TITAN PHARMACEUTICALS INC
Form 10-Q
November 09, 2012
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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, 2012.

or

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

Commission file number 000-27436

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, a 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 75,215,713 shares of the Registrant s Common Stock issued and outstanding on November 2, 2012.

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Part I. Financial Information

Item 1. Financial Statements

TITAN PHARMACEUTICALS, INC.

CONDENSED BALANCE SHEETS

(in thousands)

	September 30, 2012 (unaudited)	December 31, 2011 (Note 1)
Assets		
Current assets:		
Cash	$ 5,062	$ 5,406
Receivables	3,530	3,720
Prepaid expenses and other current assets	788	836
Total current assets	9,380	9,962
Property and equipment, net	1,364	255
Total assets	$ 10,744	$ 10,217
Liabilities and Stockholders Deficit		
Current liabilities:		
Accounts payable	$ 4,878	$ 4,789
Accrued clinical trials expenses	650	161
Other accrued liabilities	234	173
Deferred revenue	1,700	
Warrant liability, current	931	
Current portion of long-term debt, net of discount	2,500	
Total current liabilities	10,893	5,123
Warrant liabilities	7,277	3,611
Royalty liability	10,087	9,309
Long-term debt, net of discount	9,618	12,253
Total liabilities	37,875	30,296
Commitments and contingencies		
Stockholders deficit:		
Common stock, at amounts paid-in	262,052	256,436
Additional paid-in capital	20,666	18,433
Accumulated deficit	(309,849)	(294,948)
Total stockholders deficit	(27,131)	(20,079)
Total liabilities and stockholders deficit	$ 10,744	$ 10,217

See Notes to Condensed Financial Statements

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TITAN PHARMACEUTICALS, INC.

CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(in thousands, except per share amount)

(unaudited)

	Three Months Ended September 30,		Nine months Ended September 30,	
	2012	2011	2012	2011
Revenues:				
Royalty revenue	$ 1,228	$ 973	$ 3,816	$ 2,291
Grant revenue		39	42	364
Total revenue	1,228	1,012	3,858	2,655
Operating expenses:				
Research and development	2,995	2,230	8,037	9,915
General and administrative	890	739	3,750	2,480
Total operating expenses	3,885	2,969	11,787	12,395
Loss from operations	(2,657)	(1,957)	(7,929)	(9,740)
Other income (expense):				
Interest expense, net	(1,634)	(1,194)	(5,095)	(3,238)
Other expense, net	(49)	(43)	(143)	(87)
Non-cash gain (loss) on changes in the fair value of warrants	(3,673)	2,390	(1,734)	760
Other income (expense), net	(5,356)	1,153	(6,972)	(2,565)
Net loss and comprehensive loss	$ (8,013)	$ (804)	$ (14,901)	$ (12,305)
Basic and diluted net loss per common share	$ (0.12)	$ (0.01)	$ (0.23)	$ (0.21)
Weighted average shares used in computing basic and diluted net loss per common share	66,839	59,386	63,748	59,290

See Notes to Condensed Financial Statements

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TITAN PHARMACEUTICALS, INC.

CONDENSED STATEMENTS OF CASH FLOWS

(in thousands)

(unaudited)

	Nine months Ended September 30,	
	2012	**2011**
Cash flows from operating activities:		
Net loss	$ (14,901)	$ (12,305)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	13	26
Amortization of discount on long-term debt		1,272
Interest on royalty liability	778	
Non-cash (gain) loss on changes in fair value of warrants	1,734	(760)
Stock-based compensation	2,233	808
Changes in operating assets and liabilities:		
Receivables	190	(1,572)
Prepaid expenses and other assets	48	(605)
Accounts payable and other accrued liabilities	639	848
Deferred revenue	1,700	
Net cash used in operating activities	(7,566)	(12,288)
Cash flows from investing activities:		
Purchases of furniture and equipment	(1,122)	(58)
Disposals of furniture and equipment		2
Net cash used in investing activities	(1,122)	(56)
Cash flows from financing activities:		
Proceeds from issuing common stock and warrants, net of issuance costs	7,516	
Proceeds from the exercise of warrants, net of issuance costs	963	
Proceeds from long-term debt, net		19,500
Payments on long-term debt	(135)	(7,564)
Net cash provided by financing activities	8,344	11,936
Net increase (decrease) in cash and cash equivalents	(344)	(408)
Cash and cash equivalents at beginning of period	5,406	3,180
Cash and cash equivalents at end of period	$ 5,062	$ 2,772

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 biopharmaceutical company developing proprietary therapeutics primarily for the treatment of central nervous system (CNS) disorders. Our product development programs focus primarily on important pharmaceutical markets with significant unmet medical needs and commercial potential. We are directly developing our product candidates and also utilize corporate, academic and government partnerships as appropriate. Such collaborations have helped to fund product development and have enabled us to retain significant economic interest in our products. We operate in only one business segment, the development of pharmaceutical products.

