

TITAN PHARMACEUTICALS INC
Form 10-Q
November 14, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE
X ACT OF 1934**

For the quarterly period ended September 30, 2018.

OR

**..TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT
OF 1934**

For the transition period from ____ to ____

Commission File Number 001-13341

Titan Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware 94-3171940
(State or other jurisdiction of (I.R.S. Employer
incorporation or organization) Identification No.)

400 Oyster Point Blvd., Suite 505,
94080
South San Francisco, California
(Address of principal executive offices) (Zip Code)

(650) 244-4990
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐ Accelerated filer ☐
Non-accelerated filer ☒
Smaller reporting company ☒ Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

Edgar Filing: TITAN PHARMACEUTICALS INC - Form 10-Q

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

Class	Outstanding at November 9, 2018
Common Stock, Par value \$0.001	77,974,644

Titan Pharmaceuticals, Inc.

Index to Form 10-Q

Part I. Financial Information

<u>Item 1.</u>	<u>Financial Statements (unaudited)</u>	<u>3</u>
	<u>Condensed Balance Sheets as of September 30, 2018 and December 31, 2017</u>	<u>3</u>
	<u>Condensed Statements of Operations and Comprehensive Loss for the three and nine-months ended September 30, 2018 and 2017</u>	<u>4</u>
	<u>Condensed Statements of Cash Flows for the nine-months ended September 30, 2018 and 2017</u>	<u>5</u>
	<u>Notes to Condensed Financial Statements</u>	<u>6</u>
<u>Item 2.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>19</u>
<u>Item 3.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	<u>23</u>
<u>Item 4.</u>	<u>Controls and Procedures</u>	<u>24</u>

Part II. Other Information

<u>Item 1A.</u>	<u>Risk Factors</u>	<u>24</u>
Item 5.	Other Information	
<u>Item 6.</u>	<u>Exhibits</u>	<u>30</u>
<u>SIGNATURES</u>		<u>32</u>

Part I. Financial Information

Item 1. Financial Statements

TITAN PHARMACEUTICALS, INC.

CONDENSED BALANCE SHEETS

(in thousands)

	September 30, 2018 (unaudited)	December 31, 2017 (Note 1)
Assets		
Current assets:		
Cash and cash equivalents	\$ 8,427	\$ 7,522
Restricted cash	361	361
Receivables	682	65
Inventory	1,293	—
Contract assets	195	—
Prepaid expenses and other current assets	567	362
Total current assets	11,525	8,310
Property and equipment, net	329	595
Total assets	\$ 11,854	\$ 8,905
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 686	\$ 821
Accrued clinical trials expenses	453	289
Other accrued liabilities	437	354
Deferred revenue	626	—
Current portion of long-term debt	—	3,000
Total current liabilities	2,202	4,464
Long-term debt, net of discount	4,146	3,584
Derivative liability	17	—
Total liabilities	6,365	8,048
Commitments and contingencies		

Edgar Filing: TITAN PHARMACEUTICALS INC - Form 10-Q

Stockholders' equity:

Common stock, \$0.001 par value per share; 125,000,000 shares authorized, 39,367,744, and 21,203,744 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively.	39	21
Additional paid-in capital	334,525	324,107
Accumulated deficit	(329,075)	(323,271)
Total stockholders' equity	5,489	857
Total liabilities and stockholders' equity	\$ 11,854	\$ 8,905

See Notes to Condensed Financial Statements

TITAN PHARMACEUTICALS, INC.**CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS****(in thousands, except per share amount)****(unaudited)**

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenues:				
License revenue	\$ 1,406	\$ 40	\$5,063	\$ 157
Product revenue	244	—	318	—
Total revenue	1,650	40	5,381	157
Operating expenses:				
Cost of goods sold	178	—	248	—
Research and development	1,910	2,714	5,623	7,341
General and administrative	1,514	1,396	4,508	3,944
Total operating expenses	3,602	4,110	10,379	11,285
Loss from operations	(1,952)	(4,070)	(4,998)	(11,128)
Other expense:				
Other expense, net	(234)	(123)	(662)	(133)
Non-cash gain on changes in fair value	141	2	141	614
Other income (expense), net	(93)	(121)	(521)	481
Net loss and comprehensive loss	(2,045)	\$(4,191)	\$(5,519)	\$(10,647)
Deemed dividend on trigger of down round provision	(285)	—	(285)	—
Net loss attributable to common stockholders	\$(2,330)	\$(4,191)	\$(5,804)	\$(10,647)
Basic net loss per common share	\$(0.11)	\$(0.20)	\$(0.27)	\$(0.50)
Diluted net loss per common share	\$(0.11)	\$(0.20)	\$(0.28)	\$(0.53)
Weighted average shares used in computing basic net loss per common share	21,902	21,204	21,439	21,202
Weighted average shares used in computing diluted net loss per common share	21,902	21,204	21,439	21,222

See Notes to Condensed Financial Statements

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

	Nine months Ended September 30, 2018	2017
Cash flows from operating activities:		
Net loss	\$ (5,519)	\$ (10,647)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash gain on inventory received from termination of license agreement	(1,293)	—
Depreciation and amortization	337	308
Non-cash interest expense	331	—
Non-cash gain on changes in fair value of warrants	—	(614)
Non-cash gain on changes in fair value of derivatives	(141)	—
Stock-based compensation	1,222	1,207
Changes in operating assets and liabilities:		
Receivables	(617)	3,496
Contract assets	24	—
Prepaid expenses and other assets	(205)	(40)
Accounts payable and other accrued liabilities	112	(2,885)

Edgar Filing: TITAN PHARMACEUTICALS INC - Form 10-Q

Deferred revenue	626	—
Net cash used in operating activities	(5,123)	(9,175)
Cash flows from investing activities:		
Purchases of furniture and equipment	(71)	(155)
Net cash used in investing activities	(71)	(155)
Cash flows from financing activities:		
Sale of common & preferred stock	8,408	—
Issuance of warrants	51	287
Proceeds from long-term debt	640	6,725
Payments on long-term debt	(3,000)	—
Net cash provided by financing activities	6,099	7,012
Net increase (decrease) in cash, cash equivalents and restricted cash	905	(2,318)
Cash, cash equivalents and restricted cash at beginning of period	7,883	14,006
Cash, cash equivalents and restricted cash at end of period	\$ 8,788	\$ 11,688
Supplemental disclosure of cash flow information		
Interest paid	\$ 344	\$ 124
Warrants issued	\$ 6,348	\$ 287
Derivatives issued	\$ 158	\$ —
Deemed dividend on trigger of down round provision	\$ 285	\$ —

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the condensed balance sheets that sum to the total of the same such amounts shown in the condensed statement of cash flows (in thousands):

Edgar Filing: TITAN PHARMACEUTICALS INC - Form 10-Q

	September 30,	
	2018	2017
Cash and cash equivalents	\$8,427	\$11,688
Restricted cash	361	—
Cash, cash equivalents and restricted cash shown in the statement of cash flows	\$8,788	\$11,688

See Notes to Condensed Financial Statements

TITAN PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

(unaudited)

1. Organization and Summary of Significant Accounting Policies

The Company

We are a pharmaceutical company developing therapeutics for the treatment of select chronic diseases utilizing our proprietary long-term drug delivery platform, ProNeura™, and we are currently transitioning to a commercial stage enterprise having re-acquired Probuphine® in May 2018, our first product approved in the U.S. for the maintenance treatment of opioid dependence. We operate in only one business segment, the development and commercialization of pharmaceutical products.

Basis of Presentation

The accompanying unaudited condensed financial statements have been prepared in accordance with U.S. generally accepted accounting principles (“GAAP”) for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statement presentation. In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation have been included. Operating results for the three and nine-month periods ended September 30, 2018 are not necessarily indicative of the results that may be expected for the year ending December 31, 2018, or any future interim periods.

The balance sheet at December 31, 2017 has been derived from the audited financial statements at that date, but does not include all of the information and footnotes required by U.S. GAAP for complete financial statements. These unaudited condensed financial statements should be read in conjunction with the audited financial statements and footnotes thereto included in the Titan Pharmaceuticals, Inc. Annual Report on Form 10-K for the year ended December 31, 2017, as filed with the Securities and Exchange Commission (“SEC”).

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

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

At September 30, 2018, we had cash and cash equivalents of approximately \$8.4 million, which we believe, along with the \$4.5 million received from the subsequent exercise of the over-allotment option in connection with our September 2018 public offering (the “Offering”) by Alliance Global Partners (“AGP”) per the terms of the Underwriting Agreement, and the exercise of warrants sold in the Offering (the “Warrants”), are sufficient to fund our planned operations through the third quarter of 2019. Thereafter, we will require additional funds to finance our operations, including the commercialization of Probuphine in the U.S., completion of the Probuphine Phase IV clinical trials mandated by the FDA and advancement of our current ProNeura development programs to later stage clinical studies. Our efforts to obtain additional financing may not be successful.

Going concern assessment

We assess going concern uncertainty in our financial statements to determine if we have sufficient cash on hand and working capital, including available borrowings on loans, to operate for a period of at least one year from the date the financial statements are issued or available to be issued, which is referred to as the “look-forward period” as defined by Accounting Standard Update ASU No. 2014-15. As part of this assessment, based on conditions that are known and reasonably knowable to us, we will consider various scenarios, forecasts, projections, estimates and will make certain key assumptions, including the timing and nature of projected cash expenditures or programs, and its ability to delay or curtail expenditures or programs, if necessary, among other factors. Based on this assessment, as necessary or applicable, we make certain assumptions around implementing curtailments or delays in the nature and timing of programs and expenditures to the extent we deem probable those implementations can be achieved and we have the proper authority to execute them within the look-forward period in accordance with ASU No. 2014-15.

Based upon the above assessment, we concluded that, at the date of filing the financial statements in this Quarterly Report on Form 10-Q for the months ended September 30, 2018, we did not have sufficient cash to fund our operations for the next 12 months without additional funds and, therefore, there was substantial doubt about our ability to continue as a going concern within 12 months after the date the financial statements were issued.

Revenue Recognition

Beginning January 1, 2018, we have followed the provisions of ASC Topic 606, *Revenue from Contracts with Customers*. The guidance provides a unified model to determine how revenue is recognized.

We generate revenue principally from the sale of Probuphine in the U.S., collaborative research and development arrangements, technology licenses and sales, and government grants. Consideration received for revenue arrangements with multiple components is allocated among the separate performance obligations based upon their relative estimated standalone selling price.

In determining the appropriate amount of revenue to be recognized as we fulfill our obligations under our agreements, we perform the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations based on estimated selling prices; and (v) recognition of revenue when (or as) we satisfy each performance obligation.

