contract terms when third-party results are reliably measurable and collectability is reasonably assured. We no longer recognize royalty income related to the Fanapt royalty payments received from Vanda Pharmaceuticals, Inc. (“Vanda”). See Note 6 “Commitments and Contingencies – Royalty Payments.”

- Government grants, which support our research efforts in specific projects, generally provide for reimbursement of approved costs as defined in the notices of grants. Grant revenue is recognized when associated project costs are incurred.

- Collaborative arrangements typically consist of non-refundable and/or exclusive technology access fees, cost reimbursements for specific research and development spending, and various milestone and future product royalty payments. If the delivered technology does not have stand-alone value, the amount of revenue allocable to the delivered technology is deferred. Non-refundable upfront fees with stand-alone value that are not dependent on future performance under these agreements are recognized as revenue when received, and are deferred if we have continuing performance obligations and have no evidence of fair value of those obligations. Cost reimbursements for research and development spending are recognized when the related costs are incurred and when collections are reasonably expected. Payments received related to substantive, performance-based “at-risk” milestones are recognized as revenue upon achievement of the clinical success or regulatory event specified in the underlying contracts, which represent the culmination of the earnings process. Amounts received in advance are recorded as deferred revenue until the technology is transferred, costs are incurred, or a milestone is reached.

Research and Development Costs and Related Accrual

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

Recent Accounting Pronouncements

In May 2014, the Financing Accounting Standards Board ("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. The standard is effective for annual periods beginning after December 15, 2017, and interim periods therein, using either a full retrospective or a modified retrospective approach. We are currently evaluating the impact of our pending adoption of ASU 2014-09 on our financial statements and have not yet determined the method by which we will adopt the standard.

In June 2014, the FASB issued ASU No. 2014-12, *Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could Be Achieved after the Requisite Service Period* ("ASU 2014-12"). The standard provides guidance that a performance target that affects vesting of a share-based payment and that could be achieved after the requisite service condition is a performance condition. As a result, the target is not reflected in the estimation of the award's grant date fair value. Compensation cost for such award would be recognized over the required service period, if it is probable that the performance condition will be achieved. ASU 2014-12 is effective for annual reporting periods beginning after December 15, 2015 and 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.

Subsequent Events

We have evaluated events that have occurred after September 30, 2015 and through the date that the financial statements are issued.

Fair Value Measurements

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

fair value:

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

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

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

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

As a result of the fair value adjustment of the warrant liabilities, we recorded a non-cash loss on an increase in the fair value of $2,000 and $4.5 million for the three and nine months ended September 30, 2015, respectively, in our Condensed Statements of Operations and Comprehensive Income (Loss). See Note 7, “Warrant Liability” for further discussion on the calculation of the fair value of the warrant liability.

(in thousands)	**Warrant liability**
Total warrant liability at December 31, 2014	$ 5,578
Adjustment to record warrants at fair value	4,466
Reclassification of Class A and Underwriter warrant to equity	(8,646)
Total warrant liability at September 30, 2015	$ 1,398

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, 2015 and 2014:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands, except per share amounts)	2015	2014	2015	2014
Research and development	$ 42	$ 33	$ 280	$ 206
General and administrative	50	38	379	251
Total stock-based compensation expenses	$ 92	$ 71	$ 659	$ 457

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, 2015 and 2014:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Weighted-average risk-free interest rate	1.7 %	1.7 %	1.8 %	2.0 %
Expected dividend payments	—	—	—	—
Expected holding period (years) [1]	4.5	4.2	6.4	6.5
Weighted-average volatility factor [2]	1.65	1.66	1.61	1.66
Estimated forfeiture rates [3]	30 %	31 %	30 %	31 %

(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, 2015 and 2014.

The following table summarizes option activity for the nine month period ended September 30, 2015:

(in thousands, except per share amounts)	Options	**Weighted Average Exercise Price**	**Weighted Average Remaining Option Term**	**Aggregate Intrinsic Value**
Outstanding at January 1, 2015	1,204	$ 6.75	5.14	$ 1
Granted	250	3.30		
Exercised	—	—		
Expired or cancelled	(20)	13.27		
Forfeited	—	—		
Outstanding at September 30, 2015	1,434	$ 6.06	5.34	$ 202
Exercisable at September 30, 2015	1,311	$ 6.32	4.96	$ 111

No shares of restricted stock were awarded to employees, directors and consultants during the three month periods ended September 30, 2015 and 2014.

