

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 ACT OF 1934

For the quarterly period ended March 31, 2021.

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
(State or other jurisdiction of
incorporation or organization)

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

94-3171940
(I.R.S. Employer
Identification No.)

94080
(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.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>		
Smaller reporting company	<input checked="" type="checkbox"/>	Emerging growth company	<input type="checkbox"/>

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.001	TTNP	Nasdaq Capital Market

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 May 12, 2021
Common Stock, par value \$0.001	9,864,068

Titan Pharmaceuticals, Inc.

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Part I. Financial Information

Item 1. Financial Statements

TITAN PHARMACEUTICALS, INC.

CONDENSED BALANCE SHEETS
(in thousands)

	March 31, 2021 (unaudited)	December 31, 2020 (Note 1)
Assets		
Current assets:		
Cash and cash equivalents	\$ 11,629	\$ 5,413
Receivables	398	884
Inventory	218	328
Prepaid expenses and other current assets	816	522
Discontinued operations - current assets	128	181
Total current assets	13,189	7,328
Property and equipment, net	563	618
Operating lease right-of-use asset	72	141
Total assets	<u>\$ 13,824</u>	<u>\$ 8,087</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 768	\$ 1,253
Accrued clinical trials expenses	151	214
Other accrued liabilities	296	319
Operating lease liability, current	76	150
Current portion of long-term debt	572	327
Discontinued operations – current liabilities	1,893	1,960
Total current liabilities	3,756	4,223
Long-term debt	88	332
Total liabilities	3,844	4,555
Stockholders' equity:		
Common stock, at amounts paid-in	10	7
Additional paid-in capital	379,890	370,804
Accumulated deficit	(369,920)	(367,279)
Total stockholders' equity	9,980	3,532
Total liabilities and stockholders' equity	<u>\$ 13,824</u>	<u>\$ 8,087</u>

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 March 31,	
	2021	2020
Revenues:		
License revenue	\$ 2	\$ —
Product revenue	111	—
Grant revenue	569	1,126
Total revenues	<u>682</u>	<u>1,126</u>
Operating expenses:		
Cost of goods sold	110	—
Research and development	1,877	1,812
General and administrative	1,327	1,289
Total operating expenses	<u>3,314</u>	<u>3,101</u>
Loss from operations	(2,632)	(1,975)
Other expense:		
Interest expense, net	(1)	(222)
Non-cash loss on changes in the fair value of warrants	—	(923)
Other expense, net	(8)	(213)
Other expense, net	(9)	(1,358)
Loss from continuing operations	(2,641)	(3,333)
Loss from discontinued operations	—	(2,251)
Net loss and comprehensive loss	<u>\$ (2,641)</u>	<u>\$ (5,584)</u>
Basic and diluted net loss per common share from continuing operations	<u>\$ (0.28)</u>	<u>\$ (1.21)</u>
Basic and diluted net loss per common share from discontinued operations	<u>\$ —</u>	<u>\$ (0.82)</u>
Weighted average shares used in computing basic and diluted net loss per common share	<u>9,289</u>	<u>2,755</u>

See Notes to Condensed Financial Statements

TITAN PHARMACEUTICALS, INC.

CONDENSED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands)
(unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balances at December 31, 2020	7,139	\$ 7	\$ 370,804	\$ (367,279)	\$ 3,532
Net loss	—	—	—	(2,641)	(2,641)
Issuance of common stock, net	2,725	3	8,838	—	8,841
Stock-based compensation	—	—	248	—	248
Balances at March 31, 2021	9,864	\$ 10	\$ 379,890	\$ (369,920)	\$ 9,980

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balances at December 31, 2019	1,913	\$ 2	\$ 350,468	\$ (349,037)	\$ 1,433
Net loss	—	—	—	(5,584)	(5,584)
Issuance of common stock, net	290	—	452	—	452
Issuance of common stock upon exercises of warrants	913	1	6,161	—	6,162
Reclassification of warrants from liability	—	—	2,897	—	2,897
Stock-based compensation	—	—	(84)	—	(84)
Balances at March 31, 2020	3,116	\$ 3	\$ 359,894	\$ (354,621)	\$ 5,276

See Notes to Condensed Financial Statements

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

	Three Months Ended March 31,	
	2021	2020
Cash flows from operating activities:		
Net loss	\$ (2,641)	\$ (5,584)
Adjustments to reconcile loss to net cash used in operating activities:		
Depreciation and amortization	55	62
Non-cash interest expense	1	148
Non-cash loss on changes in fair value of warrants	—	923
Stock-based compensation	248	(84)
Finance costs attributable to issuance of warrants	—	211
Other	(5)	(3)
Changes in operating assets and liabilities:		
Receivables	487	(558)
Inventory	110	(66)
Prepaid expenses and other assets	(241)	(399)
Accounts payable	(482)	(64)
Accrued sales allowances	(4)	(608)
Other accrued liabilities	(153)	810
Net cash used in operating activities	(2,625)	(5,212)
Cash flows from investing activities:		
Purchases of property and equipment	—	(30)
Net cash used in investing activities	—	(30)
Cash flows from financing activities:		
Net proceeds from equity offering	8,841	1,895
Net proceeds from the exercises of common stock warrants	—	6,162
Net cash provided by financing activities	8,841	8,057
Net increase in cash and cash equivalents	6,216	2,815
Cash and cash equivalents at beginning of period	5,413	5,223
Cash and cash equivalents at end of period	\$ 11,629	\$ 8,038
Supplemental disclosure of cash flow information:		
Interest paid	\$ —	\$ 102
Purchases of property and equipment included in accounts payable	\$ —	\$ 6

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 utilizing our proprietary long-term drug delivery platform, ProNeura™, for the treatment of select chronic diseases for which steady state delivery of a drug has the potential to provide an efficacy and/or safety benefit. ProNeura consists of a small, solid implant made from a mixture of ethylene-vinyl acetate, or EVA, and a drug substance. The resulting product is a solid matrix that is designed to be administered subdermally, in a brief, outpatient procedure and is removed in a similar manner at the end of the treatment period. These procedures may be performed by trained health care providers, or HCPs, including licensed and surgically qualified physicians, nurse practitioners, and physician's assistants in a HCP's office or other clinical setting.

Our first product based on our ProNeura technology was the Probuphine® (buprenorphine) implant, which has been approved in the United States, Canada and the European Union, or EU, for the maintenance treatment of opioid use disorder in clinically stable patients taking 8 mg or less a day of oral buprenorphine. While Probuphine continues to be commercialized in Canada and the EU by other companies who have either licensed or acquired the rights from Titan, we discontinued commercialization of the product in the U.S. during Q4 2020 following disappointing revenues during the prior quarters. The disappointing commercial performance of Probuphine was multifactorial in origin, as previously enumerated in our Form 10-K for the fiscal year ended December 31, 2020. Discontinuation of our commercial operations has allowed us to focus our limited resources on important product development programs and transition back to a product development company. We operate in only one business segment, the development of pharmaceutical products.