Performance Obligations

A performance obligation is a promise in a contract to transfer a distinct good or service to the customer and is the unit of account in ASC Topic 606. Our performance obligations include commercialization license rights, development services and services associated with the regulatory approval process.

We have optional additional items in contracts, which are accounted for as separate contracts when the customer elects such options. Arrangements that include a promise for future commercial product supply and optional research and development services at the customer's discretion are generally considered as options. We assess if these options provide a material right to the customer and, if so, such material rights are accounted for as separate performance obligations. If we are entitled to additional payments when the customer exercises these options, any additional payments are recorded in revenue when the customer obtains control of the goods or services.

Transaction Price

We have both fixed and variable consideration. Non-refundable upfront payments are considered fixed, while milestone payments are identified as variable consideration when determining the transaction price. Funding of research and development activities is considered variable until such costs are reimbursed at which point they are considered fixed. We allocate the total transaction price to each performance obligation based on the relative estimated standalone selling prices of the promised goods or services for each performance obligation.

At the inception of each arrangement that includes milestone payments, we evaluate whether the milestones are considered probable of being achieved and estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the value of the associated milestone is included in the transaction price. Milestone payments that are not within our control, such as approvals from regulators, are not considered probable of being achieved until those approvals are received.

For arrangements that include sales-based royalties or earn-out payments, including milestone payments based on the level of sales, and the license or purchase agreement is deemed to be the predominant item to which the royalties or earn-out payments relate, we recognize revenue at the later of (a) when the related sales occur, or (b) when the performance obligation to which some or all of the royalty or earn-out payment has been allocated has been satisfied (or partially satisfied).

Allocation of Consideration

As part of the accounting for these arrangements, we must develop assumptions that require judgment to determine the stand-alone selling price of each performance obligation identified in the contract. Estimated selling prices for license rights are calculated using the residual approach. For all other performance obligations, we use a cost-plus margin approach.

Timing of Recognition

Significant management judgment is required to determine the level of effort required under an arrangement and the period over which we expect to complete our performance obligations under an arrangement. We estimate the performance period or measure of progress at the inception of the arrangement and re-evaluate it each reporting period. This re-evaluation may shorten or lengthen the period over which revenue is recognized. Changes to these estimates are recorded on a cumulative catch up basis. If we cannot reasonably estimate when our performance obligations either are completed or become inconsequential, then revenue recognition is deferred until we can reasonably make such estimates. Revenue is then recognized over the remaining estimated period of performance using the cumulative catch-up method. Revenue is recognized for licenses or sales of functional intellectual property at the point in time the customer can use and benefit from the license. For performance obligations that are services, revenue is recognized over time proportionate to the costs that we have incurred to perform the services using the cost-to-cost input method.

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

Recent Accounting Pronouncements

In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash*. ASU No. 2016-18 is intended to reduce diversity in practice in the classification and presentation of changes in restricted cash on the Condensed Statements of Cash Flows. The ASU requires that the Condensed Statements of Cash Flows explain the change in total cash, cash equivalents and amounts generally described as restricted cash or restricted cash equivalents when reconciling the beginning-of-period and end-of-period total amounts. The ASU also requires a reconciliation between the total of cash, cash equivalents and restricted cash presented on the Condensed Statements of Cash Flows and the cash and cash equivalents balance presented on the Condensed Balance Sheets. We adopted ASU No. 2016-18, and the guidance has been retrospectively applied to all periods presented. The adoption of the guidance did not have an impact on our Condensed Balance Sheets or Statements of Operations and Comprehensive Loss.

In July 2017, the FASB issued a two-part Accounting Standards Update, or ASU, No. 2017-11, *I. Accounting for Certain Financial Instruments With Down Round Features and II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests With a Scope Exception* amending guidance in FASB ASC 260, Earnings Per Share, FASB ASC 480, Distinguishing Liabilities from Equity, and FASB ASC 815, Derivatives and Hedging. The amendments in Part I of ASU 2017-11 change the classification analysis of certain equity-linked financial instruments (or embedded features) with down round features. The amendments in Part II of ASU 2017-11 re-characterize the indefinite deferral of certain provisions of Topic 480 that now are presented as pending content in the Codification, to a scope exception. Those amendments do not have an accounting effect. ASU 2017-11 is effective for public business entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. Early adoption is permitted. We adopted ASU 2017- 11 for the year ended December 31, 2017, and retrospectively applied ASU 2017-11 as required. There was no retrospective impact as a result of the adoption of ASU 2017-11 on the financial statements. See Note 8, “Debt Agreements.”

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

In March 2016, the FASB issued ASU No. 2016-09, *Compensation - Stock Compensation: Improvements to Employee Share-Based Payment Accounting* (“ASU 2016-09”). ASU 2016-09 addresses several aspects of the accounting for share-based payment award transactions, including: (a) income tax consequences; (b) classification of awards as either equity or liabilities; (c) classification on the statement of cash flows; and (d) accounting for forfeitures. We adopted the provisions of ASU 2016-09 in the first quarter of 2017. We have elected to continue to estimate forfeitures based on the estimated number of awards expected to vest. In addition, the adoption of ASU 2016-09 resulted in the recognition of \$12.0 million of previously unrecognized excess tax benefits in deferred tax assets, fully offset by a valuation allowance. All tax-related cash flows resulting from stock-based compensation, including the excess tax benefits related to the settlement of stock-based payment awards, are now classified as cash flows from operating activities on our Condensed Statements of Cash Flows.

The adoption of ASU 2016-09 did not have a material impact on our results of operations or financial condition.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*, which establishes a new lease accounting model for lessees. In July 2018, the FASB issued ASU No. 2018-11, *Leases (Topic 842): Targeted Improvements* which provides an optional transition method that allows entities to elect to apply the standard prospectively at its effective date, versus recasting the prior periods presented. We are currently in the process of evaluating the transition method. Unlike current GAAP which requires only capital leases to be recognized on the balance sheet, the new guidance will require both types of leases (i.e. operating and capital leases) to be recognized on the balance sheet. The

FASB lessee accounting model will continue to account for both types of leases. The capital lease will be accounted for in substantially the same manner as capital leases are accounted for under existing GAAP. The operating lease will be accounted for in a manner similar to operating leases under existing GAAP, except that lessees will recognize a lease liability and a lease asset for all of those leases. The amended guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2018, with early adoption permitted. We expect to adopt this standard beginning in 2019 and do not expect that this standard will have a material impact on our condensed statements of operations and comprehensive loss; however, we expect that upon adoption, this standard will impact the carrying value of our assets and liabilities on our condensed balance sheets as a result of the requirement to record right-of-use assets and corresponding lease obligations for current operating leases. We are still evaluating whether there are other existing contracts that may become leases under the new lease standard, and the impact of the adoption of this standard on our condensed financial statements and disclosures. We will continue to monitor additional modifications, clarifications or interpretations undertaken by the FASB that may impact our current conclusions, and will expand our analysis to include any new lease arrangements initiated prior to adoption.

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers* and has subsequently issued several supplemental or clarifying ASUs (collectively, “ASC 606”), ASC 606 supersedes nearly all existing revenue recognition guidance under U.S. GAAP. The core principle of ASC 606 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration to which an entity expects to be entitled for those goods or services. ASC 606 defines a five step process to achieve this core principle and, in doing so, more judgment and estimates may be required within the revenue recognition process than are required under existing U.S. GAAP.

The standard is effective for annual periods beginning after December 15, 2017, and interim periods therein, using either of the following transition methods: (i) a full retrospective approach reflecting the application of the standard in each prior reporting period with the option to elect certain practical expedients, or (ii) a retrospective approach with the cumulative effect of initially adopting ASC 606 recognized at the date of adoption.

We adopted the new standard effective January 1, 2018 under the modified retrospective transition method, applying the new guidance to the most current period presented. Upon adoption, there was no change to the units of accounting previously identified under legacy GAAP, which are now considered performance obligations under the new guidance, and there was no change to the revenue recognition pattern for each performance obligation. Therefore, the adoption of the new standard resulted in no cumulative effect to the opening accumulated deficit balance.

We assessed the impact that the adoption of ASC 606 would have on our financial statements by analyzing our current portfolio of customer contracts, including a review of historical accounting policies and practices to identify potential differences in the application of ASC 606. Additionally, we performed a comprehensive review of our current processes and systems to determine and implement changes required to support the adoption of ASC 606 on January 1, 2018.

Subsequent Events

We have evaluated events that have occurred after September 30, 2018 and through the date that the financial statements are issued. See Note 11. “Subsequent Events.”

Fair Value Measurements

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

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

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

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

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

We recorded no fair value adjustment of the warrant liabilities for the three and nine-month periods ended September 30, 2018. We recorded non-cash gains on decreases in the fair value of approximately \$2,000 and \$614,000 for the three and nine-month periods ended September 30, 2017, respectively, in our Condensed Statements of Operations and Comprehensive Loss. The underlying warrants expired by their terms on April 18, 2018. See Note 7 “Warrant Liability” for further discussion on the calculation of the fair value of the warrant liability.

We recorded non-cash gains of approximately \$141,000 related to decreases in the fair value of our derivative liability for the three and nine-month periods ended September 30, 2018. See Note 6 “Molteni Purchase Agreement” for further discussion on the calculation of the fair value of the derivative liability.

2. Stock Plans

The following table summarizes the stock-based compensation expense recorded for awards under the stock option plans for the three and nine-month periods ended September 30, 2018 and 2017:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands, except per share amounts)	2018	2017	2018	2017
Research and development	\$ 136	\$ 134	\$ 455	\$ 379
General and administrative	252	270	767	828
Total stock-based compensation expenses	\$ 388	\$ 404	\$ 1,222	\$ 1,207

No tax benefit was recognized related to stock-based compensation expense since we have accumulated operating losses and we have established a full valuation allowance to offset all the potential tax benefits associated with our deferred tax assets.

We use the Black-Scholes-Merton option-pricing model with the following assumptions to estimate the stock-based compensation expense for the three and nine-month periods ended September 30, 2018 and 2017:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Weighted-average risk-free interest rate	2.9 %	2.0 %	2.7 %	2.1 %
Expected dividend payments	—	—	—	—
Expected holding period (years) ¹	6.4	6.6	6.4	6.6

Edgar Filing: TITAN PHARMACEUTICALS INC - Form 10-Q

Weighted-average volatility factor ²	0.91		0.88		0.89		0.88	
Estimated forfeiture rates ³	25	%	26	%	26	%	27	%

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

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

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

No options were granted during the three-month period ended September 30, 2018. Options to purchase approximately 50,000 shares of common stock were granted during the three-month period ended September 30, 2017. Options to purchase approximately 950,000 and 546,000 shares of common stock were granted during the nine-month periods ended September 30, 2018 and 2017, respectively.

