TITAN PHARMACEUTICALS INC
Form 10-Q
August 15, 2011
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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 June 30, 2011.

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 Exchange Act 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 ¨ No ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. 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 59,385,570 shares of the Registrant s Common Stock issued and outstanding on August 11, 2011.

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Part I. Financial Information

Item 1. Financial Statements

TITAN PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands)

	June 30, 2011 (unaudited)	December 31, 2010 (Note 1)
Assets		
Current assets:		
Cash and cash equivalents	$ 6,092	$ 3,180
Receivables	1,731	1,225
Prepaid expenses and other current assets	928	294
Total current assets	8,751	4,699
Property and equipment, net	90	53
Total assets	$ 8,841	$ 4,752
Liabilities and Stockholders Deficit		
Current liabilities:		
Accounts payable	$ 3,002	$ 2,457
Accrued expenses	1,205	1,078
Current portion of long-term debt	2,000	1,870
Total current liabilities	6,207	5,405
Warrant liability	7,104	
Long-term debt, net of discount	12,515	5,400
Total liabilities	25,826	10,805
Commitments and contingencies (Note 5)		
Stockholders deficit:		
Common stock, at amounts paid-in	256,436	256,436
Additional paid-in capital	17,825	17,256
Accumulated deficit	(291,246)	(279,745)
Total stockholders deficit	(16,985)	(6,053)
Total liabilities and stockholders deficit	$ 8,841	$ 4,752

See Notes to Condensed Consolidated Financial Statements

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TITAN PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(unaudited)

(in thousands, except per share amount)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
Revenues:				
Royalty revenue	$ 602	$ 55	$ 1,318	$ 1,708
Grant revenue	93	1,287	325	2,048
License revenue				11
Total revenue	695	1,342	1,643	3,767
Operating expenses:				
Research and development	3,947	2,056	7,685	3,726
General and administrative	948	1,012	1,741	1,947
Total operating expenses	4,895	3,068	9,426	5,673
Loss from operations	(4,200)	(1,726)	(7,783)	(1,906)
Other income (expense):				
Interest expense, net	(1,113)	(120)	(2,044)	(240)
Other expense, net	(46)		(44)	(5)
Non-cash loss on increase in the fair value of warrants	(1,630)		(1,630)	
Other expense, net	(2,789)	(120)	(3,718)	(245)
Net loss	$ (6,989)	$ (1,846)	$ (11,501)	$ (2,151)
Basic and diluted net loss per share	$ (0.12)	$ (0.03)	$ (0.19)	$ (0.04)
Weighted average shares used in computing basic and diluted net loss per share	59,276	59,248	59,255	59,248

See Notes to Condensed Consolidated Financial Statements

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TITAN PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

(unaudited)

	Six Months Ended June 30	
	2011	**2010**
Cash flows from operating activities:		
Net loss	$ (11,501)	$ (2,151)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	19	49
Amortization of loan discount	783	15
Stock-based compensation	569	211
Non-cash loss on increase in fair value of warrants	1,630	
Changes in operating assets and liabilities:		
Receivables	(506)	(315)
Prepaid expenses and other assets	(634)	71
Accounts payable and other accrued liabilities	672	285
Net cash used in operating activities	(8,968)	(1,835)
Cash flows from investing activities:		
Purchases of furniture and equipment	(58)	(13)
Disposals of furniture and equipment	2	
Net cash used in investing activities	(56)	(13)
Cash flows from financing activities:		
Proceeds from long-term debt, net	19,500	
Payments on long-term debt	(7,564)	
Net cash provided by financing activities	11,936	
Net increase (decrease) in cash and cash equivalents	2,912	(1,848)
Cash and cash equivalents at beginning of period	3,180	3,300
Cash and cash equivalents at end of period	$ 6,092	$ 1,452

See Notes to Condensed Consolidated Financial Statements

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TITAN PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED 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. We currently have two key assets:

(1) Fanapt® (iloperidone), an atypical antipsychotic compound approved in the U.S. for the treatment of schizophrenia and being marketed in the U.S. by Novartis Pharma AG. We are entitled to a royalty of 8-10% on U.S. net sales of Fanapt (including a royalty of 2.5% of U.S. net sales that is owed to a third party).

(2) Probuphine , a slow release implant formulation of buprenorphine that is capable of maintaining a stable, round the clock blood level of the medicine in patients for six months following a single treatment. Probuphine is in Phase 3 clinical development for the treatment of opioid addiction with efficacy already demonstrated in two controlled Phase 3 clinical studies and a good safety and tolerability profile in all trials.

The ProNeura drug delivery technology underlying Probuphine has the potential to be used in developing products for the treatment of other chronic conditions where maintaining stable, round the clock blood levels of a drug can benefit the patient and improve medical outcomes (e.g. chronic pain, Parkinson s disease).

