

TITAN PHARMACEUTICALS INC

Form 10-Q

November 10, 2008

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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, 2008.

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)

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**Delaware**  
(State or Other Jurisdiction of

**94-3171940**  
(I.R.S. Employer

Incorporation or Organization)

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  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

Smaller reporting company

(Do not check if a 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

There were 58,287,880 shares of the Registrant's Common Stock issued and outstanding on November 6, 2008.

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**Table of Contents****Part I. Financial Information****Item 1. Condensed Financial Statements (unaudited)**  
**TITAN PHARMACEUTICALS, INC.****CONDENSED CONSOLIDATED BALANCE SHEETS**

(in thousands)

	September 30, 2008 (unaudited)	December 31, 2007 (Note A)
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 12,204	\$ 25,614
Marketable securities		4,402
Prepaid expenses, other receivables and current assets	966	440
Total current assets	13,170	30,456
Property and equipment, net	326	388
Total assets	\$ 13,496	\$ 30,844
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities		
Accounts payable	\$ 544	\$ 557
Accrued clinical trials expenses	2,078	2,388
Other accrued liabilities	1,816	1,311
Total current liabilities	4,438	4,256
Other liabilities	117	
Total liabilities	4,555	4,256
Minority interest - Series B preferred stock of Ingenex, Inc.	1,241	1,241
Stockholders' equity		
Common stock, at amounts paid-in	255,403	255,429
Additional paid-in capital	13,195	11,508
Accumulated deficit	(260,898)	(241,591)
Accumulated other comprehensive income		1
Total stockholders' equity	7,700	25,347
Total liabilities and stockholders' equity	\$ 13,496	\$ 30,844

Note A: The year end consolidated balance sheet data was derived from audited financial statements, but does not include all disclosures required by accounting principles generally accepted in the United States of America.  
See Notes to Condensed Consolidated Financial Statements



**Table of Contents****TITAN PHARMACEUTICALS, INC.****CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS****(unaudited)****(in thousands, except per share amount)**

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2008</b>	<b>2007</b>	<b>2008</b>	<b>2007</b>
License revenue	\$	\$	\$ 73	\$ 12
Operating expenses:				
Research and development	4,190	3,093	12,810	7,782
General and administrative	1,828	1,467	7,086	4,296
<b>Total operating expenses</b>	<b>6,018</b>	<b>4,560</b>	<b>19,896</b>	<b>12,078</b>
Loss from operations	(6,018)	(4,560)	(19,823)	(12,066)
Other income:				
Interest income, net	80	186	442	492
Other income	38	50	74	143
Other income, net	118	236	516	635
<b>Net loss</b>	<b>\$ (5,900)</b>	<b>\$ (4,324)</b>	<b>\$ (19,307)</b>	<b>\$ (11,431)</b>
Basic and diluted net loss per share	\$ (0.10)	\$ (0.10)	\$ (0.33)	\$ (0.27)
Weighted average shares used in computing basic and diluted net loss per share	58,288	44,478	58,284	41,901

See Notes to Condensed Consolidated Financial Statements

**Table of Contents****TITAN PHARMACEUTICALS, INC.****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS****(unaudited)****(in thousands)**

	<b>Nine Months Ended September 30,</b>	
	<b>2008</b>	<b>2007</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (19,307)	\$ (11,431)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	163	234
Gain on disposal of assets		(9)
Gain on sale of investments	(120)	(352)
Stock-based compensation	1,687	960
Changes in operating assets and liabilities:		
Prepaid expenses, receivables and other assets	(526)	253
Accounts payable and other accrued liabilities	299	(511)
<b>Net cash used in operating activities</b>	<b>(17,804)</b>	<b>(10,856)</b>
<b>Cash flows from investing activities:</b>		
Purchases of furniture and equipment	(122)	(196)
Disposals of furniture and equipment	21	11
Purchases of marketable securities		(48,872)
Proceeds from maturities of marketable securities	4,401	24,279
Proceeds from sales of marketable securities		16,048
Sale of investment in other companies	120	502
<b>Net cash provided by (used in) investing activities</b>	<b>4,420</b>	<b>(8,228)</b>
<b>Cash flows from financing activities:</b>		
Issuance of common stock, net	(26)	10,334
<b>Net cash provided by (used in) financing activities</b>	<b>(26)</b>	<b>10,334</b>
<b>Net decrease in cash and cash equivalents</b>	<b>(13,410)</b>	<b>(8,750)</b>
Cash and cash equivalents at beginning of period	25,614	9,613
Cash and cash equivalents at end of period	12,204	863
Marketable securities at end of period		12,645
<b>Cash, cash equivalents and marketable securities at end of period</b>	<b>\$ 12,204</b>	<b>\$ 13,508</b>

