TITAN PHARMACEUTICALS INC
Form 10-Q
November 09, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2016.

or

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

For the Transition Period From to

Commission file number 001-13341

Titan Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**94-3171940**
(State or Other Jurisdiction of 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 x
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 x

There were 21,198,879 shares of the Registrant's Common Stock issued and outstanding on November 4, 2016.

Titan Pharmaceuticals, Inc.

Index to Form 10-Q

Part I. Financial Information

Part II. Other Information

Part I. Financial Information

Item 1. Financial Statements

TITAN PHARMACEUTICALS, INC.

CONDENSED BALANCE SHEETS

(in thousands)

	September 30, 2016 (unaudited)	December 31, 2015 (Note 1)
Assets		
Current assets:		
Cash	$ 16,489	$ 7,857
Receivables	5,908	4,213
Prepaid expenses and other current assets	278	174
Total current assets	22,675	12,244
Property and equipment, net	860	1,043
Total assets	$ 23,535	$ 13,287
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,954	$ 4,158
Accrued clinical trials expenses	1,248	341
Other accrued liabilities	516	354
Total current liabilities	6,718	4,853
Warrant liabilities	1,555	1,444
Total liabilities	8,273	6,297
Commitments and contingencies		
Stockholders' equity:		
Common stock, at amounts paid-in	297,855	297,828
Additional paid-in capital	24,044	23,261
Accumulated deficit	(306,637)	(314,099)
Total stockholders' equity	15,262	6,990
Total liabilities and stockholders' equity	$ 23,535	$ 13,287

See Notes to Condensed Financial Statements

TITAN PHARMACEUTICALS, INC.

CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)

(in thousands, except per share amount)

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Revenues:				
License revenue	$ 26	$ —	$ 15,030	$ 1,671
Total revenue	26	—	15,030	1,671
Operating expenses:				
Research and development	1,590	1,010	4,036	3,540
General and administrative	1,052	792	3,397	2,640
Total operating expenses	2,642	1,802	7,433	6,180
Income (loss) from operations	(2,616)	(1,802)	7,597	(4,509)
Other expense:				
Other income (expense), net	1	(3)	(24)	(10)
Non-cash loss on changes in the fair value of warrants	(5)	(2)	(111)	(4,466)
Other expense, net	(4)	(5)	(135)	(4,476)
Net income (loss) and comprehensive income (loss)	$ (2,620)	$ (1,807)	$ 7,462	$ (8,985)
Basic net income (loss) per common share	$ (0.12)	$ (0.09)	$ 0.36	$ (0.45)
Diluted net income (loss) per common share	$ (0.12)	$ (0.09)	$ 0.35	$ (0.45)
Weighted average shares used in computing basic net income (loss) per common share	21,199	20,060	20,591	20,050
Weighted average shares used in computing diluted net income (loss) per common share	21,199	20,060	21,447	20,050

See Notes to Condensed Financial Statements

TITAN PHARMACEUTICALS, INC.

CONDENSED STATEMENTS OF CASH FLOWS

(in thousands)

(unaudited)

	Nine Months Ended September 30,	
	2016	2015
Cash flows from operating activities:		
Net income (loss)	$7,462	$(8,985)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and amortization	279	265
Non-cash loss on changes in fair value of warrants	111	4,466
Stock-based compensation	783	659
Changes in operating assets and liabilities:		
Receivables	(1,695)	70
Prepaid expenses and other assets	(104)	(117)
Accounts payable and other accrued liabilities	1,865	(397)
Deferred contract revenue	—	(1,671)
Net cash provided by (used in) operating activities	8,701	(5,710)
Cash flows from investing activities:		
Purchases of furniture and equipment	(96)	(56)
Net cash used in investing activities	(96)	(56)
Cash flows from financing activities:		
Issuance of common stock from the exercise of options	27	—
Issuance of common stock from the vesting of restricted shares	—	(14)
Net cash provided by (used in) financing activities	27	(14)
Net increase (decrease) in cash and cash equivalents	8,632	(5,780)
Cash at beginning of period	7,857	15,470
Cash at end of period	$16,489	$9,690
Schedule of non-cash transactions		
Fair value of warrants at the time of reclassification to equity	$—	$8,646

See Notes to Condensed Financial Statements

5

TITAN PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

(unaudited)

1. Organization and Summary of Significant Accounting Policies

The Company

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

Basis of Presentation

The accompanying unaudited condensed financial statements have been prepared in accordance with U.S. generally accepted accounting principles (“GAAP”) for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statement presentation. In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation have been included. Operating results for the three and nine month periods ended September 30, 2016 are not necessarily indicative of the results that may be expected for the year ending December 31, 2016, or any future interim periods.