The following table summarizes option activity for the nine-month period ended September 30, 2018:

(in thousands, except per share amounts)	Options	Weighted Average Exercise Price	Weighted Average Remaining Option Term	Aggregate Intrinsic Value
Outstanding at January 1, 2018	2,728	\$ 4.32	5.75	\$ 30
Granted	950	0.97		
Exercised	—	—		
Expired	(18)	8.36		
Cancelled or forfeited	(188)	3.88		
Outstanding at September 30, 2018	3,472	\$ 3.40	6.19	\$ —
Exercisable at September 30, 2018	3,064	\$ 3.65	5.95	\$ —

No shares of restricted stock were awarded to employees, directors and consultants during the three and nine-month periods ended September 30, 2018 and 2017.

As of September 30, 2018, there was approximately \$0.3 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 0.3 years.

On August 7, 2018, our stockholders approved an amendment to the Titan Pharmaceuticals, Inc. 2015 Omnibus Equity Incentive Plan to increase the number of shares authorized for awards thereunder from 2,500,000 to 3,500,000.

3. Net Loss Per Share

Basic net loss per share excludes the effect of dilution and is computed by dividing net loss by the weighted-average number of shares outstanding for the period. Diluted net loss per share reflects the potential dilution that could occur if securities or other contracts to issue shares were exercised into shares. In calculating diluted net loss per share, the numerator is adjusted for the change in the fair value of the warrant liability (only if dilutive) and the denominator is increased to include the number of potentially dilutive common shares assumed to be outstanding during the period using the treasury stock method.

The following table sets forth the reconciliation of the numerator and denominator used in the computation of basic and diluted net loss per common share for the three and nine-months ended September 30, 2018 and 2017:

(in thousands, except per share amounts)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Numerator:				
Net loss attributable to common stockholders for basic earnings per share	\$ (2,330)	\$ (4,191)	\$ (5,804)	\$ (10,647)
Less change in fair value of warrant liability	—	(2)	—	(614)
Less change in fair value of derivatives	(141)	—	(141)	—
Net loss used for diluted earnings per share	\$ (2,471)	\$ (4,193)	\$ (5,945)	\$ (11,261)
Denominator:				
Basic weighted-average outstanding common shares	21,902	21,204	21,439	21,202
Effect of dilutive potential common shares resulting from options	—	—	—	1
Effect of dilutive potential common shares resulting from warrants	—	—	—	19
Weighted-average shares outstanding—diluted	21,902	21,204	21,439	21,222
Net loss per common share:				
Basic	\$ (0.11)	\$ (0.20)	\$ (0.27)	\$ (0.50)
Diluted	\$ (0.11)	\$ (0.20)	\$ (0.28)	\$ (0.53)

The table below presents common shares underlying stock options and warrants that are excluded from the calculation of the weighted average number of common shares outstanding used for the calculation of diluted net loss per common share. These are excluded from the calculation due to their anti-dilutive effect for the three and nine-months ended September 30, 2018 and 2017:

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Weighted-average anti-dilutive common shares resulting from options	3,531	2,380	3,396	2,340
Weighted-average anti-dilutive common shares resulting from warrants	1,461	2,607	1,618	941
	4,992	4,987	5,014	3,281

4. Comprehensive Loss

Comprehensive loss for the periods presented is comprised solely of our net loss. We had no items of other comprehensive loss during the three and nine-month periods ended September 30, 2018 and 2017. Comprehensive loss for the three and nine-month periods ended September 30, 2018 was approximately \$2.0 million and \$5.5 million, respectively. Comprehensive loss for the three and nine-month periods ended September 30, 2017 was approximately \$4.2 million and \$10.6 million, respectively.

5. Braeburn License

Until its termination in May 2018, we were party to a license agreement (as amended, the “License Agreement”) pursuant to which we had granted Braeburn Pharmaceuticals, Inc. (“Braeburn”) the exclusive commercialization rights to Probuphine in the United States and its territories and Canada. Under the License Agreement, we received certain milestone payments, as well as royalties on net sales of Probuphine. Upon receipt of U.S. Food and Drug Administration (“FDA”) approval, our obligation was fulfilled and we recognized as revenue the full amount of the milestone payment. In addition, we were entitled to receive a low single digit royalty on sales by Braeburn of other competing continuous delivery treatments for opioid dependence as defined in the License Agreement. The License Agreement provided for us to be reimbursed by Braeburn for any development services and activities undertaken at Braeburn’s request. Under ASC 606, there was no change in the amount or timing of revenue recognized under the License Agreement. In February 2016, Braeburn sublicensed rights to develop and commercialize Probuphine in Canada to Knight Therapeutics, Inc. (“Knight”).

On May 25, 2018, we entered into a Termination and Transition Services Agreement (the “Transition Agreement”) with Braeburn pursuant to which we regained all rights to the commercialization and clinical development of Probuphine in

the United States and Canada. Braeburn paid us \$1.0 million, transferred inventory to us with a value of approximately \$1.1 million and agreed to provide support services through December 28, 2018. In addition, the Transition Agreement provided for the immediate transfer to us of all regulatory documentation and development data related to Probuphine. The estimated fair value of the inventory received was determined using available inputs such as existing supply agreements, prior selling prices and remaining life to expiration. We recognized approximately \$2.1 million of license related revenue related to this transaction during the three month period ended June 30, 2018. The sublicense to Knight was assigned to Titan as part of the Transition Agreement.

6. Molteni Purchase Agreement

On March 21, 2018, we entered into an Asset Purchase, Supply and Support Agreement (the “Purchase Agreement”) with Molteni pursuant to which Molteni acquired the European intellectual property related to Probuphine, including the Marketing Authorization Application (“MAA”) under review by the European Medicines Agency (“EMA”), and will have the exclusive right to commercialize the Probuphine product supplied by us in Europe, as well as certain countries of the Commonwealth of Independent States, the Middle East and North Africa (the “Molteni Territory”).

We received an initial payment of €2.0 million (approximately \$2.4 million) for the purchased assets and will receive additional potential payments totaling upon the achievement of certain regulatory and product label milestones. Additionally, we are entitled to receive earn-out payments for up to 15 years on net sales of Probuphine in the Molteni Territory ranging in percentage from the low-teens to the mid-twenties.

We concluded that the performance obligations identified in the Purchase Agreement included the transfer of the intellectual property and our efforts towards the approval by the EMA and other regulatory bodies. The initial closing payment was allocated between the property transfer and our EMA efforts as set forth below.

We used the expected cost-plus approach to estimate the standalone selling price of approximately \$1.4 million related to our efforts towards the approval by the EMA and other regulatory bodies. This includes employee related expenses as well as other manufacturing, regulatory and clinical costs which will be incurred as part of our efforts. At the time of the agreement, we believe that the services would be at a consistent rate and would be substantially complete as of December 31, 2018. As such, we recognized the revenue ratably at an amount equal to approximately \$157,000 per month through June 30, 2018. We currently estimate that the services will likely extend until March 31, 2019 and we will recognize the revenue ratably at an amount equal to approximately \$104,000 per month over the period from July 1, 2018 through March 31, 2019. If the facts and circumstances change, we will reassess these assumptions. The costs associated with these services will be expensed over the same period.

We used the residual approach to value the transfer of the intellectual property at approximately \$1.0 million as we had not established and had no reliable way to establish a standalone selling price for the intellectual property.

As a result of the outcome of the milestone and earn-out payments being unpredictable due to the involvement of third parties, we believe that using the most likely amount method is appropriate. Any subsequent revenue related to milestone and earn-out payments will be recognized at the time the milestones are achieved or when the related net sales have occurred.

The Purchase Agreement provides that we will supply Molteni with semi-finished product (i.e., the implant, the applicator and related technology) on an exclusive basis at a fixed price through December 31, 2019, with subsequent price increases not to exceed annual cost increases to us for the active pharmaceutical ingredient and under our current manufacturing agreement. Revenue will be recognized when the semi-finished product has been transferred to Molteni.

Molteni will be prohibited from marketing a Competitor Product (as defined in the Purchase Agreement) in the Molteni Territory for the five year period following approval of the MAA. Thereafter, Molteni will be required to pay

us a low single digit royalty on net sales of any Competitor Product.

The following table presents changes in contract assets and liabilities during the nine months ended September 30, 2018:

(in thousands)	Beginning Balance	Additions	Deductions	Ending Balance
Nine months ended September 30, 2018				
Contract assets	\$ —	\$ 291	\$ (96) \$ 195
Contract liabilities:				
Deferred revenue	\$ —	\$ 2,448	\$ (1,822) \$ 626

On August 3, 2018, we entered into an amendment (the “Amendment”) to the Purchase Agreement with Molteni. Under the Amendment, Molteni made an immediate payment to us of €950,000 (approximately \$1.1 million) and committed to make a convertible loan to us of €550,000 (approximately \$0.6 million) provided we have submitted our response to the 120-day letter from the EMA on or prior to September 14, 2018 in accordance with the Amendment, both in exchange for the elimination of an aggregate of €2.0 million (approximately \$2.3 million) of regulatory milestones provided for in the Purchase Agreement that are potentially payable in 2019, at the earliest. The loan (the “Convertible Loan”) was made on September 18, 2018 and will convert automatically into shares of our common stock upon the issuance by the EMA of marketing approval for Probuphine at a conversion price per share equal to the lower of (i) the closing price on the loan funding date and (ii) the closing price on the conversion date. In the event the EMA has not granted marketing approval by December 31, 2019, the Convertible Loan will become due and payable, together with accrued interest at the rate of one-month LIBOR (to the extent in excess of 1.10%) plus 9.50% per annum. We concluded that the approximately \$1.1 million immediate payment by Molteni reflected a milestone payment with no additional obligations to us and therefore was recognized as revenue during the three month period ended September 30, 2018. Due to the conversion provision of the Convertible Loan, ASC 815, *Derivatives and Hedging* required that we classify this as an embedded derivative and changes in the fair value were recorded in the Condensed Statements of Operations and Comprehensive Loss. The Convertible Loan contains other covenants and events of default substantially consistent with the Restated Loan Agreement described in Note 8. “Debt Agreements.”