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. Probuphine, which utilizes Titan s proprietary ProNeura long term drug delivery technology, has demonstrated positive results in Phase III testing for treatment of opiate addiction, and this proven sustained drug delivery technology could be used for other potential treatment applications in which conventional treatment is limited by variability in blood drug levels and poor patient compliance. Products based on ProNeura technology can provide controlled drug release on an outpatient basis over extended periods of up to 6 12 months. Titan also has two other products, gallium maltolate and DITPA, in earlier stages of development. Our product development programs focus primarily on large pharmaceutical markets with significant unmet medical needs and commercial potential. Our resources are focused primarily on the development of Probuphine for the treatment of opioid addiction.

***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. Certain prior period balances have been reclassified to conform to the current period presentation. These 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 a 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, 2008 are not necessarily indicative of the results that may be expected for the year ending December 31, 2008, or any future interim periods.

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.

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/A for the year ended December 31, 2007, as filed with the Securities and Exchange Commission ( SEC ).

We will continue to incur substantial additional operating losses from costs related to the continuation of product and technology development, clinical trials, and administrative activities. We believe that our working capital at September 30, 2008 is sufficient to sustain our planned operations through January 2009. However, if we are unable in the immediate future to obtain a corporate partner or otherwise raise the funding necessary to continue development and commercialization of Probuphine, we will be required, in light of our known and contingent financial obligations, to consider a number of alternatives prior to year end. These include the possible sale of assets, the discontinuance of our product development programs and/or the winding up of our business.

***Majority-Owned Subsidiary***

At September 30, 2008, we owned 81% of Ingenex (assuming the conversion of all preferred stock to common stock).



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### ***Revenue Recognition***

We generate revenue principally from 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 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.

### ***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 activities, sponsored research studies, product registration, patent application and prosecution, and investigator sponsored trials. In accordance with SFAS No. 2, *Accounting for Research and Development Costs*, all such costs are charged to expense as incurred. 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.

### ***Recent Accounting Pronouncements***

Effective January 1, 2008, we adopted EITF 07-3, *Accounting for Advance Payments for Goods and Services to be Received for Use in Future Research and Development Activities* ( EITF 07-3 ). EITF 07-3 requires that non-refundable advance payments for goods or services that will be used or rendered for future research and development activities be deferred and capitalized and recognized as an expense as the goods are delivered or the related services are performed, subject to an assessment of recoverability. The adoption did not have a material impact on our consolidated results or operations or financial condition.

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In December 2007, the FASB issued SFAS 141 (revised 2007), *Business Combinations* ( SFAS 141R ). SFAS 141R establishes principles and requirements for how an acquirer recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, any non-controlling interest of the acquiree and the goodwill acquired. SFAS 141R also establishes disclosure requirements to enable the evaluation of the nature and financial effects of the business combination. This statement is effective for us beginning January 1, 2009. We will assess the potential impact of the adoption of SFAS 141R if and when a future acquisition occurs.

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In September 2006, the Financial Accounting Standards Board ( FASB ) issued SFAS No. 157, *Fair Value Measurements* ( SFAS 157 ), which defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. SFAS 157 does not require any new fair value measurements, but provides guidance on how to measure fair value by providing a fair value hierarchy used to classify the source of the information. SFAS 157 is effective for fiscal years beginning after November 15, 2007. However, on December 14, 2007, the FASB issued proposed FSP FAS 157-b which would delay the effective date of SFAS 157 for all nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually). This proposed FSP partially defers the effective date of Statement 157 to fiscal years beginning after November 15, 2008, and interim periods within those fiscal years for items within the scope of this FSP. Effective January 1, 2008, we adopted SFAS 157 except as it applies to those nonfinancial assets and nonfinancial liabilities as noted in proposed FSP FAS 157-b. The adoption of SFAS 157 did not have a material impact on our consolidated financial position, results of operations or cash flows.

In November 2007, the EITF issued EITF Issue No. 07-1 ( EITF 07-1 ), *Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property*. Companies may enter into arrangements with other companies to jointly develop, manufacture, distribute, and market a product. Often the activities associated with these arrangements are conducted by the collaborators without the creation of a separate legal entity (that is, the arrangement is operated as a virtual joint venture ). The arrangements generally provide that the collaborators will share, based on contractually defined calculations, the profits or losses from the associated activities. Periodically, the collaborators share financial information related to product revenues generated (if any) and costs incurred that may trigger a sharing payment for the combined profits or losses. The consensus requires collaborators in such an arrangement to present the result of activities for which they act as the principal on a gross basis and report any payments received from (made to) other collaborators based on other applicable GAAP or, in the absence of other applicable GAAP, based on analogy to authoritative accounting literature or a reasonable, rational, and consistently applied accounting policy election. EITF 07-1 is effective for collaborative arrangements in place at the beginning of the annual period beginning after December 15, 2008. Management does not expect that the adoption EITF 07-1 will have a material impact on the Company's financial position and results of operations.