The balance sheet at December 31, 2015 has been derived from the audited financial statements at that date, but does not include all of the information and footnotes required by U.S. GAAP for complete financial statements. These unaudited condensed financial statements should be read in conjunction with the audited financial statements and footnotes thereto included in the Titan Pharmaceuticals, Inc. Annual Report on Form 10-K for the year ended December 31, 2015, as filed with the Securities and Exchange Commission (“SEC”).

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

The accompanying financial statements have been prepared assuming we will continue as a going concern.

In May 2016, the U.S. Food and Drug Administration ("FDA") approved our Probuphine New Drug Application ("NDA") and pursuant to our license agreement with Braeburn Pharmaceuticals, Inc. ("Braeburn"), as amended to date, we received a $15 million milestone payment and subsequently transferred the NDA to Braeburn.

At September 30, 2016, we had cash of approximately $16.5 million, which we believe is sufficient to fund our planned operations into early 2018. We will require additional funds, either through payments from Braeburn under the license agreement or through other financing arrangements, to advance our current ProNeura development programs to later stage clinical studies and to complete the regulatory approval process necessary to commercialize any products we might develop.

Revenue Recognition

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

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

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

- Royalties earned are based on third-party sales of licensed products and are recorded in accordance with contract terms when third-party results are reliably measurable and collectability is reasonably assured.

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

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

Research and Development Costs and Related Accrual

Research and development expenses include internal and external costs. Internal costs include salaries and employment related expenses, facility costs, administrative expenses and allocations of corporate costs. External expenses consist of costs associated with outsourced clinical research organization (“CRO”) activities, sponsored research studies, product registration, patent application and prosecution, and investigator sponsored trials. We also record accruals for estimated ongoing clinical trial costs. Clinical trial costs represent costs incurred by CROs and clinical sites. These costs are recorded as a component of research and development expenses. Under our agreements, progress payments are typically made to investigators, clinical sites and CROs. We analyze the progress of the clinical

trials, including levels of patient enrollment, invoices received and contracted costs when evaluating the adequacy of accrued liabilities. Significant judgments and estimates must be made and used in determining the accrued balance in any accounting period. Actual results could differ from those estimates under different assumptions. Revisions are charged to expense in the period in which the facts that give rise to the revision become known.

Recent Accounting Pronouncements

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

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

In June 2014, the FASB issued ASU No. 2014-12, *Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could Be Achieved after the Requisite Service Period* ("ASU 2014-12"). The standard provides guidance that a performance target that affects vesting of a share-based payment and that could be achieved after the requisite service condition is a performance condition. ASU 2014-12 is effective for annual reporting periods beginning after December 15, 2015. The adoption of this ASU did not have a significant impact on our financial statements.

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

In August 2016, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments,* addressing eight specific cash flow issues in an effort to reduce diversity in practice. The amended guidance is effective for fiscal years beginning after December 31, 2017, and for interim periods within those years. Early adoption is permitted. The Company does not expect the amended guidance to have a material impact on its statements of cash flows.

Subsequent Events

We have evaluated events that have occurred after September 30, 2016 and through the date that the financial statements are issued.

Fair Value Measurements

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

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

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

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

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

As a result of the fair value adjustment of the warrant liabilities, we recorded a non-cash loss on an increase in the fair value of $5,000 and $0.1 million for the three and nine months ended September 30, 2016, respectively, in our Condensed Statements of Operations and Comprehensive Income (Loss). See Note 6, “Warrant Liability” for further discussion on the calculation of the fair value of the warrant liability.

(in thousands)	Warrant Liability
Total warrant liability at December 31, 2015	$ 1,444
Adjustment to record warrants at fair value	111
Total warrant liability at September 30, 2016	$ 1,555

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, 2016 and 2015:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2016	2015	2016	2015
Research and development	$ 85	$ 42	$ 302	$ 280
General and administrative	117	50	481	379
Total stock-based compensation expenses	$ 202	$ 92	$ 783	$ 659

No tax benefit was recognized related to stock-based compensation expense since we have accumulated 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, 2016 and 2015:

Three Months Ended September 30,		Nine Months Ended September 30,	
2016	2015	2016	2015

Weighted-average risk-free interest rate	1.5	%	1.7	%	1.5	%	1.8	%
Expected dividend payments	—		—		—		—	
Expected holding period (years) [1]	6.5		4.5		6.5		6.4	
Weighted-average volatility factor [2]	0.92		1.65		0.92		1.61	
Estimated forfeiture rates [3]	29	%	30	%	29	%	30	%

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

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

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

No options were granted during the three month periods ended September 30, 2016 and 2015.

The following table summarizes option activity for the nine month period ended September 30, 2016: