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