Effective January 1, 2008 we adopted SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities* - including an amendment of FASB Statement No. 115 ( SFAS 159 ). SFAS 159 allows an entity the irrevocable option to elect fair value for the initial and subsequent measurement for specified financial assets and liabilities on a contract-by-contract basis. We did not elect to apply the fair value option under SFAS 159.

In December 2007, the FASB approved the issuance of SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements- an amendment of ARB No. 51* ( SFAS 160 ). SFAS 160 will change the accounting and reporting for minority interests, which will now be termed *noncontrolling interests*. SFAS 160 requires a noncontrolling interest to be presented as a separate component of equity and requires the amount of net income attributable to the parent and to the noncontrolling interest to be separately identified on the consolidated statement of operations. SFAS 160 is effective for fiscal years beginning on or after December 15, 2008. At this time, we do not expect adoption of SFAS 160 to have any impact on our financial position, results of operations or cash flows.

In March 2008, the FASB issued FAS No. 161, *Disclosures about Derivative Instruments and Hedging Activities - an amendment of FASB Statement No. 133* ( SFAS 161 ). SFAS 161 requires enhanced disclosure related to derivatives and hedging activities and thereby seeks to improve the transparency of financial reporting. Under SFAS 161, entities are required to provide enhanced disclosures relating to: (a) how and why an entity uses derivative instruments; (b) how derivatives instruments and related hedge items are accounted for under SFAS 133, *Accounting for Derivative Instruments and Hedging Activities* ( SFAS 133 ) and its related interpretations; and (c) how derivative instruments and related hedged items affect an entity's financial position, financial performance and cash flows. SFAS 161 must be applied prospectively to all derivative instruments and non-derivative instruments that are designated and qualify as hedging instruments and related hedged items accounted for under SFAS 133 for all financial statements issued for fiscal years and interim periods beginning after November 15, 2008. We do not expect adoption of SFAS 161 to have any impact on our financial position, results of operations or cash flows.

In April 2008, the FASB issued FASB Staff Position No. FAS 142-3, *Determination of the Useful Life of Intangible Assets* ( FSP 142-3 ). FSP 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under FASB Statement No. 142, *Goodwill and Other Intangible Assets* and requires enhanced disclosures relating to: (a) the entity's accounting policy on the treatment costs incurred to renew or extend the term of a recognized intangible asset; (b) in the period of acquisition or renewal, the weighted-average period prior to the next renewal or extension costs, the total amount of costs incurred in the period to renew or extend the term of a recognized intangible asset for each period for which a statement of financial position is presented by major intangible asset class. FSP 142-3 must be applied prospectively to all intangible assets acquired as of and subsequent to fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. Early adoption is prohibited. We do not expect adoption of FASP 142-3 to have any impact on our financial position, results of operations or cash flows.



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The following table summarizes the SFAS 123R share-based compensation expense recorded for awards under the stock option plans and the resulting impact on our basic and diluted loss per share for the three and nine month periods ended September 30, 2008 and 2007:

<i>(in thousands, except per share amounts)</i>	Three Months Ended		Nine Months Ended	
	September 30, 2008	September 30, 2007	September 30, 2008	September 30, 2007
Research and development	\$ 69	\$ 153	\$ 305	\$ 305
General and administrative	347	210	1,382	655
<b>Total share-based compensation expenses</b>	<b>\$ 416</b>	<b>\$ 363</b>	<b>\$ 1,687</b>	<b>\$ 960</b>
Increase in basic and diluted net loss per share	\$ (0.01)	\$ (0.01)	\$ (0.03)	\$ (0.02)

No tax benefit was recognized related to share-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 share-based compensation expense for the three and nine month periods ended September 30, 2008 and 2007:

	Three Months Ended		Nine Months Ended	
	September 30, 2008	September 30, 2007	September 30, 2008	September 30, 2007
Weighted-average risk-free interest rate	2.8%	4.3%	2.9%	4.5%
Expected dividend payments				
Expected holding period (years) <sup>1</sup>	5.3	5.9	5.4	5.9
Weighted-average volatility factor	0.72	0.76	0.66	0.84
Estimated forfeiture rates for options granted to management <sup>2</sup>	2%	2%	2%	2%
Estimated forfeiture rates for options granted to non-management <sup>2</sup>	30%	29%	30%	29%

<sup>1</sup> Based on the simplified method provided in Staff Accounting Bulletin No. 107 for plain vanilla options for the three and nine months ended September 30, 2007. For the three and nine months ended September 30, 2008, we used historical data to estimate the expected holding period.