The key assumptions used to value the Convertible Loan embedded derivative were as follows:

Assumption		
Date of issuance	September 18, 2018	
Expected price volatility	87	%
Expected term (in years)	0.75	
Risk-free interest rate	2.32	%
Dividend yield	0.00	%
Fair value of conversion provision	\$158,530	

Assumption		
Valuation date	September 30, 2018	
Expected price volatility	120	%
Expected term (in years)	0.75	
Risk-free interest rate	2.32	%
Dividend yield	0.00	%
Fair value of conversion provision	\$17,245	

7. Warrant Liability

Until they expired by their terms on April 18, 2018, we had warrants outstanding to purchase an aggregate of 983,395 shares of common stock at an exercise price of \$4.85 per share. The warrants contained a provision where the warrant

holder had the option to receive cash equal to the Black Scholes fair value of the remaining unexercised portion of the warrant as cash settlement in the event that there was a fundamental transaction (contractually defined to include various merger, acquisition or stock transfer activities). Due to this provision, ASC 480, *Distinguishing Liabilities from Equity* required that these warrants be classified as liabilities. The fair value of these warrants was determined using the Lattice valuation model, and the changes in the fair value were recorded in the Condensed Statements of Operations and Comprehensive Loss.

8. Debt Agreements

In July 2017, we entered into a venture loan and security agreement (“Original Loan Agreement”) with Horizon Technology Finance Corporation (“Horizon”), pursuant to which we received a loan in the amount of \$7.0 million

The Original Loan Agreement provided for repayment of the loan on an interest-only basis through December 31, 2018, followed by monthly payments of principal and accrued interest for the balance of the 46-month term. The loan bears interest at a floating coupon rate of one-month LIBOR (floor of 1.10%) plus 8.40%. A final payment equal to 5.0% of the loan will be due on the scheduled maturity date for such loan. The Original Loan Agreement also contained a prepayment penalty based on a percentage of the then outstanding principal balance, equal to 4% if the prepayment occurs during the interest-only payment period, 3% if the prepayment occurs during the 12 months following such period, and 2% thereafter.

Our obligations under the Original Loan Agreement were secured by a first priority security interest in all of our assets, with the exception of our intellectual property. We agreed not to pledge or otherwise encumber our intellectual property assets, subject to certain exceptions.

The Original Loan Agreement included customary affirmative and restrictive covenants, excluding any covenants to attain or maintain certain financial metrics, and also included customary events of default, including for payment failures, breaches of covenants, change of control and material adverse changes. Upon the occurrence of an event of default and following any applicable cure periods, a default interest rate of an additional 5% could be applied to the outstanding loan balance, and Horizon could declare all outstanding obligations immediately due and payable and take such other actions as set forth in such agreement.

In connection with the Original Loan Agreement, we issued Horizon seven-year warrants to purchase an aggregate of \$550,000 of our common stock at a per share exercise price equal to the lower of (i) \$1.96 or (ii) the price per share of any securities that may be issued by us in an equity financing during the 18 months following the agreement date (“Horizon Warrants”). We agreed to file a registration statement covering the resale of the shares underlying the Horizon Warrants. In accordance with ASC 480, *Distinguishing Liabilities from Equity*, as amended by ASU, No. 2017-11, which we early adopted during 2017, the Horizon Warrants have been classified as equity and their fair value at the time of issuance was determined using a Lattice valuation model and was recorded in the Condensed Balance Sheet as a discount to the debt obligation.

The key assumptions used to value the Horizon Warrants were as follows:

Assumption	July 27, 2017	
Date of issuance	47	%
Expected price volatility	7.00	
Expected term (in years)	2.12	%
Risk-free interest rate	0.00	%
Dividend yield	\$1.02	
Weighted-average fair value of warrants		

In connection with the closing of the Offering on September 25, 2018, the Horizon Warrants became exercisable to purchase an aggregate of 2,200,000 shares of common stock at an exercise price of \$0.25 per share.

In accordance with the guidance in ASU 2017-11, we recognized the effect of triggering the down round feature as a dividend in our Condensed Balance Sheets at September 30, 2018 and as an addition to net loss attributable to common stockholders and in our calculation of basic and fully diluted earnings per share in our Condensed Statements

Edgar Filing: TITAN PHARMACEUTICALS INC - Form 10-Q

of Operations and Comprehensive Loss for the three and nine months ended September 30, 2018. We calculated the dividend of approximately \$0.3 million resulting from the trigger of the down round provision on September 25, 2018 using the Black Scholes Option Pricing Model and the assumptions indicated in the table below:

Assumption	Pre-reset		Post-reset	
Exercise price per share	\$	1.96	\$	0.25
Expected price volatility	71	%	71	%
Expected term (in years)	5.84		5.84	
Risk-free interest rate	3.02	%	3.02	%
Dividend yield	0.00	%	0.00	%
Weighted-average fair value of warrants	\$	0.05	\$	0.14

On February 2, 2018, we entered into an amendment to the Original Loan Agreement (the “Amended Loan Agreement”) pursuant to which we prepaid \$3.0 million of the outstanding \$7.0 million principal amount and provided Horizon with a lien on our intellectual property. The other terms of the Original Loan Agreement remained unchanged.

On March 21, 2018, we entered into an Amended and Restated Venture Loan and Security Agreement (the “Restated Loan Agreement”) with Horizon and Molteni pursuant to which Horizon assigned approximately \$2.4 million of the \$4.0 million outstanding principal balance of the loan to Molteni and Molteni was appointed collateral agent and assumed majority and administrative control of the debt. Under the Restated Loan Agreement, the interest only payment and forbearance periods were extended to December 31, 2019. In addition, Molteni has the right to convert its portion of the debt into shares of our common stock at a conversion price of \$1.20 per share and is required to effect this conversion of debt to equity if we complete an equity financing resulting in gross proceeds of at least \$10.0 million at a price per share of common stock in excess of \$1.20 and repay the \$1.6 million balance of Horizon’s loan amount. The lien on our intellectual property remains in place at this time. As the present value of the cash flows under the terms of the Restated Loan Agreement is less than 10% different from the remaining cash flows under the terms of the Amended Loan Agreement prior to being amended and restated, the Restated Loan Agreement was accounted for as a debt modification. Accordingly, expenses incurred as a result of the modification were expensed as incurred and the previously deferred fees and costs related to the debt will continue to be amortized over the remaining term along with the related warrants issued as part of the agreement described in Note 9 “Rights Agreement.”

In connection with the Restated Loan Agreement, we issued Horizon seven-year warrants to purchase 40,000 shares of our common stock at an exercise price of \$1.20 per share. The new Horizon warrants have been classified as equity and their fair value at the time of issuance was determined using a Black Scholes valuation model and was recorded in the Condensed Balance Sheets as a discount to the debt obligation.

The key assumptions used to value the new Horizon warrants were as follows:

Assumption	
Date of issuance	March 21, 2018
Expected price volatility	86 %
Expected term (in years)	7.00
Risk-free interest rate	2.82 %
Dividend yield	0.00 %
Weighted-average fair value of warrants	\$0.81

9. Rights Agreement

In consideration of Molteni’s entry into the Restated Loan Agreement and the Purchase Agreement, on March 21, 2018, we entered into an agreement (as amended in May 2018, the “Rights Agreement”) with Molteni pursuant to which we agreed to (i) issue Molteni seven-year warrants to purchase 540,000 shares of our common stock at an exercise price of \$1.20 per share (the “Molteni Warrants”), (ii) provide Molteni customary demand and piggy-back registration rights with respect to the shares of common stock issuable upon conversion of its loan and exercise of the Molteni Warrants, (iii) appoint one member of our board of directors following conversion of its loan to equity and (iv) provide board observer rights to Molteni if it has not designated a board nominee as well as certain information rights.

The board designation, observer and information rights will terminate at such time as Molteni ceases to beneficially own at least one percent of our outstanding capital stock (inclusive of the shares issuable upon conversion of debt under the Restated Loan Agreement and exercise of the Molteni Warrants). The Molteni Warrants have been classified as equity and their fair value at the time of issuance was determined using a Black Scholes valuation model. The amount was allocated equally between the Restated Loan Agreement and the Purchase Agreement and was recorded in the Condensed Balance Sheets as a discount to the debt obligation and a contract asset, respectively.

The key assumptions used to value the Molteni Warrants were as follows:

Assumption		
Date of issuance	March 21, 2018	
Expected price volatility	86	%
Expected term (in years)	7.00	
Risk-free interest rate	2.82	%
Dividend yield	0.00	%
Weighted-average fair value of warrants	\$0.81	

10. Stockholder's Equity

On September 20, 2018, we entered into an underwriting agreement (the "Underwriting Agreement") with A.G.P./Alliance Global Partners, as representative (the "Representative") of the underwriters (the "Underwriters") pursuant to which we sold to the Underwriters in the Offering an aggregate of (i) 5,100,000 Class A Units at a public offering price of \$0.25 per unit, with each unit consisting of one share of common stock and a Warrant to purchase one share of common stock, and (ii) 8,225 Class B Units at a public offering price of \$1,000 per unit, with each unit consisting of one share of Series A Convertible Preferred Stock (the "Preferred Shares") and Warrants to purchase 4,000 shares of common stock. The Warrants have an exercise price of \$0.25 and will expire five years from the date of issuance. The Preferred Shares, which are convertible into an aggregate of 32,900,000 shares of common stock, include a beneficial ownership blocker but have no dividend rights (except to the extent that dividends are also paid on the common stock), liquidation preference or other preferences over common stock, and have no voting rights.

In addition, the Underwriters were granted an option for a period of 45 days to purchase up to an additional 5,700,000 shares of common stock and/or additional Warrants to purchase up to 5,700,000 shares of common stock.

We also agreed to issue to the Representative and its designees warrants to purchase an aggregate of 1,520,000 shares of Common Stock at an exercise price of \$0.28 per share.

The Offering closed on September 25, 2018. At the closing, the Underwriters exercised their option to purchase 5,700,000 additional Warrants at a price of \$0.01 per warrant.

Between the closing and September 30, 2018, we issued an aggregate of 13,064,000 shares of common stock upon the conversion of Preferred Shares.

11. Subsequent Events

Over-Allotment Option Exercise

On October 3, 2018, we completed the sale of 3,800,000 shares of common stock at a purchase price of \$.24 per share in connection with the exercise of the over-allotment option by the Underwriters.

On October 22, 2018, we completed the sale of 1,900,000 shares of common stock at a purchase price of \$.24 per share in connection with the final exercise of the Underwriter's over-allotment option.

From October 1, 2018 through November 9, 2018, Warrants to purchase an aggregate of 13,070,900 shares of common stock were exercised, resulting in proceeds to us of approximately \$3.3 million. On November 9, 2018, there were 30,629,100 Warrants outstanding.

In October 2018, an additional 19,836,000 shares of common stock were issued upon the conversion of Preferred Shares. There are no remaining Preferred Shares outstanding.