All share and per share amounts contained in this report on Form 10-Q give retroactive effect to the reverse split effected by the board of directors, or Board, in November 2020 at a ratio of one share for every thirty shares then outstanding.

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

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 the information and footnotes required by 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 months ended March 31, 2021 are not necessarily indicative of the results that may be expected for the year ending December 31, 2021, or any future interim periods.

The balance sheet as of December 31, 2020 is derived from the audited financial statements at that date, but does not include all the information and footnotes required by 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, 2020, as filed with the Securities and Exchange Commission ("SEC").

The preparation of condensed financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the condensed financial statements and accompanying notes. Actual results could differ from those estimates. The accompanying condensed financial statements have been prepared assuming we will continue as a going concern.

As of March 31, 2021, we had cash and cash equivalents of \$11.6 million, which we believe is sufficient to fund our planned operations into the first quarter of 2022. We will require additional funds to finance our operations. We are exploring several financing alternatives; however, there can be no assurance that our efforts to obtain the funding required to continue our operations will be successful and there is substantial doubt about our ability to continue as a going concern.

Discontinued Operations

In October 2020, we announced our decision to discontinue selling Probuphine in the U.S. and wind down our commercialization activities, and to pursue a plan that will enable us to focus on our current, early-stage ProNeura-based product development programs.

The accompanying financial statements have been recast for all periods presented to reflect the assets, liabilities, revenue and expenses related to our U.S. commercialization activities as discontinued operations (see Note 9). The accompanying financial statements are generally presented in conformity with our historical format. We believe this format provides comparability with the previously filed financial statements.

Going Concern Assessment

We assess going concern uncertainty in our condensed 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 condensed 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 that 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 condensed financial statements in this Quarterly Report on Form 10-Q for the three months ended March 31, 2021, we did not have sufficient cash to fund our operations for the next 12 months without securing additional funds and, therefore, there is substantial doubt about our ability to continue as a going concern within 12 months after the date the condensed financial statements were issued. Additionally, we have suffered recurring losses from operations and have an accumulated deficit that raises substantial doubt about our ability to continue as a going concern.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the U.S. 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.

Inventories

Inventories are recorded at the lower of cost or net realizable value. Cost is based on the first in, first out method. We regularly review inventory quantities on hand and write down to its net realizable value any inventory that we believe to be impaired. The determination of net realizable value requires judgment including consideration of many factors, such as estimates of future product demand, product net selling prices, current and future market conditions and potential product obsolescence, among others. The components of inventories are as follows:

	As of	
	March 31, 2021	December 31, 2020
Raw materials and supplies	60	170
Finished goods	158	158
	<u>\$ 218</u>	<u>\$ 328</u>

The approximately \$158,000 of finished goods inventory at March 31, 2021 included materials held for sale to Molteni and Knight.

Revenue Recognition

We generate revenue principally from collaborative research and development arrangements, sales or licenses of technology, government grants, sales of Probuphine materials to Molteni and Knight, and prior to the discontinued operations, the sale of Probuphine in the U.S. 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 for our revenue recognition: (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.

Net Product Revenue

Prior to the discontinuation of our commercialization activities relating to Probuphine in the U.S., we recognized revenue from product sales when control of the product transfers, generally upon shipment or delivery to our customers, which include distributors. As customary in the pharmaceutical industry, our gross product revenue was subject to a variety of deductions in the forms of variable consideration, such as rebates, chargebacks, returns and discounts, in order to arrive at reported net product revenue. This variable consideration was estimated using the most-likely amount method, which is the single most-likely outcome under a contract and was typically at stated contractual rates. The actual outcome of this variable consideration could materially differ from our estimates. From time to time, we would adjust our estimates of this variable consideration when trends or significant events indicated that a change in estimate is appropriate to reflect the actual experience. Additionally, we continued to assess the estimates of our variable consideration as we continued to accumulate additional historical data.

Returns – Consistent with the provisions of ASC 606, we estimated returns at the inception of each transaction, based on multiple considerations, including historical sales, historical experience of actual customer returns, levels of inventory in our distribution channel, expiration dates of purchased products and significant market changes which could impact future expected returns to the extent that we would not reverse any receivables, revenues, or contract assets already recognized under the agreement. During the year ended December 31, 2019, we entered into agreements with large national specialty pharmacies with a distribution channel different from that of our existing customers and, therefore, the related reserves had unique considerations. We continued to evaluate the activities with these specialty pharmacies and updated the related reserves accordingly.

Rebates – Our provision for rebates was estimated based on our customers' contracted rebate programs and our historical experience of rebates paid.

Discounts – The provision was estimated based upon invoice billings, utilizing historical customer payment experience.

Performance Obligations

A performance obligation is a promise in a contract to transfer distinct goods or services to the customer. 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 considerations. 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 (“CRO”) activities, sponsored research studies, product registration, patent application and prosecution, and investigator sponsored trials. When we are conducting clinical trials, we 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 the agreements, progress payments are typically made to investigators, clinical sites and CROs. The progress of the clinical trials, including levels of patient enrollment, invoices received and contracted costs, is analyzed 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.

Leases

In February 2016, the Financial Accounting Standards Board (the “FASB”) issued Accounting Standard Update, or ASU, No. 2016-02, Leases (Topic 842), to enhance the transparency and comparability of financial reporting related to leasing arrangements. We adopted the standard effective January 1, 2019.

We determine whether the arrangement is or contains a lease at inception. Operating lease right-of-use assets and lease liabilities are recognized at the present value of the future lease payments at commencement date. The interest rate implicit in lease contracts is typically not readily determinable, and therefore, we utilize our incremental borrowing rate, which is the rate incurred to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment. Certain adjustments to the right-of-use asset may be required for items such as initial direct costs paid or incentives received.

Lease expense is recognized over the expected term on a straight-line basis. Operating leases are recognized on our balance sheet as right-of-use assets, operating lease liabilities current and operating lease liabilities non-current. We no longer recognize deferred rent on our balance sheet.

The following table presents maturities of our operating lease:

2021		\$	78
Total minimum lease payments (base rent)			78
Less: imputed interest			(2)
Total operating lease liabilities		\$	<u>76</u>

Recent Accounting Pronouncements

Accounting Standards Adopted

In August 2018, the FASB issued ASU 2018-13, Fair Value Measurement (Topic 820): Disclosure Framework-Changes to the Disclosure Requirements for Fair Value Measurement, which eliminates, adds and modifies certain disclosure requirements for fair value measurements as part of the FASB's disclosure framework project. We adopted ASU 2018-13 effective January 1, 2020 with no material impact to our financial statements and related disclosures.