<sup>2</sup> Estimated forfeiture rates are based on historical data.

During the three month period ended September 30, 2008, we granted 271,000 options to employees, directors and consultants to purchase common stock. The following table summarizes option activity for the nine month period ended September 30, 2008:

<i>(in thousands, except per share amounts)</i>	Options	Weighted Average Exercise Price	Weighted Average Remaining Option Term	Aggregate Intrinsic Value
Outstanding at January 1, 2008	8,424	\$ 6.05	5.68	\$ 217
Granted	1,179	1.31		
Exercised				

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Expired or forfeited	(870)	6.74			
Outstanding at September 30, 2008	8,733	\$ 5.34	5.81	\$	4
Exercisable at September 30, 2008	6,006	\$ 6.85	4.35	\$	4

As of September 30, 2008 there was approximately \$2.4 million of total unrecognized compensation expense related to non-vested stock options. This expense is expected to be recognized over a weighted-average period of 2.4 years.

### 3. Net Loss Per Share

We calculated net loss per share using the weighted average common shares outstanding for the periods presented. For the periods ended September 30, 2008 and 2007, the effect of an additional 16,132,387 and 6,926,273 shares, respectively, representing outstanding options and warrants, were not included in the computation of diluted earnings per share because they are anti-dilutive.

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### **4. Comprehensive Loss**

Comprehensive loss is comprised of net loss and other comprehensive income or loss. The only component of other comprehensive income or loss is unrealized gains and losses on our marketable securities. Comprehensive losses for the three and nine month periods ended September 30, 2008 were \$5.9 million and \$19.3 million, respectively, and for the three and nine month periods ended September 30, 2007 were \$4.3 million and \$11.4 million, respectively.

### **5. Commitments and Contingencies**

#### ***Legal Proceedings***

In March 2005, Dr. Bernard Sabel initiated an appraisal proceeding in the Court of Chancery of the State of Delaware relating to the merger of our subsidiary ProNeura, Inc. into Titan. The complaint indicates that Mr. Sabel wants the court to appraise the value of the 108,800 shares of the common stock of ProNeura owned by him. The complaint does not specify an amount that Mr. Sabel considers the fair value of the shares. Discovery is proceeding in connection with this appraisal proceeding.

In July 2007, a complaint was filed in the United States District Court in and for the Middle District of Florida against, among others, Berlex, Inc., Schering AG, the Regents of the University of California and us alleging that a patient in the Spheramine Phase IIb clinical trial suffered certain physical effects and that she and her husband suffered emotional distress as a result of her participation in the trial. The complaint alleged breach of contract, product liability and fraud and deceit claims. The plaintiffs were seeking \$5.2 million in damages, as well as punitive damages, costs and attorney's fees. The parties have settled this dispute and we are not required to make any payments in connection with the settlement.

### **6. Stockholders' Equity**

On May 29, 2008, our shareholders approved a proposal to amend to our Certificate of Incorporation to increase the number of authorized shares of common stock from 75,000,000 to 125,000,000.

In December 2007, we completed the sale of units consisting of 13,300,000 shares of our common stock and five-year warrants to purchase 6,650,000 shares of our common stock to certain institutional investors for gross proceeds of approximately \$21.3 million. Net proceeds were approximately \$19.9 million. The warrants have an exercise price of \$2.00 per share. In January 2008, we filed a registration statement with the Securities and Exchange Commission covering the resale of the shares of common stock and shares of common stock underlying the warrants issued in the private placement.

In March 2007, we entered into a Common Stock Purchase Agreement (the "Purchase Agreement"), with Azimuth Opportunity Ltd. ("Azimuth") which provides that, upon the terms and subject to the conditions set forth therein, Azimuth is committed to purchase up to the lesser of (a) \$25.0 million of our common stock, or (b) 7,805,887 shares of our common stock over the 24 month term of the Purchase Agreement. Over the term of the Purchase Agreement, at our sole discretion, we may present Azimuth with draw down notices requiring Azimuth to purchase a specified dollar amount of shares of our common stock, subject to certain limits and so long as specified conditions are met. The price per share at which the shares will be sold, and therefore the number of shares to be sold pursuant to the draw down notice, is determined over a pricing period of up to ten consecutive trading days. The per share purchase price for the shares sold on any particular trading day during the pricing period will equal the daily volume weighted average price of our common stock for that day, less a discount ranging from 4.5% to 7.0% depending on the threshold price specified by us (which in no event may be less than \$1.50 per share). We are able to present Azimuth with up to 30 draw down notices during the 24 month term of the Purchase Agreement, with a minimum of five trading days required between each draw down pricing period. The Purchase Agreement also provides that from time to time and at our sole discretion we may grant Azimuth the right to exercise one or more options to purchase additional shares of our common stock up to an aggregate amount specified by us during each draw down pricing period. The threshold price for the option is determined by us and is subject to a discount calculated in the same manner as for the draw down notices. Any sale of the shares will be registered pursuant to the February 2007 shelf registration statement. In October 2007, we completed a sale of 486,746 shares of our common stock under the Purchase Agreement with Azimuth at a price of approximately \$2.05 per share, for gross proceeds of approximately \$1.0 million. Net proceeds were approximately \$965,000. No draw downs were made under this facility during the nine month period ended September 30, 2008.