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

The following discussion contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 (the "Exchange Act"). Such statements include, but are not limited to, any statements relating to our product development programs and any other statements that are not historical facts. Such statements involve risks and uncertainties that could negatively affect our business, operating results, financial condition and stock price. Factors that could cause actual results to differ materially from management's current expectations include those risks and uncertainties relating to our transition to a commercial enterprise, the regulatory approval process, the development, testing, production and marketing of our drug candidates, patent and intellectual property matters and strategic agreements and relationships. We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations or any changes in events, conditions or circumstances on which any such statement is based, except as required by law.

Probuphine® and ProNeura™ 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 pharmaceutical company developing therapeutics for the treatment of select chronic diseases utilizing our proprietary long-term drug delivery platform, ProNeura™, and we are currently transitioning to a commercial stage enterprise having reacquired Probuphine® in May 2018, our first product approved in the U.S. for the maintenance treatment of opioid dependence. Products utilizing the ProNeura technology are typically capable of providing long term continuous delivery of a drug and maintaining a stable blood level that could potentially provide an efficacy and/or safety benefit.

Probuphine, our first product candidate based on our proprietary ProNeura™ platform, is a subdermal implant that provides continuous delivery of buprenorphine for six months. Probuphine was approved by the FDA in May 2016 for the maintenance treatment of opioid dependence in patients who are stable on low to moderate doses of daily sublingual buprenorphine treatment. In December 2012, we licensed development and commercialization rights of Probuphine for the U.S. and Canadian markets to Braeburn and following FDA approval Braeburn commenced necessary activities to commercialize the product, subsequently announcing a full launch at the beginning of 2017. In

early 2018, Braeburn substantially reduced its field sales force and medical liaison personnel following its receipt of a complete response letter from the FDA for its weekly and monthly depot injection products. Anticipating a negative impact on Probuphine sales in the U.S., we began discussing with Braeburn terms for the return of the Probuphine U.S. commercialization rights to Titan. On May 25, 2018, we entered into an agreement with Braeburn under which we received a \$1.0 million payment from Braeburn and Braeburn's undertaking to provide transition services through 2018 to assist with commercialization activities and help maintain continuity in product supply for patients and their physicians. As part of this transaction, the sublicense agreement with Knight for the Canadian territory was assigned to Titan. In April 2018, Knight announced that it had received regulatory approval from Health Canada to commercialize the product for the maintenance treatment of stable patients with opioid use disorder and Knight commenced commercial launch at the end of October 2018.

Since reacquiring the rights, we have begun implementation of a strategy to relaunch Probuphine to targeted market segments that we believe are best suited to benefit from this product. During the three months ended September 30, 2018, we began transitioning all the Probuphine commercialization activities from Braeburn to Titan, including the supply chain and logistics functions, as well as the Medical Affairs and Risk Evaluation Mitigation Strategy, or REMS, training and reporting activities. During this transition, we have identified key areas of improvement which may allow better service for the health care provider and the patient in the long term, while continuing to supply Probuphine to prescribing health care providers.

We are pursuing a targeted market strategy that focuses on establishing inroads into select market segments where Probuphine can provide meaningful benefit for the patient, allowing for sustained market penetration and sales growth. With the proceeds from the Offering, we have commenced building our commercial infrastructure, including a small sales, marketing and medical liaison team, which will enable us to transition to a commercial enterprise during the fourth quarter of 2018 and help position Probuphine as a specialty product for the maintenance treatment of opioid use disorder, or OUD. This team will focus initially on the following key market segment:

High Probuphine-prescribing physicians with long-term recovery oriented treatment programs. There are a substantial number of certified physicians who are currently treating OUD, with Probuphine, all of whom are identified in our data base. Our plan in the short term is to focus on the top tier of prescribers to facilitate the growth of their businesses through increased utilization of Probuphine. In addition, our medical access specialists will provide resources to help lessen the complexity of the supply chain and reimbursement process. In the longer term, some top tier Probuphine providers will also engage in investigator sponsored research which can generate new and clinically meaningful data, some of which will help us assess the potential for label expansion.

We will also begin laying the groundwork in the following three market segments, with the goal of expanding these activities assuming success with our initial marketing efforts and our ability to obtain sufficient resources:

Residential treatment facilities. Historically, these facilities have mostly relied on 12-step programs with the goal of complete and sustained abstinence while avoiding any medication assisted treatment, or MAT. However, the success of such programs has not withstood scrutiny, as it has been increasingly recognized that a very high percentage of patients with opiate addiction ultimately relapse. Consequently, the use of MAT as part of the management of OUD has been increasing, and is expected to rise substantially in the near term. Our plan is to establish alliances with a few large programs.

Criminal justice system. In recent years there has been increasing recognition that the rate of recidivism among inmates with opiate addiction is very high. In addition, the incidence of overdose and death is high for recently released inmates who have “detoxed” while incarcerated (often through abrupt withdrawal or “cold turkey”). Early data suggests the use of MAT in this population can decrease recidivism and the incidence of overdose deaths. Our plan is to initially establish pilot projects with a few select criminal justice programs, such as the one we recently initiated in the State of Nevada, with the goal of generating meaningful data that potentially supports the use of Probuphine in this setting.

Academic institutions with addiction treatment and training programs. We plan to form alliances with institutions that already have the necessary trained personnel and equipment for doing small procedures, and facilitate the introduction and/or increased use of Probuphine for appropriate patients. This will also serve to introduce Probuphine to the next generation of addiction specialists. In the longer term, we expect that key opinion leaders, or KOLs, at some of these sites will initiate investigator sponsored studies which can generate clinically meaningful data while helping us assess the potential for label expansion.

We expect that demonstration of early success in these market segments will serve to increase partnering opportunities, which will then help sustain and accelerate future growth of Probuphine.

Upon reacquiring Probuphine, we became responsible for the conduct of three Phase 4 clinical studies that were requested by the FDA as part of the approval of Probuphine. The clinical studies are as follows:

A study to evaluate the pharmacokinetics, safety and tolerability of implantation of Probuphine in a previously used site or at alternate body sites in adults with OUD;

A prospective descriptive observational cohort study of insertion, localization, and removal related serious adverse events associated with use of Probuphine; and

A tQT study of Probuphine to be conducted in collaboration with other companies that market buprenorphine products for treatment of OUD

We have been in discussion with the FDA to finalize the study protocols and expect to commence these studies next year.

On March 21, 2018, we entered into the Purchase Agreement with Molteni pursuant to which Molteni acquired the European intellectual property related to Probuphine and exclusive right to commercialize the Titan supplied product in the Molteni Territory in exchange for upfront, milestone and earn-out payments for up to 15 years on net sales of Probuphine. We are working with Molteni in connection with the MAA currently under review by the EMA with the goal of receiving approval to commercialize Probuphine in the EU in the first half of 2019. Molteni has further supported us during the third quarter by providing approximately \$1.7 million in funds as a prepayment of certain future milestones (see Note 6 to the Financial Statements).

We believe that our ProNeura long term drug delivery platform has the potential to be used in the treatment of other chronic conditions where maintaining stable, around the clock blood levels of a medication may benefit the patient and improve medical outcomes. Our long-term goal is to expand our product pipeline using the ProNeura implant platform, and, depending on available funds, we have been opportunistically evaluating other drugs and disease settings for use with the ProNeura platform in potential treatment applications where conventional treatment is limited by variability in blood drug levels and poor patient compliance. The pursuit of any of these programs in the short-term will depend on our ability to obtain the necessary funding through either government grants or third party collaborations. In September 2018, we announced the receipt of a two year grant of approximately \$6.7 million from the National Institutes of Health's National Institute on Drug Abuse ("NIDA") for the development of a ProNeura™ based six-month implantable formulation of Nalmefene, an opioid antagonist, intended for the prevention of relapse to opioid addiction, following opioid detoxification. The NIDA grant provides approximately \$2.7 million for the project through August 31, 2019 with the balance to be funded over the subsequent year, subject to satisfactory project progress, fund availability and certain other conditions including company matching funds (50% of grant) as required by recently enacted regulation. We have commenced work on this project, and if successfully completed it will provide the necessary information for an Investigational New Drug, or IND, application to the FDA.

We operate in only one business segment, the development and commercialization of pharmaceutical products.

Recent Accounting Pronouncements

See Note 1 to the accompanying unaudited condensed financial statements included in Part 1, Item 1 of this Quarterly Report on Form 10-Q for information on recent accounting pronouncements.

Results of Operations for the Three and Nine-Months Ended September 30, 2018 and September 30, 2017

License revenues were approximately \$1.4 million and \$5.1 for the three and nine-month periods ended September 30, 2018, respectively. Revenues for the three-month period ended September 30, 2018 period reflect approximately \$0.3 million related to the amortization of deferred revenue related to the sale to Molteni of the European intellectual property rights to our Probuphine product and approximately \$1.1 million related to the amendment to our Purchase Agreement with Molteni in August 2018. Revenues for the nine-month period ended September 30, 2018 period reflect approximately \$1.8 million related to the up-front payment and amortization of deferred revenue related to the sale to Molteni of the European intellectual property rights to our Probuphine product, approximately \$1.1 million related to the amendment to our Purchase Agreement with Molteni in August 2018, approximately \$2.1 million related to the return of the Braeburn license and approximately \$32,000 related to the recognition of royalties earned on net sales of our Probuphine product by Braeburn. License revenues of approximately \$40,000 and \$157,000 for the three and nine-month periods ended September 30, 2017 primarily reflect the recognition of the royalties earned on net sales of our Probuphine product by Braeburn.

Product revenues for the three and nine-month periods ended September 30, 2018 were approximately \$244,000 and \$318,000, respectively. Product revenues reflect net revenues generated from sales of our Probuphine product by us after reacquiring the product in May, 2018.

Research and development expenses for the three-month period ended September 30, 2018 were approximately \$1.9 million, compared to approximately \$2.7 million for the comparable period in 2017, a decrease of approximately \$0.8 million, or 30%. The decrease in research and development costs was primarily associated with decreases in external research and development expenses related to the support of the ropinirole implant program and some expenses on other ProNeura product development programs, employee related expenses and other research and development expenses. Research and development expenses for the nine-month period ended September 30, 2018 were approximately \$5.6 million, compared to approximately \$7.3 million for the comparable period in 2017, a decrease of approximately \$1.7 million, or 23%. The decrease in research and development costs was primarily associated with decreases in external research and development expenses related to the support of the ropinirole implant program and limited expenses on other ProNeura product development programs, employee related expenses and other research and development expenses. During the three and nine-month periods ended September 30, 2018, external research and development expenses relating to our product development programs were approximately \$1.0 million and \$2.7 million, respectively, compared to approximately \$1.8 million and \$4.3 million, respectively, for the comparable periods in 2017. 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 research and development programs or the timing of material cash inflows, if any, from our product candidates.