Accounting Standards Not Yet Adopted

In June 2016, the FASB issued ASU 2016-13, Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses, which requires an organization to measure all expected credit losses for financial assets held at the reporting date based on historical experience, current conditions, and reasonable and supportable forecasts. Financial institutions and other organizations will now use forward-looking information to better inform their credit loss estimates. The amendments in this ASU are effective for us in our interim period ending March 31, 2023. We are currently assessing the impact of the adoption of Topic 326 on our financial statements and disclosures.

In March 2020, the FASB issued ASU 2020-04, Reference Rate Reform, which provides companies with optional guidance, including expedients and exceptions for applying GAAP to contracts and other transactions affected by reference rate reform, such as the London Interbank Offered Rate (LIBOR). This new standard was effective upon issuance and generally can be applied to applicable contract modifications through December 31, 2022. We are evaluating the effects that the adoption of this guidance will have on our financial statements and disclosures.

In August 2020, the FASB issued ASU No. 2020-06, Accounting for Convertible Instruments and Contracts in an Entity's Own Equity, which simplifies the accounting for convertible instruments. ASU 2020-06 eliminates certain models that require separate accounting for embedded conversion features, in certain cases. Additionally, among other changes, the guidance eliminates certain of the conditions for equity classification for contracts in an entity's own equity. The guidance also requires entities to use the if converted method for all convertible instruments in the diluted earnings per share calculation and include the effect of share settlement for instruments that may be settled in cash or shares, except for certain liability-classified share-based payment awards. This guidance is effective beginning after December 15, 2023 and must be applied using either a modified or full retrospective approach. Early adoption is permitted. We are currently evaluating the impact this guidance will have on our financial statements and related disclosures.

Subsequent Events

We have evaluated events that have occurred after March 31, 2021 and through the date that our condensed financial statements are issued.

Fair Value Measurements

Financial instruments, including receivables, accounts payable and accrued liabilities are carried at cost, approximate their fair values due to the short-term nature of these instruments. Our investments in money market funds are classified within Level 1 of the fair value hierarchy. Our derivative liability is classified within level 3 of the fair value hierarchy because the fair value is calculated using significant judgment based on our own assumptions in the valuation of this liability.

At March 31, 2021 and December 31, 2020, the fair value of our investments in money market funds were approximately \$10.7 million and \$5.1 million, respectively, which are included within our cash and cash equivalents in our condensed balance sheets.

There were no warrant liabilities at March 31, 2021. The following table presents a roll forward of the fair value of our warrant liability, the fair value of which is determined by Level 3 inputs for the three month period ended March 31, 2020 (in thousands):

	March 31, 2020
Fair value, beginning of period	\$ 320
Issuance of warrants	1,654
Change in fair value ⁽¹⁾	923
Reclassification of warrants to additional paid-in capital	(2,897)
Fair value, end of period	<u>\$ —</u>

(1) Recognized as non-cash loss on changes in fair value of warrants in the statement of operations and comprehensive loss.

2. Stock Plans

The following table summarizes option activity:

	Options (in thousands)	Weighted Average Exercise Price per share	Weighted Average Remaining Option Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2020	28	\$ 242.70	6.35	\$ —
Granted	670	4.02		
Forfeited or expired	(1)	74.92		
Outstanding at March 31, 2021	697	\$ 13.46	9.72	\$ —
Exercisable at March 31, 2021	26	\$ 254.22	5.97	\$ —

Approximately 670,000 options to purchase common shares were granted during the three month period ended March 31, 2021.

The following table summarizes the stock-based compensation expense recorded for awards under our stock option plans (in thousands):

	Three Months Ended March 31,	
	2021	2020
Research and development	\$ 120	\$ —
Selling, general and administrative	128	(84)
Total stock-based compensation expense	\$ 248	\$ (84)

We use the Black-Scholes-Merton option-pricing model with the following assumptions to estimate the fair value of our stock options:

	Three Months Ended March 31,	
	2021	2020
Weighted-average risk-free interest rate	0.54%	—%
Expected dividend payments	—	—
Expected holding period (years) ⁽¹⁾	5.5	—
Weighted-average volatility factor ⁽²⁾	113.9	—
Estimated forfeiture rates for options granted ⁽³⁾	29.6%	—%

(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.

As of March 31, 2021, there was approximately \$1.3 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 approximately 1.6 years.

3. Net Loss Per Share

The table below presents common shares underlying stock options, warrants and convertible loans 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:

(in thousands)	Three months ended March 31,	
	2021	2020
Weighted-average anti-dilutive common shares resulting from options	399	34
Weighted-average anti-dilutive common shares resulting from warrants	719	279
Weighted-average anti-dilutive common shares resulting from convertible loans	—	109
Total	1,118	422

4. Molteni Purchase Agreement

On March 21, 2018, we entered into a purchase agreement (“Molteni Purchase Agreement”) with L. Molteni & C. Dei Fratelli Alitti Società Di Esercizio S.P.A. (“Molteni”) pursuant to which Molteni acquired the European intellectual property related to Probuphine and gained the exclusive right to commercialize the Probuphine product supplied by us, to be marketed under the tradename Sixmo, in the EU, as well as certain countries of the Commonwealth of Independent States, the Middle East and North Africa.

Following certain amendments to the Molteni Purchase Agreement in August 2018 and September 2019, in October 2020, we entered into a Debt Settlement and Release Agreement (“DSRA Agreement”) with Molteni and Horizon Technology Finance Corporation (“Horizon”), the holders of our outstanding secured debt, to settle such obligations for \$1.6 million in cash, the transfer of certain Probuphine assets to Molteni, including all of our manufacturing equipment, and the termination of our rights to future payments under the Molteni Purchase Agreement. The DSRA Agreement, provided for the release to us of the remaining collateral.

5. JT Pharmaceuticals Asset Purchase Agreement

In October 2020, in connection with our decision to discontinue our commercial operations, we entered into an Asset Purchase Agreement (the “JT Agreement”) with JT Pharmaceuticals, Inc. (“JT Pharma”) to acquire JT Pharma’s kappa opioid agonist peptide, TP-2021 (formerly JT-09) for use in combination with our ProNeura long-term, continuous drug delivery technology, for the treatment of chronic pruritus and other medical conditions. Under the terms of the JT Agreement, JT Pharma received a \$15,000 closing payment and is entitled to receive future milestone payments, payable in cash or in stock, based on the achievement of regulatory milestones, and single-digit percentage earn-out payments on net sales of the product if successfully developed and approved for commercialization. To date, none of these events have occurred and no contingent consideration, milestone or earn-out payments have been recognized.

6. Commitments and Contingencies

Minimum payments

Our manufacturing agreement, as amended, with DPT, our contract manufacturer, provides for a minimum manufacturing fee of \$1.0 million. In the event we do not have DPT manufacture sufficient quantities of product to exceed the minimum manufacturing fee, DPT is able to invoice us for the amount of the shortfall.

Legal Proceedings

A legal proceeding has been initiated by a former employee alleging wrongful termination, retaliation, infliction of emotional distress, negligent supervision, hiring and retention and slander. An independent investigation into this individual’s allegations of whistleblower retaliation, while still an employee, was conducted utilizing an outside investigator and concluded that such allegations were not substantiated. We intend to vigorously defend the lawsuit; however, in light of our cash position, there can be no assurance that the defense and/or settlement of this matter will not have a material adverse impact on our business.

7. Debt Agreements

Horizon and Molteni Loans

In March 2018, we entered into an Amended and Restated Venture Loan and Security Agreement (the “Loan Agreement”) with Horizon and Molteni pursuant to which Horizon assigned approximately \$2.4 million of the \$4.0 million outstanding principal balance of its loan to us to Molteni and Molteni was appointed as the collateral agent and assumed majority and administrative control of the loan. Under the Loan Agreement, Molteni had the right to convert its portion of the debt into shares of our common stock at a conversion price of \$216.00 per share and was required to effect this conversion of debt to equity upon completion of an equity financing meeting specified criteria. In connection with the Loan Agreement, we issued warrants to purchase an aggregate of 223 shares of our common stock with an exercise price per share of \$216.00 to Horizon.

In September 2019, we entered into an amendment to the Loan Agreement pursuant to which the interest-only payment and forbearance periods were extended by one year to December 31, 2020 and the maturity date was extended by one year to June 1, 2022. In connection with the amendment to the Loan Agreement, the final payments to the lenders were increased by an aggregate of approximately \$0.3 million (exclusive of a restructuring fee payable to Horizon) and the conversion provisions related to Molteni's portion of the loan amount were revised to eliminate the mandatory conversion feature, to reduce the conversion price to \$6.75 and to cap the number of shares issuable upon conversion to 114,093.

In October 2020, we entered into the DSRA Agreement with Molteni and Horizon to settle our obligations for \$1.6 million in cash, the transfer of certain Probuphine assets to Molteni, including all of our manufacturing equipment, and the termination of our rights to future payments under the Purchase Agreement with Molteni.

Paycheck Protection Program Loan

On April 20, 2020, we received an approximately \$654,000 loan ("PPP Loan") pursuant to the Paycheck Protection Program of the CARES Act. The proceeds of the PPP Loan are to be used to retain workers and maintain payroll and make mortgage interest, lease and utility payments. The PPP Loan matures in April 2022 with an annual interest rate of 1.0%. The PPP Loan originally had a six month deferral of payments period which was extended to sixteen months during the third quarter of 2020 and may be prepaid at any time without penalty. All other terms remained the same. Forgiveness of the loan, when requested, is not automatic and is only available for principal that is used for the limited purposes that expressly qualify for forgiveness under SBA requirements. A loan forgiveness application was submitted in December 2020. Approximately \$0.6 million of the PPP loan is included in current portion of long-term debt and approximately \$0.1 million is included in long-term debt on our balance sheet at March 31, 2021.

8. Stockholders' Equity

Our common stock outstanding as of March 31, 2021 and December 31, 2020 was 9,864,068 shares and 7,139,068 shares, respectively.

Annual Meeting of Stockholders

In January 2021, our stockholders approved an amendment to the 2015 Omnibus Equity Incentive plan to increase the number of authorized shares to 1,000,000 shares.

January 2021 Offering

In January 2021, we completed an offering with several accredited institutional investors pursuant to which we issued 2,725,000 shares of our common stock in a registered direct offering and warrants to purchase 2,725,000 shares of our common stock with an exercise price of \$3.55 per share in a concurrent private placement. The warrants were exercisable immediately and will expire in July 2026. The net cash proceeds from this offering were approximately \$8.9 million after deduction of underwriting fees and other offering expenses.

January 2020 Offering

In January 2020, we completed a financing with several institutional investors pursuant to which we issued 290,000 shares of our common stock in a registered direct offering and warrants to purchase 290,000 shares of our common stock with an exercise price of \$7.50 per share in a concurrent private placement (the "January 2020 Warrants") pursuant to which we received net cash proceeds of approximately \$1.9 million, after deduction of underwriting fees and other offering expenses. The January 2020 Warrants became exercisable in September 2020 following receipt of stockholder approval of an increase in our authorized shares of common stock and they expire in July 2025. Financing costs of approximately \$0.2 million allocated to the January 2020 warrant liability were expensed and included in other income (expense) in the statements of operations and comprehensive loss.

9. Discontinued Operations

The components of loss from discontinued operations as reported in our statements of operations were as follows:

	Three months ended March 31, 2020
<i>(In thousands, except per share data)</i>	
Revenue:	
Product revenue	\$ 210
Costs and expenses:	
Cost of goods sold	171
Research and development	465
Selling, general and administrative	1,825
Total costs and expenses	2,461
Loss from discontinued operations	(2,251)
Other expense	—
Net loss from discontinued operations	\$ (2,251)
Basic and diluted net loss per common share from discontinued operations	\$ (0.82)
Weighted average shares used in computing basic and diluted net loss per common share	2,755

The following table presents information related to assets and liabilities reported as discontinued operations in our balance sheet:

	March 31, 2021	December 31, 2020
<i>(In thousands)</i>		
Prepaid expenses and other current assets	\$ 128	\$ 181
Discontinued operations – current assets	\$ 128	\$ 181
Accounts payable	\$ 1,518	\$ 1,515
Accrued clinical trials expenses	9	80
Accrued sales allowances	57	61
Other accrued liabilities	309	304
Discontinued operations – current liabilities	\$ 1,893	\$ 1,960

During the three months ended March 31, 2020 we recognized non-cash stock-based compensation expenses of approximately \$24,000 which is included in discontinued operations.

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

Forward-Looking Statements

This Quarterly Report on Form 10-Q or in the documents incorporated by reference herein may contain "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934 (the "Exchange Act") that involve substantial risks and uncertainties. We have attempted to identify forward-looking statements by terminology including "anticipates," "believes," "can," "continue," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "should," or "will" or the negative of these terms or other comparable terminology. Although we do not make forward looking statements unless we believe we have a reasonable basis for doing so, we cannot guarantee their accuracy. Forward-looking statements included or incorporated by reference in this report or our other filings with the Securities and Exchange Commission, or the SEC, include, but are not necessarily limited to, those relating to uncertainties relating to:

- the ability to raise capital when needed;
- the wind-down of Probuphine commercialization activities;
- financing and strategic agreements and relationships;
- difficulties or delays in the regulatory approval process;
- uncertainties relating to manufacturing, sales, marketing and distribution of our drug candidates that may be successfully developed and approved for commercialization;
- adverse side effects or inadequate therapeutic efficacy of our drug candidates that could slow or prevent product development or commercialization;
- dependence on third party suppliers;
- the uncertainty of protection for our patents and other intellectual property or trade secrets; and
- competition.