The following table summarizes restricted stock activity for the nine month period ended September 30, 2015:

(in thousands, except per share amounts)	**Restricted Stock**	**Weighted Average Exercise Price**	**Weighted Average Remaining Term**	**Aggregate Intrinsic Value**
Outstanding at January 1, 2015	65	$ —	9.12	$ 166
Granted	—	—		
Released	(65)	—		
Expired or cancelled	—	—		
Forfeited	—	—		
Outstanding at September 30, 2015	—	$ —	—	$ —
Exercisable at September 30, 2015	—	$ —	—	$ —

As of September 30, 2015, there was approximately $142,000 of unrecognized compensation expense related to non-vested stock options and restricted stock. This expense is expected to be recognized over a weighted-average period of 0.5 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 and nine months ended September 30, 2015 and 2014:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands, except per share amounts)	2015	2014	2015	2014
Numerator:				
Net income (loss) used for basic earnings per share	$ (1,807)	$ 716	$(8,985)	$(1,930)
Less change in fair value of warrant liability	—	1,461	—	313
Net loss used for diluted earnings per share	$ (1,807)	$ (745)	$(8,985)	$(2,243)
Denominator:				
Basic weighted-average outstanding common shares	20,060	16,182	20,050	16,177
Effect of dilutive potential common shares resulting from options	—	67	—	56
Effect of dilutive potential common shares resulting from warrants	—	—	—	—
Weighted-average shares outstanding—diluted	20,060	16,249	20,050	16,233
Net income (loss) per common share:				
Basic	$ (0.09)	$ 0.04	$(0.45)	$(0.12)
Diluted	$ (0.09)	$ (0.05)	$(0.45)	$(0.14)

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 and nine months ended September 30, 2015 and 2014:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2015	2014	2015	2014
Weighted-average anti-dilutive common shares resulting from options	1,349	1,157	1,341	1,184
Weighted-average anti-dilutive common shares resulting from warrants	289	672	210	696
	1,638	1,829	1,551	1,880

4. Comprehensive Income (Loss)

Comprehensive income (loss) for the periods presented is comprised solely of our net income (loss). We had no items of other comprehensive income (loss) during the three and nine month periods ended September 30, 2015 and 2014.

Comprehensive loss for the three and nine month periods ended September 30, 2015 was $1.8 million and $9.0 million, respectively. Comprehensive income for the three month period ended September 30, 2014 was $0.7 million. Comprehensive loss for the nine month period ended September 30, 2014 was $1.9 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 an 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 a 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 a stock purchase agreement pursuant to which Braeburn made a $5 million equity investment in our company and a third amendment to the Agreement 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

Royalty Payments

In 1997, we entered into an exclusive license agreement with Sanofi-Aventis. The agreement gave us a worldwide license to the patent rights and know-how related to the antipsychotic agent iloperidone, including the ability to develop, use, sublicense, manufacture and sell products and processes claimed in the patent rights. We are required to make additional benchmark payments as specific milestones are met. Upon commercialization of the product, the license agreement provides that we will pay royalties based on net sales.

We are party to an agreement with Novartis Pharma AG (“Novartis”), which, as amended, granted Novartis a worldwide sublicense to iloperidone (Fanapt®) in exchange for tiered royalties on net sales ranging from 8% to 10% and assumption of responsibility for all clinical development, registration, manufacturing and marketing of the product. Novartis sublicensed its rights to Vanda Pharmaceuticals, Inc. (“Vanda”) in 2004. Upon approval of Fanapt in 2009, Novartis acquired from Vanda the right to commercialize Fanapt in the United States and Canada. In December 2014, Novartis transferred all rights to commercialize Fanapt in the United States and Canada to Vanda. Our rights under the agreements have not changed. Pursuant to agreements entered into during 2011, we sold substantially all of our remaining future royalties on the sales of Fanapt ® to a third party and, accordingly, we no longer recognize royalty income related to the Fanapt royalty payments received from Vanda, which are transmitted to such third party, unless Fanapt sales exceed certain thresholds.

7. Warrant Liability

On April 9, 2012, in connection with subscription agreements with certain institutional investors for the purchase and sale of 1,185,034 shares of our common stock, we issued (i) six-year warrants ("Series A Warrants") to purchase 1,185,034 shares of common stock at an exercise price of $6.32 per share and (ii) six-month warrants ("Series B Warrants") to purchase 1,185,034 shares of common stock at an exercise price of $4.67 per share. As a result of our public offering in October 2014 and anti-dilution provisions contained in the outstanding Series A warrants, the exercise price of such warrants was reduced from $6.32 to $4.89 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 Binomial Lattice ("Lattice") valuation model, and the changes in the fair value are recorded in the Statements of Operations and Comprehensive Income (Loss). The Lattice model provides for assumptions regarding volatility and risk-free interest rates within the total period to maturity.