General and administrative expenses for the three-month periods ended September 30, 2018 and 2017 were approximately \$1.5 million, compared to approximately \$1.4 million for the comparable period in 2017, an increase of approximately \$0.1 million, or 7%. General and administrative expenses for the nine-month period ended September 30, 2018 were approximately \$4.5 million, compared to approximately \$3.9 million for the comparable period in 2017, an increase of approximately \$0.6 million, or 15%. The increase in general and administrative expenses during the nine-month period ended September 30, 2018 was primarily related to increases in legal and professional fees of approximately \$0.5 million and facilities and depreciation of approximately \$0.1 million.

Net other expense for the three and nine-month periods ended September 30, 2018 was approximately \$0.1 million and \$0.5 million, respectively. Net other expense consisted primarily of interest expense which was partially offset by approximately \$0.1 million related to non-cash gains on changes in the fair value of derivatives. Net other expense for the three-month period ended September 30, 2017 was approximately \$0.1 million. Net other expense consisted primarily of interest expense related to our outstanding secured loan. Net other income for the nine-month period ended September 30, 2017 was approximately \$0.5 million. Net other income consisted primarily of non-cash gains on changes in the fair value of warrants of approximately \$0.6 million which was partially offset by interest expense related to the loan of approximately \$0.1 million.

Our net loss for the three-month period ended September 30, 2018 was approximately \$2.0 million, or approximately \$0.11 per share, compared to our net loss of approximately \$4.2 million, or approximately \$0.20 per share, for the comparable period in 2017. Our net loss for the nine-month period ended September 30, 2018 was approximately \$5.5 million, or approximately \$0.27 per share, compared to our net loss of approximately \$10.6 million, or approximately \$0.50 per share, for the comparable period in 2017. Our net loss per share for the three and nine month periods ended September 30, 2018 includes a deemed dividend of approximately \$0.3 million.

Liquidity and Capital Resources

We have funded our operations since inception primarily through the sale of debt and equity securities, as well as with proceeds from Warrant and option exercises, technology licensing, collaborative agreements and government-sponsored research grants. At September 30, 2018, we had working capital of approximately \$9.3 million compared to working capital of approximately \$3.8 million at December 31, 2017.

Our operating activities used approximately \$5.1 million during the nine months ended September 30, 2018. This consisted primarily of the net loss for the period of approximately \$5.5 million, approximately \$1.3 million related to a non-cash gain on inventory received from the Transition Agreement and approximately \$0.1 million related to net changes in other operating assets and liabilities. This was offset, in part, by non-cash charges of approximately \$1.2 million related to stock-based compensation, approximately \$0.3 million related to depreciation and amortization, approximately \$0.3 million related to non-cash interest expense and approximately \$0.1 million related to non-cash gains on changes in the fair value of derivatives. Uses of cash in operating activities were primarily to fund product development programs and administrative expenses.

Our investing activities used approximately \$71,000 during the nine months ended September 30, 2018, which was primarily related to purchases of equipment.

Our financing activities provided approximately \$6.1 million during the nine months ended September 30, 2018, which consisted of approximately \$8.5 million related to net proceeds from the Offering and approximately \$0.6 million from the issuance of debt. This was offset in part by \$3.0 million related to the repayment of debt.

In May 2018, we entered into the Transition Agreement pursuant to which we regained all Probuphine commercialization and clinical development rights we had granted to Braeburn. Braeburn paid us \$1.0 million and transferred inventory to us with a value of approximately \$1.1 million.

In August 2018, we amended the Purchase Agreement to eliminate an aggregate of €2,000,000 of future regulatory milestones in exchange for which Molteni made an immediate payment to us of €950,000 (approximately \$1.1 million) and a Convertible Loan to us of €550,000 (approximately \$0.6 million) on September 18, 2018 following the submission of our response to the 120-day letter from the European Medicines Agency (“EMA”) before September 14, 2018.

In September 2018, we completed the Offering which provided net proceeds of approximately \$8.5 million.

At September 30, 2018, we had restricted cash of approximately \$0.4 million. This represents a cash security deposit for an outstanding letter of credit established to fund upcoming EMA filing fees.

At September 30, 2018, we had cash and cash equivalents of approximately \$8.4 million.

In October, the Underwriters exercised their remaining over-allotment option to purchase an aggregate of 5,700,000 shares of common stock, resulting in net proceeds to us of approximately \$1.3 million.

Between October 1, 2018 and November 9, 2018, investors in the Offering exercised their Warrants for an aggregate of 13,070,900 shares of common stock, resulting in proceeds to us of approximately \$3.3 million.

We believe our cash and cash equivalents at September 30, 2018, together with the proceeds from the over-allotment option and Warrant exercises will be sufficient to fund our planned operations through the third quarter of 2019.

We will require additional funds to finance our operations, including the commercialization of Probuphine in the U.S., completion of the Probuphine Phase IV clinical trials mandated by the FDA and advancement of our current ProNeura development programs to later stage clinical studies. Our efforts to obtain financing in the future may not be successful.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our market risk disclosures set forth in our Annual Report on Form 10-K for the year ended December 31, 2017 have not changed materially.

Item 4. Controls and Procedures

Disclosure Controls and Procedures

Our President and Chief Executive Officer, being our principal executive and financial officer, has evaluated the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act as of September 30, 2018, the end of the period covered by this report, and has concluded that our disclosure controls and procedures were effective to ensure that the information required to be disclosed by us in reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC, and that such information is accumulated and communicated to our principal executive and principal financial officer as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the nine months ended September 30, 2018 that have materially affected, or are reasonably likely to materially affect, Titan's internal control over financial reporting.

PART II

Item 1A. Risk Factors

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 for the year ended December 31, 2017, which could materially affect our business, financial condition or future results (the "10-K Risk Factors"). The risks described in our Annual Report on Form 10-K are not the only risks facing us. 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. Except for the risks set forth below, there are no material changes to the 10-K Risk Factors.

We may not be successful in transitioning from a research and development company to a commercial enterprise.

Since our inception, we have been engaged in product research and development and have never directly commercialized any product. Since we regained the U.S. commercial rights to Probuphine in May 2018, we have been largely dependent on Braeburn's provision of support services, as well as those of advisors and consultants, as we transition to a commercial enterprise. We do not currently employ a sales force or have any internal sales and marketing capabilities. Without hiring or contracting for an experienced and active sales force, we will not be in a position to relaunch Probuphine and sales, if any, will continue to be limited. We will face intense competition for sales and marketing personnel with the necessary experience in addiction, reimbursement, specialty pharmacies and our targeted markets and there can be no assurance that we will be successful in our efforts to transition to a commercial stage company.

If Probuphine does not achieve broad market acceptance by physicians, patients or others in the medical community or coverage by third-party payors, our business will suffer.

Although Braeburn commenced a full commercial launch of Probuphine in the first quarter of 2017, minimal progress was made and for the year ended December 31, 2017 we derived royalty revenues of only \$215,000 from sales of Probuphine. The commercial success of Probuphine and our product relaunch will depend upon its acceptance by physicians, patients, healthcare payors and the medical community. Coverage and reimbursement of Probuphine by third-party payors is also necessary for commercial success. Since its initial commercial launch by Braeburn, Probuphine's adoption by physicians has been hindered both by the Risk Evaluation and Mitigation Strategy, or REMS, requirements mandated by the product label, which are more expansive than those required for other buprenorphine products, as well as the current payment and reimbursement model, which differs from some of the existing treatment options for opioid addiction. For example, the current standard of care for outpatient treatment of opioid addiction is oral daily buprenorphine, which typically requires frequent patient visits and a per visit fee, which the patient may pay directly to the healthcare provider in cash. Reimbursement for an implantable drug product that requires administration by a healthcare provider requires drug codes as well as a separate procedure code for the insertion and removal procedures and less frequent office visits. Physicians may prefer more frequent patient visits and the accompanying reimbursement and payment model, which oftentimes includes cash payments. The commercial success of Probuphine depends on several factors, including:

our ability to train and certify healthcare providers to insert and remove implants of Probuphine in accordance with the REMS;

- the perceived and actual advantages of our Probuphine over current and emerging treatment options;
- the willingness of healthcare providers to prescribe, and the target patient population to try novel products;
- the competitiveness of our pricing;

the willingness of healthcare providers to accept alternative reimbursement models, such as the “buy-and-bill” system, where prescribers are required to buy Probuphine inventory themselves and then bill patients or payors following the procedure, or the specialty pharmacy distribution model, where a specialty pharmacy carries inventory and ships it to healthcare providers as requested and prescribed, and directly handles the subsequent billing and payment process with payors;

our ability to provide adequate support to physicians and other healthcare providers to lessen the burden of current reimbursement models;

our ability to establish and maintain adequate levels of coverage for Probuphine from commercial health plans and government health programs, which we refer to collectively as third-party payors, particularly in light of the availability of other branded and generic competitive products;

the willingness for patients to pay out-of-pocket in the absence of third-party coverage and the success of patient assistance programs; and

· our ability to promote products through marketing and sales activities and any other arrangements; and

· our ability to successfully educate prescribers and patients on the applicable product’s efficacy and safety;

In light of the difficulties encountered to date, we cannot predict either the timing or the degree to which Probuphine will be accepted by the medical community. If we are unable to generate ample royalty revenue from Probuphine, we will be unable to fund our research and development programs without additional financing, which may not be available on acceptable terms, and our business will be materially harmed.

We must comply with post-approval clinical trial requirements

The New Drug Application, or NDA, for Probuphine mandated the post-approval completion of several Phase IV clinical trials. Prior to the reversion of the commercialization rights to us, Braeburn had been in negotiations with the FDA with respect to the various trial protocols and had not commenced the required clinical trials. Upon transfer of the NDA back to us, we began communicating with the FDA regarding the Phase IV requirements. There can be no assurance that the FDA will provide us with the time we need to initiate and complete the necessary clinical trials, or that we will have the necessary funds to do so, in which event we may be subject to possible sanctions, including monetary penalties or suspension of Probuphine commercial activities. Furthermore, unexpected negative findings from a Phase IV trial could negatively impact the product label and/or acceptance by patients, healthcare providers and insurers.

The Probuphine REMS program has negatively impacted initial uptake and may continue to do so, which could materially adversely impact our business prospects.