Forward-looking statements should not be read as a guarantee of future performance or results and will not necessarily be accurate indications of the times at, or by which, that performance or those results will be achieved. Forward-looking statements are based on information available at the time they are made and/or management's good faith belief as of that time with respect to future events, and are subject to risks and uncertainties, including the risks outlined under "Risk Factors" or elsewhere in this report, that could cause actual performance or results to differ materially from what is expressed in or suggested by the forward-looking statements.

Forward-looking statements speak only as of the date they are made. You should not put undue reliance on any forward-looking statements. We assume no obligation to update forward-looking statements to reflect actual results, changes in assumptions or changes in other factors affecting forward-looking information, except to the extent required by applicable securities laws. If we do update one or more forward-looking statements, no inference should be drawn that we will make additional updates with respect to those or other forward-looking statements. We caution you not to give undue weight to such projections, assumptions and estimates.

References herein to "we," "us," "Titan," and "our company" refer to Titan Pharmaceuticals, Inc. unless the context otherwise requires.

Probuphine[®] and ProNeura[™] are trademarks of our company. This Annual Report on Form 10-K also includes trade names and trademarks of companies other than Titan.

All share and per share data in this report gives retroactive effect to a one-for-30 reverse stock split effected in November 2020.

Overview

We are a pharmaceutical company developing therapeutics utilizing our proprietary long-term drug delivery platform, ProNeura[™], for the treatment of select chronic diseases for which steady state delivery of a drug has the potential to provide an efficacy and/or safety benefit. ProNeura consists of a small, solid implant made from a mixture of ethylene-vinyl acetate, or EVA, and a drug substance. The resulting product is a solid matrix that is designed to be administered subdermally, in a brief, outpatient procedure and is removed in a similar manner at the end of the treatment period. These procedures may be performed by trained health care providers, or HCPs, including licensed and surgically qualified physicians, nurse practitioners, and physician's assistants in a HCP's office or other clinical setting.

Our first product based on our ProNeura technology was the Probuphine® (buprenorphine) implant, which has been approved in the United States, Canada and the European Union, or EU, for the maintenance treatment of opioid use disorder in clinically stable patients taking 8 mg or less a day of oral buprenorphine. While Probuphine continues to be commercialized in Canada and the EU by other companies who have either licensed or acquired the rights from Titan, we discontinued commercialization of the product in the U.S. during Q4 2020 following disappointing revenues during the prior quarters. The disappointing commercial performance of Probuphine was multifactorial in origin, as previously enumerated in our Form 10-K for the fiscal year ended December 31, 2020. Discontinuation of our commercial operations has allowed us to focus our limited resources on important product development programs and transition back to a product development company.

Development Programs

Kappa Opioid Agonist Peptide Program

On October 27, 2020, we entered into an Asset Purchase Agreement with JT Pharmaceuticals for the acquisition and development of JT Pharma's kappa opioid agonist peptide, or TP-2021 (formerly JT-09), for use in combination with our ProNeura technology. James McNab, Jr., a member of our board of directors, is a principal of JT Pharma. Several years ago, we began limited non-clinical laboratory experiments in collaboration with JT Pharma to assess the feasibility of delivering TP-2021 using TP-2021 peptide-infused ProNeura implants inserted subdermally in animal models. Our initial work focused on TP-2021's ability to activate peripheral kappa opioid receptors, potentially providing a non-addictive treatment for certain types of pain. Recently, our experiments have pivoted to explore the feasibility of also using TP-2021 ProNeura implants in the treatment of chronic pruritus, a debilitating condition defined as itching of the skin lasting longer than six weeks. In February 2021, we announced that early non-clinical studies of TP-2021 injected subdermally in mice demonstrated high potency and specificity for the human kappa opioid receptor and this has enabled us to move forward to begin initial work on proof-of-concept studies in appropriate animal models of pruritus in order to test the implant formulation. Currently, these studies are ongoing and we hope to share results in the second half of 2021.

In 2015, an estimated 23 – 44 million Americans suffered from chronic pruritus in the setting of both cutaneous and systemic conditions. Current treatments include antihistamines, corticosteroids, and over-the-counter lotions, all of which are relatively ineffective and may have undesirable side-effect profiles. The antipruritic effect of kappa opioid agonists is thought to be related to their binding to kappa opioid receptors on keratinocytes, immune cells and peripheral itch neurons. We believe, based on our early non-clinical data, that subcutaneous implantation of the TP-2021 ProNeura implants could potentially deliver therapeutic concentrations of TP-2021 for up to six months or longer following a single in-office procedure. We are currently conducting the initial non-clinical studies designed to establish proof-of-concept, and if successful, we will need to conduct Investigational New Drug, or IND, enabling non-clinical safety and pharmacology studies prior to any clinical studies.

Nalmefene Development Program

In September 2019, the National Institute on Drug Abuse, or NIDA, awarded us a grant of approximately \$8.7 million over two years for our nalmefene implant development program for the prevention of opioid relapse following detoxification of patients suffering opioid use disorder. An injectable formulation of nalmefene was approved by the FDA in 1995 for the management and reversal of opioid overdose, including respiratory depression, but this is no longer marketed in the U.S. Oral nalmefene was approved by the EMA in 2013 for treating alcohol dependence. A nasally administered formulation of nalmefene is currently in clinical development by another company for the acute treatment of opioid overdose.

The NIDA grant provides funds for the completion of implant formulation development, cGMP manufacturing and non-clinical studies required for filing an IND. During the first quarter of 2020 we met with the FDA to review our non-clinical development plans and obtain guidance regarding filing an IND. Since other nalmefene formulations had already been approved by the FDA, we were pursuing a shorter, more streamlined 505(b)(ii) regulatory pathway in our development program. However, the FDA provided clear guidance on the type of development plan that we should follow. Specifically, the FDA has indicated that this product development should follow the more expansive 505(b)(i) regulatory pathway due to the lack of chronic safety data on nalmefene employing a long acting formulation, and the specific non-clinical studies that will be required to file an IND. Based on this input, collection of all the non-clinical chronic toxicology data will require an additional study, and will also require increasing the duration of an ongoing study that will delay filing of the IND to at least mid-2021. We have discussed the change in development plan with NIDA and they have accepted our plan to reallocate previously approved funds for conduct of the studies. Based on pursuing the 505(b)(i) pathway, the overall product development program cost is expected to increase considerably, and while we will discuss this further with NIDA, it is uncertain whether these additional funds will be available from NIDA or from any other sources.