We are directly developing our product candidates and we also utilize resources provided through partnerships with other companies and government organizations. These 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.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements include the accounts of Titan Pharmaceuticals, Inc. and its subsidiaries after elimination of all significant intercompany accounts and transactions. These 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. 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 six month periods ended June 30, 2011 are not necessarily indicative of the results that may be expected for the year ending December 31, 2011, or any future interim periods.

The balance sheet at December 31, 2010 has been derived from the audited consolidated financial statements at that date, but does not include all of the information and footnotes required by GAAP for complete financial statements. These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and footnotes thereto included in the Titan Pharmaceuticals, Inc. Annual Report on Form 10-K for the year ended December 31, 2010, as filed with the Securities and Exchange Commission (SEC).

The preparation of financial statements in conformity with 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.

We expect to continue to incur substantial additional operating losses from costs related to the continuation of product and technology development, clinical trials, the regutatory process, and administrative activities. We believe that our working capital at June 30, 2011, together with the revenues from royalties on the sale of Fanapt, is sufficient to sustain our planned operations to the end of the year.

We will need to seek additional financing sources to fund our product development activities, and we will be required to obtain substantial funding to commercialize any products other than iloperidone that we may successfully develop. 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 one or more of our product development programs.

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TITAN PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(unaudited)

Majority-Owned Subsidiary

In December 2010, Ingenex, Inc., our majority-owned subsidiary, was dissolved under the laws of Delaware. At the time of dissolution, we owned 81% of Ingenex (assuming the conversion of all preferred stock to common stock). Ingenex was not an operating company and had no assets.

Revenue Recognition

We generate revenue principally from royalty payments, collaborative research and development arrangements, technology licenses, and government grants. Revenue arrangements with multiple components are divided into separate units of accounting if certain criteria are met, including whether the delivered component has stand-alone value to the customer, and whether there is objective and reliable evidence of the fair value of the undelivered items. Consideration received is allocated among the separate units of accounting based on their respective fair values, and 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) collectibility 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 or if we do not have objective or reliable evidence of the fair value of the undelivered component, the amount of revenue allocable to the delivered technology is deferred. Non-refundable upfront fees with stand-alone value that are not dependent on future performance under these agreements are recognized as revenue when received, and are deferred if we have continuing performance obligations and have no evidence of fair value of those obligations. Cost reimbursements for research and development spending are recognized when the related costs are incurred and when collections are reasonably expected. Payments received related to substantive, performance-based at-risk milestones are recognized as revenue upon achievement of the clinical success or regulatory event specified in the underlying contracts, which represent the culmination of the earnings process. Amounts received in advance are recorded as deferred revenue until the technology is transferred, costs are incurred, or a milestone is reached.

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

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 collectibility 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 consolidated

statement of operations.

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

Warrants Issued in Connection with Equity Financing

We generally account for warrants issued in connection with equity financings as a component of equity, unless there is a deemed possibility that we may have to settle warrants in cash. For warrants issued with deemed possibility of cash settlement, we record the fair value of the issued warrants as a liability at each reporting period and record changes in the estimated fair value as a non-cash gain or loss in the Condensed Consolidated Statements of Operations.

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Recent Accounting Pronouncements

In June 2011, the FASB issued Accounting Standards Update (ASU) No. 2011-05 *Presentation of Comprehensive Income* that improves the comparability, consistency, and transparency of financial reporting and increases the prominence of items reported in other comprehensive income by eliminating the option to present components of other comprehensive income as part of the statement of changes in stockholders equity. The amendments in this standard require that all non-owner changes in stockholders equity be presented either in a single continuous statement of comprehensive income or in two separate but consecutive statements. Under either method, adjustments must be displayed for items that are reclassified from other comprehensive income (OCI) to net income, in both net income and OCI. The standard does not change the current option for presenting components of OCI gross or net of the effect of income taxes, provided that such tax effects are presented in the statement in which OCI is presented or disclosed in the notes to the financial statements. Additionally, the standard does not affect the calculation or reporting of earnings per share. For public entities, the amendments in this ASU are effective for fiscal years, and interim periods within those years, beginning after December 15, 2011 and are to be applied retrospectively, with early adoption permitted. We do not expect the adoption of this standard to have a material impact on our consolidated financial statements.

In May 2011, the FASB issued ASU No. 2011-04 which amends GAAP to conform to the measurement and disclosure requirements in International Financial Reporting Standards (IFRS). The amendments in this ASU change the wording used to describe the requirements in U.S. GAAP for measuring fair value and for disclosing information about fair value measurements. The amendments include the following:

Those that clarify the FASB s intent regarding the application of existing fair value measurement and disclosure requirements; and