There is currently a REMS program in place for Probuphine as required by the FDA. The REMS program was implemented by Braeburn in May 2016 and is designed to mitigate the risk of complications of migration, protrusion, expulsion and nerve damage associated with the insertion and removal of Probuphine and the risks of accidental overdose, misuse and abuse. The REMS program requires training and certification of healthcare providers who prescribe and implant Probuphine and provide patient counseling. Probuphine distribution is restricted to healthcare providers who have completed training and received certification under the REMS program. We believe the REMS program has been an obstacle to adoption of Probuphine to date by the medical community. Healthcare providers may be unwilling to undergo training and certification in order to be able to prescribe or implant Probuphine due to time constraints or concerns with the product. If we are unable to adequately address this issue, our ability (or the ability of potential future commercial partners) to generate revenue from sales of Probuphine could be materially compromised, which would have a material adverse effect on our business, results of operations, financial condition and prospects. In addition, if a patient suffers an injury during the insertion and removal of Probuphine, it may give rise to liability against us by patients, clinicians or others or result in non-compliance with the REMS program. Non-compliance with the REMS program may bring serious consequences to us, including warning letters from the FDA, fines, criminal charges and other prohibitions and exclusions as well as reputational damage.

The FDA-approved product labeling for Probuphine allows prescribing for a limited patient population.

Probuphine was approved with an indicated use limited to the long-term maintenance treatment of opioid dependence in clinically stable patients on 8 mg or less a day of oral buprenorphine. The approved labeling also contains other limitations on use and warnings and contraindications for risks. If potential purchasers or those influencing purchasing decisions, such as physicians and pharmacists or third party payers, react negatively to Probuphine because of their perception of the limitations or safety risks in the approved product labeling, it may result in lower product acceptance and lower product revenues.

In addition, our promotion of Probuphine must reflect only the specific approved indication as well as other limitations on use, and disclose the safety risks associated with the use of Probuphine as set out in the approved product labeling. We must submit all promotional materials to the FDA at the time of their first use. If the FDA raises concerns regarding our promotional materials or messages, we may be required to modify or discontinue using them and provide corrective information to healthcare practitioners, and we may face other adverse enforcement action.

Probuphine is a controlled substance subject to DEA regulations and failure to comply with these regulations, or the cost of compliance with these regulations, may adversely affect our business.

Probuphine contains buprenorphine, a regulated Schedule III “controlled substance” under the CSA, which establishes, among other things, certain registration, production quotas, security, recordkeeping, reporting, import, export and other requirements administered by the DEA. The DEA regulates controlled substances as Schedule I, II, III, IV or V substances. Schedule I substances by definition have no established medicinal use and may not be marketed or sold in the United States. A pharmaceutical product may be listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest risk of abuse and Schedule V substances the lowest relative risk of abuse among such substances. Our failure to comply with DEA requirements could result in the loss of our ability to supply Probuphine, significant restrictions on Probuphine, civil penalties or criminal prosecution.

The DEA, and some states, also conduct periodic inspections of registered establishments that handle controlled substances. Facilities that conduct research, manufacture, store, distribute, import or export controlled substances must be registered to perform these activities and have the security, control and inventory mechanisms required by the DEA to prevent drug loss and diversion. Failure to maintain compliance, particularly non-compliance resulting in loss or diversion, can result in regulatory action that could have a material adverse effect on our business, results of operations, financial condition and prospects. The DEA may seek civil penalties, refuse to renew necessary registrations or initiate proceedings to revoke those registrations. In certain circumstances, violations could lead to criminal proceedings.

Individual states also have controlled substances laws. Though state controlled substances laws often mirror federal law, because the states are separate jurisdictions, they may separately schedule drugs, as well. While some states automatically schedule a drug when the DEA does so, in other states there has to be rulemaking or a legislative action. State scheduling may delay commercial sale of any controlled substance drug product for which we obtain federal regulatory approval and adverse scheduling could have a material adverse effect on the commercial attractiveness of such product. We or our partners must also obtain separate state registrations in order to be able to obtain, handle, and distribute controlled substances for clinical trials or commercial sale, and failure to meet applicable regulatory requirements could lead to enforcement and sanctions from the states in addition to those from the DEA or otherwise arising under federal law.

We may be subject to enforcement action if we engage in improper marketing or promotion of Probuphine.

Our promotional materials and training methods must comply with the Federal Food, Drug and Cosmetic Act, or the FDCA, and FDA regulations and other applicable laws and regulations, including the prohibition of the promotion of unapproved, or “off-label”, use. Companies may not promote drugs for off-label use, which include uses that are not described in the product’s labeling and that differ from those approved by the FDA. Physicians may prescribe drug products for off-label uses and such off-label uses are common across some medical specialties. Although the FDA and other regulatory agencies do not regulate a physician’s choice of treatments, the FDCA and FDA regulations restrict communications on the subject of off-label uses of drug products by pharmaceutical companies. The Office of Inspector General of the Department of Health and Human Services, or OIG, the FDA, and the Department of Justice, or DOJ, all actively enforce laws and regulations prohibiting promotion of off-label use and the promotion of products for which marketing approval has not been obtained.

Other federal, state and foreign regulatory agencies, including the U.S. Federal Trade Commission, have issued guidelines and regulations that govern how we promote our products, including how we use endorsements and testimonials.

If we are found to be out of compliance with the requirements and restrictions described above, and we are investigated for or found to have improperly promoted off-label use, we may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions, and the off-label use of our products may increase the risk of product liability claims. In addition, management’s attention could be diverted from our business operations and our reputation could be damaged.

In addition to FDA and related regulatory requirements, we are subject to health care “fraud and abuse” laws, such as the federal False Claims Act, the anti-kickback provisions of the federal Social Security Act, and other state and federal laws and regulations. Federal and state anti-kickback laws prohibit, among other things, payments or other remuneration to induce or reward someone to purchase, prescribe, endorse, or recommend a product that is reimbursed

under federal or state healthcare programs. If we provide payments or other remuneration to a healthcare professional to induce the prescribing of our products, we could face liability under state and federal anti-kickback laws.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Pharmaceutical companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product or submitting inflated best price information to the Medicaid Rebate program. The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines, and imprisonment. Even if it is determined that we have not violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which would harm our business, prospects, operating results, and financial condition. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be challenged under one or more of such laws.

We obtain some of our raw materials, components and finished goods from a single source or a limited group of suppliers. The partial or complete loss of one of these suppliers could cause significant production delays, an inability to meet customer demand and a substantial loss in revenue.

We use a number of single-source suppliers for certain of our raw materials, components and finished goods, including:

- the supplier of the active ingredient for Probuphine;
- the supplier of the finished Probuphine implants; and
- the manufacturer of the Probuphine applicator.

We are in the process of qualifying a new EVA manufacturer. In addition, the vendor that used to sterilize the Probuphine implants indicated that it will no longer sterilize Schedule III controlled substances, including Probuphine. While we are in the process of qualifying another sterilization vendor and will also be transitioning to a new sterilization process, we cannot guarantee that such qualification or transition will be successful. Our use of these and other single-source suppliers of raw materials, components and finished goods exposes us to several risks, including disruptions in supply, price increases, late deliveries and an inability to meet customer demand. This could lead to customer dissatisfaction, damage to our reputation or customers switching to competitive products. Any interruption in supply could be particularly damaging to our ability to develop and commercialize Probuphine.

Finding alternative sources for these raw materials, components and finished goods would be difficult and in many cases entail a significant amount of time, disruption and cost. Any disruption in supply from any single-source supplier or manufacturing location could lead to supply delays or interruptions which would damage our business, financial condition, results of operations and prospects.

We rely on third parties to provide services in connection with the manufacture and distribution of Probuphine, and these third parties may not perform satisfactorily.

We do not own or operate, and currently do not plan to own or operate, facilities for production and packaging of Probuphine or our other product candidates. We are dependent on third parties for the timely supply of specified raw materials, equipment, contract manufacturing, formulation or packaging services, product distribution services, customer service activities and product returns processing. For example, we contract with DPT Laboratories, Ltd., or

DPT, for the manufacture of Probuphine, which in turn depends on delivery of the active ingredient buprenorphine hydrochloride and milled EVA, which we currently source from Teva and Southwest Research Institute, respectively. We are similarly dependent on third parties for the manufacture and sterilization of Probuphine applicators and the assembly and distribution of packaged kits.

Our reliance on third parties for the activities described above will reduce our control over these activities but will not relieve us of our responsibility to ensure compliance with all required regulations. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or manufacture our product in accordance with regulatory requirements, or proprietary specifications, or adhere to product processing best practices, or if there are disagreements between us and these third parties, our business could be materially adversely impacted.

We are solely reliant on the efforts of third parties to commercialize Probuphine outside of the United States.

Our ability to generate revenues from the sale of Probuphine in the European Union and the rest of the Molteni Territory, assuming regulatory approval is ultimately obtained, will be wholly dependent on Molteni's ability to successfully launch and commercialize the product in the Molteni Territory. We are similarly dependent on the efforts of Knight with respect to product launch and commercialization in Canada. We do not have control over the amount and timing of resources that Molteni will dedicate to these efforts. We will be similarly dependent on the development, regulatory and marketing efforts of third parties with respect to revenues, if any, from sales of Probuphine in additional territories.

Our dependence on third party collaborators and license agreements subjects us to a number of risks, including:

our collaborators may not comply with applicable regulatory guidelines with respect to developing or commercializing our products, which could adversely impact sales or future development of our products;

we and our collaborators could disagree as to future development plans and our collaborators may delay, fail to commence or stop future clinical trials or other development; and

there may be disputes between us and our collaborators, including disagreements regarding the license agreements, that may result in the delay of or failure to achieve developmental, regulatory and commercial objectives that would result in milestone or royalty payments and/or the delay or termination of any future development or commercialization of our products.

In addition, collaborators may, to the extent permitted by our agreements, develop products that divert resources from our products, preclude us from entering into collaborations with their competitors or terminate their agreements with us prematurely. Moreover, disagreements could arise with our collaborators or strategic partners over rights to our intellectual property and our rights to share in any of the future revenues from products or technologies resulting from use of our technologies, or our activities in separate fields may conflict with other business plans of our collaborators.

We face potential liability related to the privacy of health information we obtain from clinical trials sponsored by us or our collaborators, from research institutions and our collaborators, and directly from individuals.

Numerous federal and state laws, including state security breach notification laws, state health information privacy laws, and federal and state consumer protection laws, govern the collection, use, and disclosure of personal information. In addition, most health care providers, including research institutions from which we or our collaborators obtain patient health information, are subject to privacy and security regulations promulgated under the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act. Although we are not directly subject to HIPAA, we could potentially be subject to criminal penalties if we, our affiliates, or our agents knowingly obtain or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

We will seek to raise additional funds, and may finance acquisitions or develop strategic relationships by issuing securities that would dilute your ownership. Depending on the terms available to us, if these activities result in significant dilution, it may negatively impact the trading price of our shares of common stock.