We operate in only one business segment, the development of pharmaceutical products. We make available free of charge through our website, www.titanpharm.com, our periodic reports as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

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 Months Ended March 31, 2021 and March 31, 2020

Revenues

	Three Months Ended March 31,		
	2021	2020	Change
(In thousands)			
Revenues:			
License revenue	\$ 2	\$ —	\$ 2
Product revenue	111	—	111
Grant revenue	569	1,126	(557)
Total revenues	<u>\$ 682</u>	<u>\$ 1,126</u>	<u>\$ (444)</u>

The decrease in total revenues from continuing operations for the three months ended March 31, 2021 was primarily due to a decrease in grant revenue, partially offset by increases in license and product revenues. Product revenues from continuing operations for the three months ended March 31, 2021 consisted of sales of Probuphine product materials to Molteni for the EU. Revenue from the sale of Probuphine in the U.S. during the three months ended March 31, 2020 has been reclassified to discontinued operations (see Note 9 to the condensed financial statements included in this report for more information).

Operating Expenses

	Three Months Ended March 31,		
	2021	2020	Change
Operating expenses:			
Cost of goods sold	\$ 110	\$ —	\$ 110
Research and development	1,877	1,812	65
General and administrative	1,327	1,289	38
Total operating expenses	<u>\$ 3,314</u>	<u>\$ 3,101</u>	<u>\$ 213</u>

Cost of goods sold from continuing operations reflects costs and expenses associated with sales of our Probuphine product to Molteni for the EU. Cost of goods sold related to the sale of Probuphine in the U.S. during the three months ended March 31, 2020 has been reclassified to discontinued operations (see Note 9 to the condensed financial statements included in this report for more information).

The increase in research and development costs from continuing operations was primarily associated with activities related to non-clinical studies required for the planned IND submission as part of our NIDA grant for the development of a nalmefene implant and initial non-clinical proof of concept studies related to our TP-2021 implant program. Other research and development expenses include internal operating costs such as research and development personnel-related expenses, non-clinical and clinical product development related travel expenses, and allocation of facility and corporate costs. Research and development expenses related to our U.S. Probuphine activities during the three months ended March 31, 2020 have been reclassified to discontinued operations (see Note 9 to the condensed financial statements included in this report for more information). As a result of the risks and uncertainties inherently associated with pharmaceutical research and development activities described elsewhere in this document, we are unable to estimate the specific timing and future costs of our clinical development programs or the timing of material cash inflows, if any, from our product candidates. However, we anticipate that our research and development expenses will increase as we continue our current or any future ProNeura development programs to the extent these costs are not supported through grants or partners.

General and administrative expenses were essentially unchanged. Selling and marketing expenses related to the sale of Probuphine in the U.S. during the three months ended March 31, 2020 have been reclassified to discontinued operations (see Note 9 to the condensed financial statements included in this report for more information).

Other Expense, Net

	Three Months Ended March 31,		
	2021	2020	Change
Other expense:			
Interest expense, net	\$ (1)	\$ (222)	\$ 221
Non-cash loss on changes in fair value of warrants	—	(923)	923
Other income (expense)	(8)	(213)	205
Total other expense, net	<u>\$ (9)</u>	<u>\$ (1,358)</u>	<u>\$ 1,349</u>

The decrease in other expense net for the three months ended March 31, 2021 was primarily due to non-cash losses on changes in the fair value of our warrants, approximately \$0.2 million in costs attributable to the issuance of warrants and a decrease of approximately \$0.2 million in interest expense resulting from the settlement of debt in October 2020.

Net Loss and Net Loss per Share

Our net loss from continuing operations for the three-month period ended March 31, 2021 was approximately \$2.6 million, or approximately \$0.28 per share, compared to our net loss from continuing operations of approximately \$3.3 million, or approximately \$1.21 per share, for the comparable period in 2020. Our net loss from discontinued operations for the three-month period ended March 31, 2020 was approximately \$2.3 million, or approximately \$0.82 per share.

Liquidity and Capital Resources

We have funded our operations since inception primarily through the sale of our securities and the issuance of debt, as well as with proceeds from warrant and option exercises, corporate licensing and collaborative agreements, and government-sponsored research grants. At March 31, 2021, we had working capital of approximately \$9.4 million compared to working capital of approximately \$3.1 million at December 31, 2020.

In January 2021, we completed an offering with several accredited institutional investors pursuant to which we issued 2,725,000 shares of our common stock in a registered direct offering and warrants to purchase 2,725,000 shares of our common stock with an exercise price of \$3.55 per share in a concurrent private placement. The warrants were exercisable immediately and will expire in July 2026. The net cash proceeds from this offering were approximately \$8.9 million after deduction of underwriting fees and other offering expenses.

In January 2020, we completed a financing with several institutional investors pursuant to which we issued 8,700,000 shares of our common stock in a registered direct offering and warrants to purchase 290,000 shares of our common stock with an exercise price of \$7.50 per share in a concurrent private placement pursuant to which we received net cash proceeds of approximately \$1.9 million, after deduction of underwriting fees and other offering expenses.

During the three months ended March 31, 2020, we received an aggregate of approximately \$6.2 million in cash proceeds from the exercises of warrants to purchase approximately 912,949 shares of our common stock.

At March 31, 2021, we had cash and cash equivalents of \$11.6 million, which we believe is sufficient to fund our planned operations into the first quarter of 2022. There is substantial doubt about our ability to continue as a going concern. We will require additional funds to finance our operations. We are exploring several financing alternatives; however, there can be no assurance that our efforts to obtain the funding required to continue our operations will be successful.

Sources and Uses of Cash

	Three Months Ended March 31,	
	2021	2020
	(in thousands)	
Net cash used in operating activities	(2,625)	(5,212)
Net cash used in investing activities	—	(30)
Net cash provided by financing activities	8,841	8,057
Change in cash, cash equivalents and restricted cash	<u>6,216</u>	<u>2,815</u>

Net cash used in operating activities for the three months ended March 31, 2021 consisted primarily of our net loss of approximately \$2.6 million and approximately \$0.3 million related to net changes in operating assets and liabilities, partially offset by approximately \$0.3 million of non-cash charges primarily related to stock-based compensation and depreciation and amortization. Net cash used in operating activities for the three months ended March 31, 2020 consisted primarily of our net loss of approximately \$5.6 million and approximately \$0.9 million related to net changes in operating assets and liabilities, partially offset by approximately \$1.0 million of non-cash charges mainly related to non-cash losses on changes in fair value of warrants, interest expense, stock based compensation and depreciation and amortization and approximately \$0.2 million in costs attributable to the issuance of warrants. Uses of cash in operating activities were primarily to fund product development programs, administrative expenses and our commercialization activities which were discontinued during the fourth quarter of 2020.