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In February 2007, we filed a shelf registration statement with the Securities and Exchange Commission to sell up to \$50 million of common or preferred stock. Under this registration statement, shares may be sold periodically to provide additional funds for our operations. In April 2007, we entered into a stock purchase agreement with certain individual and institutional investors for the purchase and sale of 5,445,546 shares of our common stock under the shelf registration statement at a price of \$2.02 per share. In May 2007, we completed the sale of such shares for gross proceeds of \$11.0 million. Net proceeds were approximately \$10.2 million.

### **7. Subsequent Events**

In October 2008, we implemented an employee retention program in order to bolster our ability to pursue our objective of completing an appropriate transaction for the advancement of the Probuphine development program in light of recent adverse events that have negatively impacted our financial position and the market price of our common stock. The retention program consists of two components the issuance of restricted shares and modifications to existing severance provisions.

#### **Restricted Shares**

As part of the retention program, in lieu of the annual option grants that would otherwise be made in January 2009, an aggregate of 1,430,000 restricted shares were granted to our employees pursuant to our Amended and Restated 2002 Incentive Plan. A total of 900,000 of such restricted shares were granted to our executive officers. One-half of the shares granted to the executives vested on the date of grant of October 21, 2008 with the balance to vest in 24 equal monthly installments commencing one-year from the date of grant. The 530,000 restricted shares granted to all other employees vest as to one-third on the one year anniversary of the date of grant and the balance in 24 equal monthly installments commencing one year from the date of grant. All restricted share grants provide for the acceleration of the unvested shares in the event the employee's employment is terminated (other than for cause) within 12 months following a change in control of the Company.

#### **Severance Provisions**

As part of the retention program, we made a determination to increase the severance period for substantially all of our employees in the event that there is a change in control of the Company and within one year following such change in control the employee's employment is terminated (including constructive termination) other than for cause. The severance period for each of our executive officers will increase from 12 months to 24 months if the termination following change in control provision is triggered and will be payable in a lump sum. The increased severance period for substantially all other employees in such event will range from two months to 12 months.



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### **Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations**

*The following discussion contains certain forward-looking statements, within the meaning of the "safe harbor" provisions of the Private Securities Reform Act of 1995, the attainment of which involves various risks and uncertainties. Forward-looking statements may be identified by the use of forward-looking terminology such as may, will, expect, believe, estimate, plan, anticipate, continue, or similar terms, variations of those terms or the negative of those terms. Our actual results may differ materially from those described in these forward-looking statements due to, among other factors, the results of research and development efforts, the results of pre-clinical and clinical testing, the effect of regulation by the United States Food and Drug Administration (FDA) and other agencies, the impact of competitive products, product development, commercialization and technological difficulties, the Company's ability to obtain additional financing, the effect of our accounting policies, and other risks detailed in our Securities and Exchange Commission filings.*

*Probuphine<sup>®</sup>, Spheramine<sup>®</sup>, ProNeura and CCM 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 biopharmaceutical company developing proprietary therapeutics primarily for the treatment of central nervous system ( CNS ) disorders. Our product development programs focus primarily on large pharmaceutical markets with significant unmet medical needs and commercial potential. Our resources are focused primarily on the development of Probuphine for the treatment of opioid addiction. On July 28, 2008, we issued a press release announcing positive, statistically significant results from our randomized, double-blind, placebo controlled, multi-center Phase III clinical trial of Probuphine for the treatment of opioid addiction. Probuphine also has the potential to provide treatment for chronic pain, and hope to evaluate this application in a proof of concept clinical study if we are able in the very near term to obtain a corporate partner or otherwise raise the funds necessary to continue this program. See Liquidity and Capital Resources below.

On July 2, 2008, we issued a press release announcing the results of the initial analyses of data from a Phase IIb clinical study of Spheramine in Parkinson's disease conducted by our licensee, Bayer Schering Pharma AG, Germany (Bayer Schering). Spheramine did not meet the Phase IIb clinical study's primary or key secondary endpoints, with no significant differences detected between the Spheramine and sham surgery arms of the study. We will continue to further analyze the data collected; however, Bayer Schering has announced that it will no longer pursue this program.

Vanda Pharmaceuticals, Inc. (Vanda) is a sub-licensee for the development of iloperidone, our novel atypical anti-psychotic for the treatment of schizophrenia and related psychotic disorders. On July 28, 2008, Vanda announced the receipt of a Not Approvable letter for iloperidone from the FDA and stated that they plan to meet with the FDA to further discuss their decision and determine next steps in the development and commercialization of iloperidone.

We also have rights to the following compounds 3,5 diiodothyropropionic acid, or DITPA, a proprietary product with potential for the treatment of cardiovascular disease and gallium maltolate, a novel oral agent for the potential treatment of chronic bacterial infections, bone disease and cancer. We are only incurring minimal expenses associated with these compounds.

### **Liquidity and Capital Resources**

We have funded our operations since inception primarily through sales of our securities, as well as proceeds from warrant and option exercises, corporate licensing and collaborative agreements, and government sponsored research grants. At September 30, 2008, we had approximately \$12.2 million of cash, cash equivalents, and marketable securities compared to approximately \$30.0 million at December 31, 2007.

Our operating activities used approximately \$17.8 million during the nine months ended September 30, 2008. This consisted primarily of the net loss for the period of approximately \$19.3 million, \$0.2 million related to net changes in operating assets and liabilities and \$0.1 million related to gains on the sale of investments. This was offset in part by non-cash charges of approximately \$0.2 million related to depreciation, approximately and \$1.7 million related to share-based compensation expenses. Uses of cash in operating activities were primarily to fund product development programs and administrative expenses. We have entered into various agreements with research institutions, universities, and other entities for the performance of research and development activities and for the acquisition of licenses related to those activities. Certain of the licenses require us to pay royalties on future product sales, if any. In addition, in order to maintain license and other rights while products are under development, we must comply with customary licensee obligations, including the payment of patent-related costs, annual minimum license fees, meeting project-funding milestones and diligent efforts in product development. The aggregate commitments we have under these

agreements, including minimum license payments, for the next twelve months is approximately \$0.2 million.

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Net cash provide by investing activities of approximately \$4.4 million during the nine months ended September 30, 2008 consisted of purchases of furniture and equipment of approximately \$0.1 million. This was offset in part by sales and maturities of marketable securities of approximately \$4.4 million and \$0.1 million related to gains on the sale of investments.

Net cash used by financing activities during the nine months ended September 30, 2008 was approximately \$26,000, which consisted primarily of expense related to filing of a registration statement with the SEC covering the resale of the shares of common stock and shares of common stock underlying the warrants issued in the private placement in December 2007 (described below).

In December 2007, we completed the sale of units consisting of 13,300,000 shares of our common stock and five-year warrants to purchase 6,650,000 shares of our common stock to certain institutional investors for gross proceeds of approximately \$21.3 million. Net proceeds were approximately \$19.9 million. The warrants have an exercise price of \$2.00 per share. In January 2008, we filed a registration statement with the SEC covering the resale of the shares of common stock and shares of common stock underlying the warrants issued in the private placement.

In February 2007, we filed a shelf registration statement with the Securities and Exchange Commission to sell up to \$50 million of common or preferred stock. Under this registration statement, shares may be sold periodically to provide additional funds for our operations. In April 2007, we entered into a stock purchase agreement with certain individual and institutional investors for the purchase and sale of 5,445,546 shares of our common stock under the shelf registration statement at a price of \$2.02 per share. In May 2007, we completed the sale of such shares for gross proceeds of \$11.0 million. Net proceeds were approximately \$10.2 million.

In March 2007, we entered into a Common Stock Purchase Agreement (the "Purchase Agreement"), with Azimuth Opportunity Ltd. ("Azimuth") which provided that, upon the terms and subject to the conditions set forth therein, Azimuth was committed to purchase up to the lesser of (a) \$25.0 million of our common stock, or (b) 7,805,887 shares of our common stock over the 24 month term of the Purchase Agreement. On October 26, 2007, we completed a sale of 486,746 shares of our common stock under the Purchase Agreement with Azimuth at a price of approximately \$2.05 per share, for gross proceeds of approximately \$1.0 million. Net proceeds were approximately \$965,000. No draw downs were made under this facility during the nine month period ended September 30, 2008. In light of the fact that our current stock price is below the minimum threshold provided for in the Purchase Agreement and we have not sought the required stockholder approval for additional draw downs thereunder, we will not be able to access additional funds under the Purchase Agreement during the near term.

We expect to continue to incur substantial additional operating losses from costs related to the continuation of product and technology development, clinical trials, and administrative activities. We believe that our working capital at September 30, 2008 is sufficient to sustain our planned operations through January 2009. However, if we are unable in the immediate future to obtain a corporate partner or otherwise raise the funding necessary to continue development of and commercialization of Probuphine, we will be required, in light of our known and contingent financial obligations, to consider various alternatives prior to year end. These include the possible sale of assets, the discontinuance of our product development programs and/or the winding up of our business.

## **Results of Operations**

Our net loss for the three month period ended September 30, 2008 was approximately \$5.9 million, or \$0.10 per share, compared to our net loss of approximately \$4.3 million, or \$0.10 per share, for the comparable period in 2007. For the nine month period ended September 30, 2008, our loss was approximately \$19.3 million, or \$0.33 per share, compared to approximately \$11.4 million, or \$0.27 per share, for the comparable period in 2007.

We had no revenues from licensing agreements during the three month periods ended September 30, 2008 and 2007. We had revenues from licensing agreements of \$73,000 and \$12,000 during the nine month periods ended September 30, 2008 and 2007, respectively.

Research and development expenses for the three month period ended September 30, 2008 were approximately \$4.2 million, compared to approximately \$3.1 million for the comparable period in 2007, an increase of \$1.1 million, or 36%. Research and development expenses for the nine month period ended September 30, 2008 were approximately \$12.8 million, compared to approximately \$7.8 million for the comparable period in 2007, an increase of \$5.0 million, or 64%. The increase in research and development costs during the three and nine month periods ended September 30, 2008 was primarily associated with an increase in costs associated with the continuation of planned clinical trials related to our Probuphine product. This was partially offset by the conclusion of certain clinical study related activities and reductions in employee-related costs and other internal expenditures. External research and development expenses include direct expenses such as clinical research organization charges, investigator and review board fees, patient expense reimbursements and contract manufacturing expenses. In the third quarter of 2008, our external research and development expenses relating to our Probuphine product development program were approximately \$2.7 million. 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

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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.

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General and administrative expenses for the three month period ended September 30, 2008 were approximately \$1.8 million, compared to approximately \$1.5 million for the comparable period in 2007, an increase of \$0.3 million, or 20%. General and administrative expenses for the nine month period ended September 30, 2008 were approximately \$7.1 million, compared to approximately \$4.3 million for the comparable period in 2007, an increase of \$2.8 million, or 65%. The increase in general and administrative expenses during the three month period ended September 30, 2008 was primarily related to increases in non-cash stock compensation costs of approximately \$0.1 million and market research costs of approximately \$0.2 million. The increase in general and administrative expenses during the nine month period ended September 30, 2008 was primarily related to increases in non-cash stock compensation costs of approximately \$0.7 million, employee salary costs of approximately \$0.2 million, salary continuation costs of approximately \$0.6 million, market research costs of approximately \$1.0 million, legal fees of approximately \$0.1 million, travel related costs of approximately \$0.1 million and other general and administrative costs of approximately \$0.1 million.

Net other income for the three month period ended September 30, 2008 was approximately \$0.1 million, compared to net other income of approximately \$0.2 million in the comparable period in 2007. Net other income for the nine month periods ended September 30, 2008 and 2007 was approximately \$0.5 million and \$0.6 million, respectively. The decrease in net other income during the three month period ended September 30, 2008, was primarily related to a decrease in interest income on investments. This was partially offset by gains of approximately \$0.1 million resulting from the sale of certain investments. Net other income during the nine month period ended September 30, 2008, consisted primarily of interest income on investments and gains of approximately \$0.1 million resulting from the sale of certain investments. Net other income during the nine month period ended September 30, 2007 consisted primarily of interest income on investments and a gain of approximately \$0.4 million resulting from the sale of our investment in Molecular Medicine BioServices, Inc. during the second quarter of 2007. This was offset by the write off of deferred offering expenses of approximately \$0.2 million associated with the termination of the Cornell Capital Stand by Equity Distribution Agreement in March 2007.

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**Item 3. Quantitative and Qualitative Disclosures About Market Risk**

Our market risk disclosures set forth in our Annual Report on Form 10-K/A for the year ended December 31, 2007 have not changed materially.

**Item 4. Controls and Procedures**

We maintain disclosure controls and procedures, as such term is defined under Exchange Act Rule 13a-15(e), that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures. In designing and evaluating the disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives and in reaching a reasonable level of assurance our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. We have carried out an evaluation under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of September 30, 2008. Based upon their evaluation and subject to the foregoing, the Chief Executive Officer and Chief Financial Officer concluded that as of September 30, 2008 our disclosure controls and procedures were effective at the reasonable assurance level in ensuring that material information relating to us is made known to the Chief Executive Officer and Chief Financial Officer by others within our company during the period in which this report was being prepared.

There were no changes in our internal controls or in other factors during the most recent quarter that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

**Item 4T. Controls and Procedures**

**Not applicable.**

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**PART II**

**Item 1. Legal Proceedings**

In March 2005, Dr. Bernard Sabel initiated an appraisal proceeding in the Court of Chancery of the State of Delaware relating to the merger of our subsidiary ProNeura, Inc. into Titan. The complaint indicates that Mr. Sabel wants the court to appraise the value of the 108,800 shares of the common stock of ProNeura owned by him. The complaint does not specify an amount that Mr. Sabel considers the fair value of the shares. Discovery is proceeding in connection with this appraisal proceeding.

In July 2007, a complaint was filed in the United States District Court in and for the Middle District of Florida against, among others, Berlex, Inc., Schering AG, the Regents of the University of California and us alleging that a patient in the Spheramine Phase IIb clinical trial suffered certain physical effects and that she and her husband suffered emotional distress as a result of her participation in the trial. The complaint alleged breach of contract, product liability and fraud and deceit claims. The plaintiffs were seeking \$5.2 million in damages, as well as punitive damages, costs and attorney's fees. The parties have settled this dispute and we are not required to make any payments in connection with the settlement.

**Item 1A. Risk Factors**

**Our available capital is sufficient to fund our operations through January 2009 and if we are unable in the immediate future to obtain additional financing, through a corporate partnering arrangement, the sale of debt or equity securities or otherwise, we will be forced to consider various alternatives, including the sale of assets and the winding up of our business.**

At September 30, 2008, we had cash and cash equivalents of \$12.2 million, which we believe is sufficient to sustain our planned operations through January 2009. However, if we are unable in the immediate future to obtain a corporate partner or otherwise raise the funding necessary to continue development and commercialization of Probuphine we will be forced, in light of our known and contingent financial obligations, to consider various alternatives prior to year end, including the possible sale of assets, the discontinuance of our product development programs and/or the winding up of our business.

**Due to our current share price and operating losses during recent fiscal years, our stock could be at risk of being delisted by the American Stock Exchange.**

Our stock currently trades on the American Stock Exchange ( Amex ). The Amex, as a matter of policy, will consider the suspension of trading in, or removal from listing of any stock when, in the opinion of the Amex (i) the financial condition and/or operating results of an issuer of stock listed on the Amex appear to be unsatisfactory, (ii) it appears that the extent of public distribution or the aggregate market value of the stock has become so reduced as to make further dealings on the Amex inadvisable, (iii) the issuer has sold or otherwise disposed of its principal operating assets, or (iv) the issuer has sustained losses which are so substantial in relation to its overall operations or its existing financial condition has become so impaired that it appears questionable, in the opinion of Amex, whether the issuer will be able to continue operations and/or meet its obligations as they mature. For example, the Amex will consider suspending dealings in, or delisting the stock of an issuer if the issuer has sustained losses from continuing operations and/or net losses in its five most recent fiscal years. Another instance where the Amex would consider suspension or delisting of a stock is if it has been selling for a substantial period of time at a low price per share and the issuer fails to effect a reverse split of such stock within a reasonable time after being notified that the Amex deems such action to be appropriate. The delisting of our common stock by the American Stock Exchange would adversely affect the price and liquidity of our common stock.

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/A for the year ended December 31, 2007, which could materially affect our business, financial condition or future results. The risks described in our Annual Report on Form 10-K/A 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.

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**Item 6. Exhibits**

**Exhibits**

- 10.49 Amendment to Employment Agreement between Registrant and Marc Rubin, dated October 21, 2008.
- 10.50 Amendment to Employment Agreement between Registrant and Sunil Bhonsle, dated October 21, 2008.
- 10.51 Amendment to Employment Agreement between Registrant and Robert E. Farrell, dated October 21, 2008.
- 10.52 Form of Restricted Stock Agreement between Registrant and Executive.
- 31.1 Rule 13a-14(a) Certification of Chairman, President and Chief Executive Officer.
- 31.2 Rule 13a-14(a) Certification of Executive Vice President and Chief Financial Officer.
- 32 Certifications pursuant to 18 U.S.C Section 1350.



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**SIGNATURES**

In accordance with the requirements of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**TITAN PHARMACEUTICALS, INC.**

November 7, 2008

By: /s/ Marc Rubin  
Marc Rubin, M.D.  
President and Chief Executive Officer

November 7, 2008

By: /s/ Robert E. Farrell  
Robert E. Farrell, J.D.  
Executive Vice President and Chief Financial Officer