During the year ended December 31, 2012, Series B Warrants to purchase 1,047,609 shares of common stock were exercised at a price of $4.67 per share. The remaining Series B Warrants to purchase 137,425 shares of common stock expired in October 2012.

During the year ended December 31, 2013, Series A Warrants to purchase 201,639 shares of common stock were exercised resulting in gross proceeds of approximately $1,275,000. The remaining Series A Warrants to purchase 983,395 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, 2015	
Expected price volatility	90	%
Expected term (in years)	2.5	
Risk-free interest rate	0.78	%
Dividend yield	0.00	%
Weighted-average fair value of warrants	$ 1.42	

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

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

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

At the time these warrants were issued, we did not have adequate authorized and unissued common shares to be able to satisfy the exercise of these warrants. ASC 480, *Distinguishing Liabilities from Equity* requires that these warrants be classified as liabilities. The fair values of these warrants have been determined using the Lattice valuation model, and the changes in the fair value are recorded in the Statements of Operations and Comprehensive Income (Loss). The Lattice model provides for assumptions regarding volatility and risk-free interest rates within the total period to maturity. On September 29, 2015, we effected the Reverse Split, which will permit the exercise in full of the Class A Warrants in accordance with their terms and, accordingly, the associated warrant liability was reclassified to stockholders’ equity.

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

Assumption	September 29, 2015	
Expected price volatility	90	%
Expected term (in years)	5.0	
Risk-free interest rate	1.37	%
Dividend yield	0.00	%
Weighted-average fair value of warrants	$ 2.91	

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

Assumption	September 29, 2015	
Expected price volatility	90	%
Expected term (in years)	4.0	
Risk-free interest rate	1.15	%
Dividend yield	0.00	%
Weighted-average fair value of warrants	$ 2.71	

8. Stockholders' Equity

Reverse Stock Split

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

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

Common Stock

In October 2014, we completed the 2014 Offering. Net proceeds were approximately $9.6 million after deducting underwriting discounts, commissions and other related expenses. As a result of the 2014 Offering, and pursuant to the terms of the existing Series A Warrants, the exercise price of the Series A Warrants (See Note 7, “Warrant Liability” for further discussion) was adjusted to $4.89 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 diseases for which steady state delivery of a drug provides an efficacy and/or safety benefit over oral administration.

Probuphine®, our first product candidate to utilize ProNeura, is being developed for the long term maintenance treatment of opioid dependence and is designed to maintain a stable, around the clock blood level of the medicine buprenorphine in patients for six months following a single treatment. We have licensed the rights to commercialize Probuphine in the U.S. and Canada to Braeburn and we have been supporting Braeburn and a team of experts to implement the program developed in cooperation with the FDA to address the items in the Complete Response Letter issued in April 2013. This included conducting a double blind, double dummy clinical study of a four implant dose of Probuphine in clinically stable patients who are receiving maintenance treatment with an approved sublingual formulation containing buprenorphine at a daily dose of 8mg or less. This clinical study, which was funded and managed by Braeburn, was successfully completed in June 2015 and the Probuphine NDA was resubmitted in late

August 2015. In late September 2015, the FDA accepted the Probuphine NDA for review and set an FDA action date of February 27, 2016. Pursuant to our license agreement with Braeburn, as amended to date, we are entitled to receive a $15 million milestone payment upon FDA approval of the Probuphine NDA and royalties on net sales of Probuphine ranging in percentage from the mid-teens to the low twenties. The Agreement also provides for up to $165 million in sales milestones and $35 million in regulatory milestones for additional indications, including the chronic pain indication, and entitles us to royalty in the low single digit percentage on sales by Braeburn, if any, of certain other future products in the addiction market.

We believe that our ProNeura technology has the potential to be used in 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. During this quarter we have continued the formulation development work on an implant containing ropinirole, a dopamine agonist approved for the treatment of PD and we are conducting non-clinical studies to optimize the pharmacokinetic profile of the implant. During the fourth quarter, we expect to submit a pre-Investigational New Drug (IND) meeting request to the FDA and our goal is to complete the non-clinical studies required in support of an IND application by late next year and enable commencement of a 'proof of concept' clinical study by the end of next year following the potential approval of Probuphine.

Our goal is to expand the product pipeline using the ProNeura drug delivery platform and add at least one more product development program before the end of 2015. We are currently evaluating the feasibility of certain drugs and disease settings for opportunities to develop additional product candidates in the pipeline using the ProNeura drug delivery technology, especially in situations 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 and Nine Months Ended September 30, 2015 and September 30, 2014

We recognized no license revenue during the three month period ended September 30, 2015 and license revenues of approximately $1.7 million for the nine month period ended September 30, 2015 compared to approximately $0.9 million and $2.7 million for the three and nine month periods ended September 30, 2014, respectively. License revenues reflect the amortization of the upfront license fee received from Braeburn in December 2012.