Net cash used in investing activities was primarily related to purchases of equipment during the three months ended March 31, 2020.

Net cash provided by financing activities for the three months ended March 31, 2021 consisted of net cash proceeds from the January 2021 offering. Net cash provided by financing activities for the three months ended March 31, 2020 consisted of net cash proceeds from the January 2020 offering and exercises of warrants.

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, 2020 have not materially changed.

Item 4. Controls and Procedures

Disclosure Controls and Procedures

Our Executive Chairman, 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 March 31, 2021, 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 three months ended March 31, 2021 that materially affected, or were reasonably likely to materially affect, our internal controls over financial reporting.

PART II

Item 1. Legal Proceedings

A legal proceeding has been initiated by a former employee alleging wrongful termination, retaliation, infliction of emotional distress, negligent supervision, hiring and retention and slander. An independent investigation into this individual's allegations of whistleblower retaliation, while still an employee, was conducted utilizing an outside investigator and concluded that such allegations were not substantiated. We intend to vigorously defend the lawsuit; however, in light of our cash position, there can be no assurance that the defense and/or settlement of this matter will not have a material adverse impact on our business.

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, 2020, which could materially affect our business, financial condition or future results. The risks described in our Annual Report on Form 10-K are not the only risks facing our company. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results.

We are increasingly dependent on information technology systems, infrastructure and data. Cybersecurity breaches could expose us to liability, damage our reputation, compromise our confidential information or otherwise adversely affect our business.

We are increasingly dependent upon information technology systems, infrastructure and data. Our computer systems may be vulnerable to service interruption or destruction, malicious intrusion and random attack. Security breaches pose a risk that sensitive data, including intellectual property, trade secrets or personal information may be exposed to unauthorized persons or to the public. Cyber-attacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyber-attacks could include the deployment of harmful malware, denial-of service, social engineering and other means to affect service reliability and threaten data confidentiality, integrity and availability. Our key business partners face similar risks, and a security breach of their systems could adversely affect our security posture. While we continue to invest in data protection and information technology, there can be no assurance that our efforts will prevent service interruptions, or identify breaches in our systems, that could adversely affect our business and operations and/or result in the loss of critical or sensitive information, which could result in financial, legal, business or reputational harm.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

On January 20, 2021, in connection with a registered direct offering of 2,725,000 shares of common stock, we issued warrants to purchase 2,725,000 shares of common stock at an exercise price of \$3.55 per share in a private placement to several institutional investors. The warrants are exercisable through July 20, 2026. On February 5, 2021, we registered the shares underlying the warrants for resale under the Securities Act.

Item 6. Exhibits

(b) Exhibits

No.	Description
1.1	Underwriting Agreement dated October 28, 2020 between Titan Pharmaceuticals, Inc. and Maxim Group LLC⁽²⁶⁾
3.1.1	Amended and Restated Certificate of Incorporation of the Registrant, as amended⁽⁴⁾
3.1.2	Certificate of Amendment to the Restated Certificate of Incorporation dated September 24, 2015⁽⁶⁾
3.1.3	Certificate of Amendment to the Restated Certificate of Incorporation dated January 23, 2019⁽¹⁶⁾
3.1.4	Certificate of Amendment to the Restated Certificate of Incorporation dated September 24, 2020⁽¹⁶⁾
3.2	By-laws of the Registrant⁽¹⁾
4.1	Form of Lender Warrant⁽⁸⁾
4.2	Form of Rights Agreement Warrant⁽¹⁰⁾
4.3	Warrant Agency Agreement between Titan Pharmaceuticals, Inc. and Continental Stock Transfer & Trust Company and Form of Offering Warrant⁽¹⁵⁾
4.4	Representative's Purchase Warrant⁽¹⁵⁾
4.5	Form of August 2019 Private Placement Warrant⁽¹⁷⁾
4.6	Class B Warrant Agency Agreement dated October 16, 2019 between Titan Pharmaceuticals, Inc. and Maxim Group LLC Form of January 2020 Private Placement Warrant⁽¹⁸⁾
4.7	Form of January 2020 Private Placement Warrant⁽¹⁹⁾
4.8	Form of March 3, 2020 Warrant Amendment Agreement⁽²³⁾
4.9	Description of the Registrant's Common Stock⁽²²⁾
4.10	Warrant Agency Agreement between Titan Pharmaceuticals, Inc. and Continental Stock Transfer & Trust Company and Form of Warrant⁽²⁵⁾
4.11	Form of Lock-Up and Voting Agreement⁽²⁵⁾
4.12	Form of January 2021 Private Placement Warrant⁽²⁸⁾
10.1	2001 Non-Qualified Employee Stock Option Plan⁽²⁾
10.2	2002 Stock Option Plan⁽³⁾
10.3	Titan Pharmaceuticals, Inc. 2014 Incentive Plan⁽⁵⁾
10.4	Titan Pharmaceuticals, Inc. Third Amended and Restated 2015 Omnibus Equity Incentive Plan⁽¹⁶⁾
10.5	Employment Agreement between Titan Pharmaceuticals, Inc. and Sunil Bhonsle⁽⁷⁾
10.6	Employment Agreement between Titan Pharmaceuticals, Inc. and Marc Rubin⁽⁷⁾
10.7	Venture Loan and Security Agreement, dated July 27, 2017, by and between Titan Pharmaceuticals, Inc. and Horizon Technology Finance Corporation⁽⁸⁾
10.8	Amendment of Venture Loan and Security Agreement, dated February 2, 2018, by and between Titan Pharmaceuticals, Inc. and Horizon Technology Finance Corporation⁽⁹⁾
10.9	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 Fratelli Alitti Società Di Esercizio S.P.A.⁽¹⁰⁾
10.10 ±	Asset Purchase, Supply and Support Agreement dated March 21, 2018, by and between Titan Pharmaceuticals, Inc. and L. Molteni & C. Dei Fratelli Alitti

- [Società Di Esercizio S.P.A.](#)⁽¹⁰⁾
- [10.11](#) [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.](#)⁽¹⁰⁾
- [10.12 ±](#) [Termination and Transition Services Agreement dated May 25, 2018 by and between Titan Pharmaceuticals, Inc. and Braeburn Pharmaceuticals, Inc.](#)⁽¹¹⁾
- [10.13 ±](#) [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.](#)⁽¹²⁾
- [10.14 ±](#) [Distribution and Sublicense Agreement dated February 1, 2016 as amended by agreement dated August 2, 2018 between Titan Pharmaceuticals, Inc. and Knight Therapeutics Inc.](#)⁽¹³⁾