Our principal asset is Probuphine®, the first slow-release implant formulation of buprenorphine hydrochloride (buprenorphine), designed to maintain a stable, round-the-clock blood level of the medicine in patients for up to six months following a single treatment. The outpatient treatment of opioid addiction with daily dosed sublingual buprenorphine formulations represented a $1.3 billion market in the U.S. in 2011, and a seven day transdermal patch formulation of buprenorphine for the treatment of chronic pain was launched in the U.S. in 2011. The development of Probuphine for the treatment of opioid addiction is complete. This novel implant formulation is inserted subdermally in a patient s upper arm providing continuous medication, and has the potential to enhance patient compliance to treatment, and limit diversion for illicit use and accidental exposure to the sublingual formulations. The New Drug Application (NDA) was submitted to the FDA in October 2012 and seeks approval for treatment of opioid dependence. Our goal is to enter into one or more partnerships to commercialize Probuphine in the U.S. and foreign markets, as well as to potentially develop the product for the treatment of chronic pain.

Probuphine is the first product to utilize ProNeura , a novel, proprietary, long-term drug delivery technology. The ProNeura technology has the potential to be used in developing products for the treatment of other chronic conditions, such as Parkinson s disease, where maintaining stable, round-the-clock blood levels of a drug could potentially benefit the patient and improve medical outcomes.

Finally, we are also entitled to royalty revenue of 8-10% of net sales of Fanapt® (iloperidone), an atypical antipsychotic compound being marketed in the U.S. for the treatment of schizophrenia by Novartis Pharma AG (Novartis) under a sub-license agreement based on a licensed U.S. patent that expires in October 2016 (does not include a possible six month pediatric extension). Substantially all of this future royalty revenue has been sold to Deerfield Management (Deerfield), a healthcare investment fund, in exchange for cash and debt considerations which have been used to advance the development of Probuphine and for general corporate purposes.

Basis of Presentation

The accompanying unaudited condensed financial statements have been prepared in accordance with U.S. generally accepted accounting principles 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. generally accepted accounting principles 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, 2012 are not necessarily indicative of the results that may be expected for the year ending December 31, 2012, or any future interim periods.

The balance sheet at December 31, 2011 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. generally accepted accounting principles 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/A for the year ended December 31, 2011, as filed with the Securities and Exchange Commission (SEC).

The preparation of financial statements in conformity with U.S. generally accepted accounting principles 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. We expect to continue to incur substantial additional operating losses from costs related to the continuation of research and development

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and administrative activities across product development functions including clinical and non-clinical testing, process development and manufacturing and regulatory affairs. We believe that our working capital at September 30, 2012, along with the proceeds from the subsequent exercise of outstanding warrants, is sufficient to sustain our planned operations through March 2013. In the event we are unable to enter into a corporate partnership or licensing arrangement that provides us with the funds required to complete the regulatory process and commercialize Probuphine (if approved), we will need to obtain additional financing, either through the sale of debt or equity securities, in order for us to continue our Probuphine program and other product development activities. If we are unable to complete a debt or equity offering, or otherwise obtain sufficient financing when and if needed, we may be required to reduce, defer or discontinue the Probuphine program and other product development activities. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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:

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 collectability is reasonably assured. Payments received related to substantive, performance-based at-risk milestones are recognized as revenue upon achievement of the clinical success or regulatory event specified in the underlying contracts, which represent the culmination of the earnings process. Amounts received in advance are recorded as deferred revenue until the technology is transferred, costs are incurred, or a milestone is reached.

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

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.

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. Pursuant to certain license agreements, we earn royalties on the sale of Fanapt by Novartis Pharma AG in the U.S. As described in Note 5, Commitments and Contingencies, we are obligated to pay royalties on such sales to Sanofi-Aventis and another third party. As we have no performance obligations under the license agreements, we have recorded the royalties earned, net of royalties we are obligated to pay, as revenue in our condensed statements of operations and comprehensive loss.

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 organizat