TITAN PHARMACEUTICALS INC Form 10-Q May 12, 2008 Table of Contents

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 March 31, 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)

Edgar Filing: TITAN PHARMACEUTICALS INC - Form 10-Q

Delaware (State or Other Jurisdiction of 94-3171940 (I.R.S. Employer

Incorporation or Organization) 400 Oyster Point Blvd., Suite 505, South San F 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 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 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
 Yes " No x

There were 58,281,460 shares of the Registrant s Common Stock issued and outstanding on May 9, 2008.

Titan Pharmaceuticals, Inc.

Index to Form 10-Q

Part I. Financial Information

Item 1.	Condensed Financial Statements (unaudited)	
	Condensed Consolidated Balance Sheets as of March 31, 2008 and December 31, 2007	3
	Condensed Consolidated Statements of Operations for the Three months ended March 31, 2008 and 2007	4
	Condensed Consolidated Statements of Cash Flows for the Three months ended March 31, 2008 and 2007	5
	Notes to Condensed Consolidated Financial Statements	6
Item 2.	Management s Discussion and Analysis of Financial Condition and Results of Operations	11
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	14
Item 4.	Controls and Procedures	14
Item 4T.	Controls and Procedures	14
<u>Part II. Ot</u>	her Information	
Item 1.	Legal Proceedings	15
Item 1A.	<u>Risk Factors</u>	15
Item 6.	Exhibits	15
SIGNATU	RES	16



Part I. Financial Information

Item 1. Condensed Financial Statements (unaudited)

TITAN PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands)

	March 31, 2008 (unaudited)		December 31, 2007 (Note A)	
Assets				
Current assets				
Cash and cash equivalents	\$	24,340	\$	25,614
Marketable securities				4,402
Prepaid expenses, other receivables and current assets		980		440
Total current assets		25,320		30,456
Property and equipment, net		419		388
Total assets	\$	25,739	\$	30,844
	Ψ	23,737	Ψ	50,011
Liabilities and Stockholders Equity				
Current liabilities				
Accounts payable	\$	1,098	\$	557
Accrued clinical trials expenses		1,779		2,388
Other accrued liabilities		1,523		1,311
Total current liabilities		4,400		4,256
		.,		.,200
Minority interest Series B preferred stock of Ingenex, Inc.		1,241		1,241
Stockholders equity		1,241		1,241
Common stock, at amounts paid-in		255,402		255,429
Additional paid-in capital		12,011		11,508
Accumulated deficit		(247,315)		(241,591)
Accumulated other comprehensive income		(217,515)		(211,391)
Accumulated other comprehensive medine				1
Total stockholders equity		20,098		25,347
Total liabilities and stockholders equity	\$	25,739	\$	30,844

Note A: The year end condensed 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

TITAN PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(unaudited)

(in thousands, except per share amount)

	Three Months Ended March 31, 2008 2007		
License revenue	\$	61	\$
Operating expenses:			
Research and development	3	3,801	2,040
General and administrative	2	2,214	1,453
Total operating expenses	(5,015	3,493
Loss from operations Other income (expense):	(5	5,954)	(3,493)
Interest income, net		236	124
Other income (expense)		(6)	(204)
Other income (expense), net		230	(80)
Net loss	\$ (5	5,724)	\$ (3,573)
Basic and diluted net loss per share		(0.10)	\$ (0.09)
Weighted average shares used in computing basic and diluted net loss per share	58	3,281	39,023

See Notes to Condensed Consolidated Financial Statements

TITAN PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

(in thousands)

	Three months Ended March 31, 2008 2007	
Cash flows from operating activities:		
Net loss	\$ (5,724)	\$ (3,573)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	56	96
Gain on disposal of assets	(1)	(5)
Stock-based compensation	503	317
Changes in operating assets and liabilities:		
Prepaid expenses, receivables and other assets	(540)	22
Accounts payable and other accrued liabilities	144	(92)
Net cash used in operating activities	(5,562)	(3,235)
Cash flows from investing activities:		
Purchases of furniture and equipment	(87)	(80)
Disposals of furniture and equipment		5
Purchases of marketable securities		(9,052)
Proceeds from maturities of marketable securities		4,499
Proceeds from sales of marketable securities	4,401	
Net cash provided by (used in) investing activities	4,314	(4,628)
Cash flows from financing activities:		
Issuance of common stock, net	(26)	96
Net cash provided by (used in) financing activities	(26)	96
Net decrease in cash and cash equivalents	(1,274)	(7,767)
Cash and cash equivalents at beginning of period	25,614	9,613
Cash and cash equivalents at end of period	24,340	1,846
Marketable securities at end of period		8,658
Cash, cash equivalents and marketable securities at end of period	\$ 24,340	\$ 10,504

See Notes to Condensed Consolidated Financial Statements

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. Our product development programs focus primarily on large pharmaceutical markets with significant unmet medical needs and commercial potential. We are both directly developing our product candidates and utilizing strategic partnerships to help fund product development that enable us to retain significant economic interest in our products. We operate in 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. 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 month period ended March 31, 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 expect to continue to incur substantial additional operating losses from costs related to continuation and expansion of product and technology development, clinical trials, and administrative activities. We believe that our working capital at March 31, 2008 is sufficient to sustain our planned operations through 2008. Additionally, we have funds available under a Common Stock Purchase Agreement (the Purchase Agreement) with Azimuth Opportunity Ltd. (See note 6) provided we obtain the necessary shareholder approval to access such funds.

Although the Purchase Agreement provides us with up to an additional \$24.0 million of financing, subject to the receipt of required shareholder approval, we will need to seek additional financing sources to fund our product development activities, and will be required to obtain substantial funding to commercialize any products other than iloperidone or Spheramine 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.

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 07-03). EITF 07-03 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.

In December 2007, the FASB issued SFAS 141 (revised 2007), Business Combinations (SFAS141R). 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.

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

Edgar Filing: TITAN PHARMACEUTICALS INC - Form 10-Q

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.

Majority-Owned Subsidiary

At March 31, 2008, we owned 81% of Ingenex (assuming the conversion of all preferred stock to common stock).

2. Stock Option Plans

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 month periods ended March 31, 2008 and 2007:

		Three Months Ended March 31,	
(in thousands, except per share amounts)	2008	2007	
Research and development	\$ 134	\$ 72	
General and administrative	369	245	
Total share-based compensation expenses	\$ 503	\$ 317	
Increase in basic and diluted net loss per share	\$ (0.01)	\$ (0.01)	

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 month periods ended March 31, 2008 and 2007:

		Three Months Ended March 31,	
	2008	2007	
Weighted-average risk-free interest rate	2.8%	4.5%	
Expected dividend payments			
Expected holding period (years) ¹	5.5	5.9	
Weighted-average volatility factor	0.64	0.85	
Estimated forfeiture rates for options granted to management ²	2%	2%	
Estimated forfeiture rates for options granted to non-management ²	30%	29%	

¹ Based on the simplified method provided in Staff Accounting Bulletin No. 107 for plain vanilla options for the three months ended March 31, 2007. For the three months ended March 31, 2008, we used historical data to estimate the expected holding period.

² Estimated forfeiture rates are based on historical data.

During the three month period ended March 31, 2008 we granted 735,427 options to employees, directors and consultants to purchase common stock. The following table summarizes option activity for the three month period ended March 31, 2008:

(in thousands, except per share amounts)	Options	Av Ex	eighted verage vercise Price			Aggregate Intrinsic Value	
Outstanding at January 1, 2008	8,424	\$	6.05	5.68	\$	217	
Granted	735		1.58				
Exercised							
Expired or forfeited							
Outstanding at March 31, 2008	9,159	\$	5.69	5.66	\$	128	
Exercisable at March 31, 2008	6,387	\$	7.20	4.08	\$	98	

As of March 31, 2008 there was approximately \$3.2 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 2.76 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 March 31, 2008 and 2007, the effect of an additional 16,668,000 and 7,009,723 shares, respectively, representing outstanding options and warrants, were not included in the computation of diluted earnings per share because they are anti-dilutive.

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 month periods ended March 31, 2008 and 2007 were \$5.7 million and \$3.5 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. In September 2007, the plaintiff voluntarily dismissed the complaint and filed a substantially similar action in the Superior Court of the State of California, Alameda County. The parties have settled this dispute and we are not required to make any payments in connection with the settlement.

6. Stockholders Equity

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

Edgar Filing: TITAN PHARMACEUTICALS INC - Form 10-Q

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 three month period ended March 31, 2008.

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 Event

On April 29, 2008, we entered into an agreement with Dr. Louis R. Bucalo pursuant to which he retired and resigned as Executive Chairman and a member of our board of directors. Under the terms of the agreement, we will pay Dr. Bucalo his base monthly salary at the rates provided for in his prior employment agreement through May 14, 2010 (the Compensation Period). The agreement provides that the January 2008 annual grant of 150,000 options to Dr. Bucalo will vest in full immediately. All other options held by Dr. Bucalo will continue to vest in accordance with their terms and shall remain exercisable during the Compensation Period.

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[®], Spheramine[®], 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. We are focused primarily on clinical development of the following products:

Probuphine: for the treatment of opioid addiction

Iloperidone: for the treatment of schizophrenia and related psychotic disorders (partnered with Vanda Pharmaceuticals, Inc.)

Spheramine: for the treatment of advanced Parkinson s disease (partnered with Bayer Schering Pharma AG) We are directly developing our product candidates and also utilizing corporate partnerships, including a collaboration with (i) Bayer Schering Pharma AG, Germany (Bayer Schering) for the development of Spheramine to treat Parkinson s disease, and (ii) Vanda Pharmaceuticals, Inc. (Vanda) for the development of iloperidone for the treatment of schizophrenia and related psychotic disorders. We also utilize grants from government agencies to fund development of our product candidates.

Our resources are focused primarily on the development of Probuphine; and while 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, there will be minimal expenses associated with these compounds, while we evaluate further activities in these programs.

Our products are at various stages of development and may not be successfully developed or commercialized. We do not currently have any products being commercially sold. Our proposed products will require significant further capital expenditures, development, testing, and regulatory clearances prior to commercialization. We may experience unanticipated problems relating to product development and cannot predict whether we will successfully develop and commercialize any products.

For a full discussion of risks and uncertainties of our product development, see Risk Factors Our products are at various stages of development and may not be successfully developed or commercialized in our 2007 Annual Report on Form 10-K/A.

Results of Operations

Our net loss for the three month period ended March 31, 2008 was approximately \$5.7 million, or \$0.10 per share, compared to approximately \$3.6 million, or \$0.09 per share, for the comparable period in 2007.

Edgar Filing: TITAN PHARMACEUTICALS INC - Form 10-Q

We had revenues from licensing agreements during the three month period ended March 31, 2008 of approximately \$61,000 and no revenues for the comparable period in 2007.

Research and development expenses for the three month period ended March 31, 2008 were approximately \$3.8 million, compared to approximately \$2.0 million for the comparable period in 2007, an increase of \$1.8 million, or 90%. The increase in research and development costs during the three month period ended March 31, 2008 was primarily associated with the continuation of planned clinical trials related to our Probuphine product. In the first quarter 2008, our external research and development expenses relating to our Probuphine product development program were approximately \$2.4 million. External research and development expenses include direct expenses such as clinical research organization charges, investigator and review board fees, patient expense reimbursements, pre-clinical activities and contract manufacturing expenses. 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 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.

General and administrative expenses for the three month period ended March 31, 2008 were approximately \$2.2 million, compared to approximately \$1.5 million for the comparable period in 2007, an increase of \$0.7 million, or 47%. The increase in general and administrative expenses during the three month period ended March 31, 2008 was primarily related to increases in non-cash stock compensation costs of approximately \$0.1 million, market research costs of approximately \$0.5 million and other general and administrative costs of approximately \$0.1 million.

Net other income for the three month period ended March 31, 2008 was approximately \$0.2 million, compared to net other expense of approximately \$80,000 in the comparable period in 2007. The increase in other income, which includes primarily interest income, resulted from an increase in cash balances resulting from our equity offering in December 2007. The net expense in the comparable period of 2007 resulted primarily from a one time charge related to the write-off of deferred offering expenses of \$0.2 million associated with the termination of the Cornell Capital Standby Equity Distribution Agreement in March 2007.

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 March 31, 2008, we had approximately \$24.3 million of cash, cash equivalents, and marketable securities compared to approximately \$30.0 million at December 31, 2007.

Our operating activities used approximately \$5.6 million during the three months ended March 31, 2008. This consisted primarily of the net loss for the period of approximately \$5.7 million and approximately \$0.4 million related to changes in operating assets and liabilities. This was offset in part by non-cash charges of approximately \$0.1 million related to depreciation and approximately \$0.5 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.

Net cash provide by investing activities of approximately \$4.3 million during the three months ended March 31, 2008 consisted of purchases of furniture and equipment of approximately \$0.1 million. This was offset by sales and maturities of marketable securities of approximately \$4.4 million.

Net cash used by financing activities during the three months ended March 31, 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.

On March 14, 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. 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 three month period ended March 31, 2008.

We expect to continue to incur substantial additional operating losses from costs related to continuation and expansion of product and technology development, clinical trials, and administrative activities. We believe that our working capital at March 31, 2008 is sufficient to sustain our planned operations through 2008. Additionally, we have funds available under the Purchase Agreement provided we obtain the necessary shareholder approval to access such funds.

Although the Purchase Agreement provides us with up to an additional \$24.0 million of financing, subject to the receipt of required shareholder approval, we will need to seek additional financing sources to fund our product development activities, and will be required to obtain substantial funding to commercialize any products other than iloperidone or Spheramine 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.

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. <u>Controls and Procedures</u>

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 March 31, 2008. Based upon their evaluation and subject to the foregoing, the Chief Executive Officer and Chief Financial Officer concluded that as of March 31, 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. <u>Controls and Procedures</u> Not applicable.

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. In September 2007, the plaintiff voluntarily dismissed the complaint and filed a substantially similar action in the Superior Court of the State of California, Alameda County. The parties have settled this dispute and we are not required to make any payments in connection with the settlement.

Item 1A. <u>Risk Factors</u>

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.

Item 6. <u>Exhibits</u>

Exhibits

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.

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.

By: /s/ Marc Rubin Marc Rubin, M.D.

President and Chief Executive Officer

By: /s/ Robert E. Farrell Robert E. Farrell, J.D.

Executive Vice President and Chief Financial Officer

16

May 12, 2008

May 12, 2008