<u>10.15</u>	<u>Amendment to lease for Registrant’s facility dated March 21, 2016</u> ⁽¹³⁾
<u>10.16</u>	<u>Unsecured Convertible Loan Agreement dated September 18, 2018</u> ⁽¹⁴⁾
<u>10.17</u>	<u>Employment Agreement between the Registrant and Katherine Beebe DeVarney</u> ⁽²⁰⁾
<u>10.18</u>	<u>Employment Agreement between the Registrant and Dane Hallberg</u> ⁽²⁰⁾
<u>10.19</u>	<u>Securities Purchase Agreement, dated August 7, 2019, by and between Titan Pharmaceuticals, Inc. and the investors named therein</u> ⁽¹⁷⁾
<u>10.20</u>	<u>Securities Purchase Agreement, dated January 7, 2020, by and between Titan Pharmaceuticals, Inc. and the investors named therein</u> ⁽¹⁹⁾
<u>10.21</u>	<u>Placement Agency Agreement, dated August 7, 2019, by and between Titan Pharmaceuticals, Inc. and Maxim Group LLC</u> ⁽¹⁷⁾
<u>10.22</u>	<u>Placement Agency Agreement, dated January 7, 2020, by and between Titan Pharmaceuticals, Inc. and Maxim Group LLC</u> ⁽¹⁹⁾
<u>10.23</u>	<u>Amendment dated September 10, 2019 to 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.</u> ⁽²¹⁾
<u>10.24 ±</u>	<u>Amendment No. 2 dated September 10, 2019 to Asset Purchase, Supply and Support Agreement by and between Titan Pharmaceuticals, Inc. and L. Molteni & C. Dei Frattelli Alitti Società Di Esercizio S.P.A.</u> ⁽²¹⁾
<u>10.25</u>	<u>Amendment No. 2 dated March 12, 2020 to 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.</u> ⁽²²⁾
<u>10.26 ±±</u>	<u>Agreement for Co-Promotion Partnership, dated June 23, 2020, by and between Titan Pharmaceuticals, Inc. and Indegene, Inc.</u> ⁽²³⁾
<u>10.27</u>	<u>Debt Settlement and Release Agreement by and between Titan Pharmaceuticals, Inc., Horizon Technology Finance Corporation and L. Molteni & C. Dei Frattelli Alitti Società Di Esercizio S.P.A.</u> ⁽²⁴⁾
<u>10.28 ±±</u>	<u>Asset Purchase Agreement dated October 27, 2020 between Titan Pharmaceuticals, Inc. and JT Pharmaceuticals, Inc.</u> ⁽²⁷⁾
<u>10.29</u>	<u>Form of January 15, 2021 Securities Purchase Agreement</u> ⁽²⁸⁾
<u>10.30</u>	<u>Placement Agency Agreement dated January 15, 2021, by and between Titan Pharmaceuticals, Inc. and Maxim Group LLC</u> ⁽²⁸⁾
<u>14.1</u>	<u>Code of Business Conduct and Ethics</u> ⁽⁵⁾
<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.

±± Certain information has been omitted from this exhibit in reliance upon Item 601(b)(10) of Regulation S-K.

- (1) Incorporated by reference from the Registrant’s Registration Statement on Form S-3 (File No. 333-221126).
- (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 Registration Statement on Form 10 filed on January 14, 2010.
- (5) Incorporated by reference from the Registrant’s Annual Report on Form 10-K for the year ended December 31, 2013.
- (6) Incorporated by reference from the Registrant’s Current Report on Form 8-K filed on September 28, 2015.
- (7) Incorporated by reference from the Registrant’s Current Report on Form 8-K filed on April 3, 2019.
- (8) Incorporated by reference from the Registrant’s Current Report on Form 8-K filed on July 27, 2017.
- (9) Incorporated by reference from the Registrant’s Current Report on Form 8-K filed on February 7, 2018.
- (10) Incorporated by reference from the Registrant’s Current Report on Form 8-K filed on March 26, 2018.
- (11) Incorporated by reference from the Registrant’s Current Report on Form 8-K filed on May 30, 2018.
- (12) Incorporated by reference from the Registrant’s Current Report on Form 8-K filed on August 3, 2018.
- (13) Incorporated by reference from the Registrant’s Quarterly Report on Form 10-Q for the period ended June 30, 2018.
- (14) Incorporated by reference from the Registrant’s Current Report on Form 8-K dated September 20, 2018.
- (15) Incorporated by reference from the Registrant’s Current Report on Form 8-K dated September 25, 2018.
- (16) Incorporated by reference from the Registrant’s Current Report on Form 8-K dated January 25, 2019.
- (17) Incorporated by reference from the Registrant’s Current Report on Form 8-K dated August 8, 2019.
- (18) Incorporated by reference from the Registrant’s Current Report on Form 8-K dated October 18, 2019.
- (19) Incorporated by reference from the Registrant’s Current Report on Form 8-K dated January 7, 2020.
- (20) Incorporated by reference from the Registrant’s Annual Report on Form 10-K dated April 1, 2019.
- (21) Incorporated by reference from the Registrant’s Registration Statement on Form S-1 dated September 12, 2019.
- (22) Incorporated by reference from the Registrant’s Annual Report on Form 10-K dated March 30, 2020.
- (23) Incorporated by reference from the Registrant’s Quarterly Report on Form 10-Q for the period ended June 30, 2020.
- (24) Incorporated by reference from the Registrant’s Current Report on Form 8-K dated October 26, 2020.
- (25) Incorporated by reference from the Registrant’s Registration Statement on Form S-1/A dated October 27, 2020.
- (26) Incorporated by reference from the Registrant’s Current Report on Form 8-K dated November 2, 2020.
- (27) Incorporated by reference from the Registrant’s Quarterly Report on Form 10-Q for the period ended September 30, 2020.
- (28) Incorporated by reference from the Registrant’s Current Report on Form 8-K dated January 19, 2021.

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: May 17, 2021

By: _____ /s/ Marc Rubin, M.D.
Name: **Marc Rubin, M.D.**
Title: **Executive Chairman**
(Principal Executive and Principal Financial Officer)

CERTIFICATION

I, Marc Rubin, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Titan Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f) for the registrant and have:

- (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the registrant is made known to me by others within those entities, particularly during the period in which this report is being prepared;
- (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under my supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
- (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
- (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

- (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
- (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 17, 2021

 /s/ Marc Rubin, M.D.

Name: Marc Rubin, M.D.

Title: Executive Chairman

(Principal Executive Officer and Principal
Financial Officer)

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002**

In connection with this quarterly report on Form 10-Q of Titan Pharmaceuticals, Inc. (the “Company”) for the period ended March 31, 2021, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), the undersigned officer of the Company hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 17, 2021

 /s/ Marc Rubin, M.D.

Name: Marc Rubin, M.D.
Title: Executive Chairman
(Principal Executive Officer and Principal
Financial Officer)