We have financed our operations, and we expect to continue to finance our operations, acquisitions, if any, and the development of strategic relationships by issuing equity and/or convertible securities, which could significantly reduce the percentage ownership of our existing stockholders. Following this offering, raising sufficient capital will likely require an amendment to our certificate of incorporation to either effect a reverse stock split or increase our authorized capital, which will require the affirmative vote of holders of a majority of our then outstanding common stock. Further, any additional financing that we secure, including any debt financing, may require the granting of rights, preferences or privileges senior to, or pari passu, with those of our common stock. Any issuances by us of equity securities may be at or below the prevailing market price of our common stock and in any event may have a dilutive impact on your ownership interest, which could cause the market price of our common stock to decline. We may also raise additional funds through the incurrence of debt or the issuance or sale of other securities or instruments senior to our shares of common stock. The holders of any securities or instruments we may issue may have rights superior to the rights of our common stockholders. If we experience dilution from the issuance of additional securities and we grant superior rights to new securities over common stockholders, it may negatively impact the trading price of our shares of common stock and you may lose all or part of your investment.

Item 6. Exhibits

Exhibit No.	Description
<u>1.1</u>	<u>Underwriting Agreement between Titan Pharmaceuticals, Inc. and A.G.P./Alliance Global Partners⁽²⁵⁾</u>
<u>3.1.1</u>	<u>Amended and Restated Certificate of Incorporation of the Registrant, as amended⁽⁵⁾</u>
<u>3.1.2</u>	<u>Certificate of Amendment to the Restated Certificate of Incorporation dated September 24, 2015⁽¹⁴⁾</u>
<u>3.2</u>	<u>By-laws of the Registrant⁽¹⁾</u>
<u>3.3</u>	<u>Certificate of Designation of Series A Convertible Preferred Stock⁽²⁵⁾</u>
<u>4.1</u>	<u>Form of 2014 Class A Warrant⁽¹³⁾</u>
<u>4.3</u>	<u>Form of 2014 Underwriter Warrant⁽¹³⁾</u>
<u>4.4</u>	<u>Form of Lender Warrant⁽¹⁸⁾</u>
<u>4.5</u>	<u>Form of Rights Agreement Warrant⁽²⁰⁾</u>
<u>4.6</u>	<u>Warrant Agency Agreement between Titan Pharmaceuticals, Inc. and Continental Stock Transfer & Trust Company and Form of Offering Warrant⁽²⁵⁾</u>
<u>4.7</u>	<u>Representative's Purchase Warrant⁽²⁵⁾</u>
<u>10.1</u>	<u>2001 Non-Qualified Employee Stock Option Plan⁽²⁾</u>
<u>10.2</u>	<u>2002 Stock Option Plan⁽³⁾</u>
<u>10.3</u>	<u>Lease for the Registrant's facilities, amended as of October 1, 2004⁽⁴⁾</u>
<u>10.4</u>	<u>Amendments to lease for Registrant's facilities dated May 21, 2007 and March 12, 2009⁽⁵⁾</u>
<u>10.5</u>	<u>Amendment to lease for Registrant's facilities dated June 15, 2010⁽⁶⁾</u>
<u>10.6±</u>	<u>License Agreement by and between Titan Pharmaceuticals, Inc. and Braeburn Pharmaceuticals Sprl, dated December 14, 2012⁽⁸⁾</u>
<u>10.7</u>	<u>Amendment dated May 28, 2013 to License Agreement by and between Titan Pharmaceuticals, Inc. and Braeburn Pharmaceuticals Sprl⁽⁹⁾</u>
<u>10.8</u>	<u>Second Amendment dated July 2, 2013 to License Agreement by and between Titan Pharmaceuticals, Inc. and Braeburn Pharmaceuticals Sprl⁽¹⁰⁾</u>
<u>10.9</u>	<u>Third Amendment dated November 12, 2013 to License Agreement by and between Titan Pharmaceuticals, Inc. and Braeburn Pharmaceuticals Sprl⁽¹⁵⁾</u>
<u>10.10</u>	<u>Titan Pharmaceuticals, Inc. 2014 Incentive Plan⁽¹²⁾</u>
<u>10.11</u>	<u>Titan Pharmaceuticals, Inc. Second Amended and Restated 2015 Omnibus Equity Incentive Plan⁽²²⁾</u>
<u>10.12</u>	<u>Controlled Equity OfferingSM Sales Agreement, dated September 1, 2016, between Titan Pharmaceuticals, Inc. and Cantor Fitzgerald & Co.⁽¹⁶⁾</u>
<u>10.13</u>	<u>Employment Agreement between Titan Pharmaceuticals, Inc. and Titan Pharmaceuticals, Inc. and Sunil Bhonsle⁽¹⁷⁾</u>
<u>10.14</u>	<u>Employment Agreement between Titan Pharmaceuticals, Inc. and Titan Pharmaceuticals, Inc. and Marc Rubin⁽¹⁷⁾</u>
<u>10.15</u>	<u>Venture Loan and Security Agreement, dated July 27, 2017, by and between Titan Pharmaceuticals, Inc. and Horizon Technology Finance Corporation⁽¹⁸⁾</u>
<u>10.16</u>	<u>Amendment of Venture Loan and Security Agreement, dated February 2, 2018, by and between Titan Pharmaceuticals, Inc. and Horizon Technology Finance Corporation⁽¹⁹⁾</u>
<u>10.17</u>	<u>Amended and Restated Venture Loan and Security Agreement, dated March 21, 2018, by and between Titan Pharmaceuticals, Inc., Horizon Technology Finance Corporation and L. Molteni & C. Dei Frattelli Alitti Società Di Esercizio S.P.A.⁽²⁰⁾</u>

Edgar Filing: TITAN PHARMACEUTICALS INC - Form 10-Q

- 10.18± Asset Purchase, Supply and Support Agreement dated March 21, 2018, by and between Titan Pharmaceuticals, Inc. and L. Molteni & C. Dei Frattelli Alitti Società Di Esercizio S.P.A.⁽²⁰⁾
- 10.19 Rights Agreement dated March 21, 2018, by and between Titan Pharmaceuticals, Inc. and L. Molteni & C. Dei Frattelli Alitti Società Di Esercizio S.P.A.⁽²⁰⁾
- 10.20± Termination and Transition Services Agreement dated May 25, 2018 by and between Titan Pharmaceuticals, Inc. and Braeburn Pharmaceuticals, Inc.⁽²¹⁾

Exhibit No.	Description
<u>10.21±</u>	<u>Amendment to Asset Purchase, Supply and Support Agreement dated August 3, 2018, by and between Titan Pharmaceuticals, Inc. and L. Molteni & C. Dei Frattelli Alitti Società Di Esercizio S.P.A.⁽²²⁾</u>
<u>10.22±</u>	<u>Distribution and Sublicense Agreement dated February 1, 2016 as amended by agreement dated August 2, 2018 between Titan Pharmaceuticals, Inc. and Knight Therapeutics Inc.⁽²³⁾</u>
<u>10.23</u>	<u>Amendment to lease for Registrant's facility dated March 21, 2016⁽²³⁾</u>
<u>10.24</u>	<u>Amendment to Employment Agreement with Sunil Bhonsle dated August 9, 2018⁽²³⁾</u>
<u>10.25</u>	<u>Amendment to Employment Agreement with Marc Rubin dated August 9, 2018⁽²³⁾</u>
<u>10.26</u>	<u>Unsecured Convertible Loan Agreement dated September 18, 2018⁽²⁴⁾</u>
<u>14.1</u>	<u>Code of Business Conduct and Ethics⁽¹³⁾</u>
<u>31.1</u>	<u>Certification of the Principal Executive and Financial Officer pursuant to Rule 13(a)-14(a) of the Securities Exchange Act of 1934</u>
<u>32.1</u>	<u>Certification of the Principal Executive and Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</u>
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document
±	Confidential treatment has been granted as to certain portions of this exhibit.
(1)	Incorporated by reference from the Registrant's Registration Statement on Form S-3 (File No. 333-21126).
(2)	Incorporated by reference from the Registrant's Annual Report on Form 10-K for the year ended December 31, 2001.
(3)	Incorporated by reference from the Registrant's Annual Report on Form 10-K for the year ended December 31, 2002.
(4)	Incorporated by reference from the Registrant's Annual Report on Form 10-K for the year ended December 31, 2005.
(5)	Incorporated by reference from the Registrant's Registration Statement on Form 10 filed on January 14, 2010.
(6)	Incorporated by reference from the Registrant's Quarterly Report on Form 10-Q for the period ended June 30, 2010.
(7)	Incorporated by reference from the Registrant's Current Report on Form 8-K filed on April 10, 2012.
(8)	Incorporated by reference from the Registrant's Current Report on Form 8-K/A filed on February 28, 2013.
(9)	Incorporated by reference from the Registrant's Current Report on Form 8-K filed on May 29, 2013.
(10)	Incorporated by reference from the Registrant's Current Report on Form 8-K filed on July 5, 2013.
(11)	Incorporated by reference from the Registrant's Current Report on Form 8-K filed on November 13, 2013.
(12)	Incorporated by reference from the Registrant's Annual Report on Form 10-K for the year ended December 31, 2013.
(13)	Incorporated by reference from the Registrant's Registration Statement on Form S-1/A dated September 30, 2014.
(14)	Incorporated by reference from the Registrant's Current Report on Form 8-K filed on September 28, 2015.

Edgar Filing: TITAN PHARMACEUTICALS INC - Form 10-Q

- (15) Incorporated by reference from the Registrant's Current Report on Form 8-K filed on August 3, 2016.
- (16) Incorporated by reference from the Registrant's Current Report on Form 8-K filed on September 1, 2016.
- (17) Incorporated by reference from the Registrant's Current Report on Form 8-K filed on October 3, 2016.
- (18) Incorporated by reference from the Registrant's Current Report on Form 8-K filed on July 27, 2017.
- (19) Incorporated by reference from the Registrant's Current Report on Form 8-K filed on February 7, 2018.
- (20) Incorporated by reference from the Registrant's Current Report on Form 8-K filed on March 26, 2018.
- (21) Incorporated by reference from the Registrant's Current Report on Form 8-K filed on May 30, 2018.
- (22) Incorporated by reference from the Registrant's Current Report on Form 8-K filed on August 3, 2018.
- (23) Incorporated by reference from the Registrant's Quarterly Report on Form 10-Q for the period ended June 30, 2018.
- (24) Incorporated by reference from the Registrant's Current Report on Form 8-K dated September 20, 2018.
- (25) Incorporated by reference from the Registrant's Current Report on Form 8-K dated September 25, 2018.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

TITAN PHARMACEUTICALS, INC.

Dated: November 14,
2018

By: /s/ Sunil Bhonsle

Name: **Sunil Bhonsle**

Title: **President and Chief Executive Officer**
(Principal Executive and Principal Financial Officer)