Research and development expenses for the three month period ended September 30, 2015 were approximately $1.0 million, compared to approximately $0.8 million for the comparable period in 2014, an increase of approximately $0.2 million, or 25%. Research and development expenses for the nine month period ended September 30, 2015 were approximately $3.5 million, compared to approximately $2.5 million for the comparable period in 2014, an increase of approximately $1.0 million, or 40%. 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-ropinirole product development programs, employee related expenses and other research and development expenses. During the three and nine month periods ended September 30, 2015, external research and development expenses relating to our product development programs were approximately $0.3 million and $1.1 million, respectively, compared to approximately $0.1 million and $0.2 million, respectively, for the comparable periods in 2014. 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, 2015 were approximately $0.8 million, compared to approximately $0.9 million for the comparable period in 2014, a decrease of approximately $0.1 million, or 11%. The decrease in general and administrative expenses during the three month period ended September 30, 2015 was primarily related to decreases in professional fees and other outside services expenses. General and administrative expenses for the nine month period ended September 30, 2015 were approximately $2.6 million, compared to approximately $2.5 million for the comparable period in 2014, an increase of approximately $0.1 million, or 4%. The increase in general and administrative expenses during the nine month period ended September 30, 2015 was primarily related to increases in non-cash stock compensation and employee related costs of approximately $0.1 million and travel related expenses of approximately $0.1 million. This was offset in part by decreases in other outside

services expenses of approximately $0.1 million.

Net other expenses for the three and nine month periods ended September 30, 2015 were approximately $5,000 and $4.5 million, respectively. Net other income for the three and nine month periods ended September 30, 2014 were approximately $1.5 million and $0.3 million, respectively. Net other income and expense consisted primarily of non-cash gains and losses on changes in the fair value of our warrant liabilities.

Our net loss for the three month period ended September 30, 2015 was approximately $1.8 million, or approximately $0.09 per share, compared to our net income of approximately $0.7 million, or approximately $0.04 per share, for the comparable period in 2014. Our net loss for the nine month period ended September 30, 2015 was approximately $9.0 million, or approximately $0.45 per share, compared to our net loss of approximately $1.9 million, or approximately $0.12 per share, for the comparable period in 2014.

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, 2015, we had working capital of approximately $9.3 million compared to working capital of approximately $12.9 million at December 31, 2014.

Our operating activities used approximately $5.7 million during the nine months ended September 30, 2015. This consisted primarily of the net loss for the period of approximately $9.0 million and approximately $2.1 million related to net changes in other operating assets and liabilities. This was offset, in part, by non-cash charges of approximately $0.7 million related to stock-based compensation, approximately $4.5 million related to non-cash losses resulting from changes in the fair value of warrants 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 investing activities used approximately $56,000 during the nine months ended September 30, 2015 which was primarily related to purchases of equipment.

Our financing activities used approximately $14,000 during the nine months ended September 30, 2015 which was primarily related to taxes on the vesting of restricted shares.

In October 2014, we completed an underwritten public offering with net proceeds of approximately $9.6 million after deducting underwriting discounts, commissions and other related expenses.

At September 30, 2015, we had cash of approximately $9.7 million, which we believe is sufficient to fund our planned operations into the fourth quarter of 2016.

Although Braeburn has completed the PRO-814 clinical study and the resubmitted Probuphine NDA has been accepted for review by the FDA with an action date of February 27, 2016, under our December 2012 Agreement with Braeburn, Braeburn currently has the technical right to terminate the Agreement. If Braeburn were to exercise its right to terminate the Agreement following the FDA action date, we would need to raise additional capital to have sufficient funds available to us to complete the FDA regulatory process and, in the event of ultimate approval, commercialize Probuphine. If we are unable to complete a debt or equity offering, or otherwise obtain sufficient financing in such event, our business and prospects would be materially adversely impacted. Furthermore, in order to advance our current ProNeura development program for Parkinson’s disease to later stage clinical studies, we will require additional funds, either through payments from Braeburn under the 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, 2014 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, 2015, 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, 2015 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, 2014, 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
3.4	Certificate of Amendment to the Restated Certificate of Incorporation [1]
10.31	2015 Titan Pharmaceuticals, Inc. Omnibus Equity Incentive Plan [2]
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 Current Report on Form 8-K dated September 28, 2015.
(2) Incorporated by reference from the Registrant's Current Report on Form 8-K dated August 25, 2015.

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 16, 2015 By: /s/ Sunil Bhonsle
Name: **Sunil Bhonsle**
Title: **President**