

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, 2022.

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, 2022
Common Stock, par value \$0.001	13,339,421

Titan Pharmaceuticals, Inc.

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Part I. Financial Information**Item 1. Financial Statements****TITAN PHARMACEUTICALS, INC.****CONDENSED BALANCE SHEETS**
(in thousands)

	<u>March 31,</u> <u>2022</u> <u>(unaudited)</u>	<u>December 31,</u> <u>2021</u> <u>(Note 1)</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 8,138	\$ 6,037
Restricted cash	211	295
Receivables	218	112
Inventory	293	293
Prepaid expenses and other current assets	749	480
Discontinued operations - current assets	24	12
Total current assets	<u>9,633</u>	<u>7,229</u>
Property and equipment, net	368	420
Other assets	48	48
Operating lease right-of-use asset	269	297
Total assets	<u>\$ 10,318</u>	<u>\$ 7,994</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 468	\$ 795
Accrued clinical trials expenses	39	9
Other accrued liabilities	320	314
Operating lease liability, current	114	112
Deferred grant revenue	211	295
Discontinued operations – current liabilities	1,126	1,144
Total current liabilities	<u>2,278</u>	<u>2,669</u>
Operating lease liability, non-current	158	187
Total liabilities	<u>2,436</u>	<u>2,856</u>
Stockholders' equity:		
Common stock, at amounts paid-in, \$0.001 par value per share; 225,000,000 shares authorized, 12,039,421 and 9,914,158 shares issued and outstanding at March 31, 2022 and December 31, 2021, respectively.	12	10
Additional paid-in capital	386,465	381,183
Accumulated deficit	(378,595)	(376,055)
Total stockholders' equity	<u>7,882</u>	<u>5,138</u>
Total liabilities and stockholders' equity	<u>\$ 10,318</u>	<u>\$ 7,994</u>

See Notes to Condensed Financial Statements

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

	Three Months Ended March 31,	
	2022	2021
Revenues:		
License revenue	\$ 3	\$ 2
Product revenue	—	111
Grant revenue	189	569
Total revenues	192	682
Operating expenses:		
Cost of goods sold	—	110
Research and development	1,409	1,877
General and administrative	1,322	1,327
Total operating expenses	2,731	3,314
Loss from operations	(2,539)	(2,632)
Other expense:		
Interest expense, net	—	(1)
Other expense, net	(1)	(8)
Other expense, net	(1)	(9)
Net loss	\$ (2,540)	\$ (2,641)
Basic and diluted net loss per common share	\$ (0.24)	\$ (0.28)
Weighted average shares used in computing basic and diluted net loss per common share	10,729	9,289

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, 2021	9,914	\$ 10	\$ 381,183	\$ (376,055)	\$ 5,138
Net loss	—	—	—	(2,540)	(2,540)
Issuance of common stock, net	1,151	1	5,029	—	5,030
Issuance of common stock upon exercises of warrants	974	1	—	—	1
Amortization of restricted stock	—	—	27	—	27
Stock-based compensation	—	—	226	—	226
Balances at March 31, 2022	<u>12,039</u>	<u>\$ 12</u>	<u>\$ 386,465</u>	<u>\$ (378,595)</u>	<u>\$ 7,882</u>

	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	<u>9,864</u>	<u>\$ 10</u>	<u>\$ 379,890</u>	<u>\$ (369,920)</u>	<u>\$ 9,980</u>

See Notes to Condensed Financial Statements

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

	Three Months Ended March 31,	
	2022	2021
Cash flows from operating activities:		
Net loss	\$ (2,540)	\$ (2,641)
Adjustments to reconcile loss to net cash used in operating activities:		
Depreciation and amortization	52	55
Non-cash interest expense	—	1
Stock-based milestone payment	50	—
Stock-based compensation	253	248
Other	1	(5)
Changes in operating assets and liabilities:		
Receivables	(106)	487
Inventory	—	110
Prepaid expenses and other assets	(281)	(241)
Accounts payable	(350)	(482)
Deferred grant revenue	(84)	—
Other accrued liabilities	41	(157)
Net cash used in operating activities	<u>(2,964)</u>	<u>(2,625)</u>
Cash flows from financing activities:		
Net proceeds from equity offering	4,980	8,841
Net proceeds from the exercises of common stock warrants	1	—
Net cash provided by financing activities	<u>4,981</u>	<u>8,841</u>
Net increase in cash, cash equivalents and restricted cash	2,017	6,216
Cash, cash equivalents and restricted cash at beginning of period	6,332	5,413
Cash, cash equivalents and restricted cash at end of period	<u>\$ 8,349</u>	<u>\$ 11,629</u>

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 statements of cash flows (in thousands):

	March 31,	
	2022	2021
Cash and cash equivalents	\$ 8,138	\$ 11,629
Restricted cash	211	—
Cash, cash equivalents and restricted cash shown in the condensed statements of cash flows	<u>\$ 8,349</u>	<u>\$ 11,629</u>

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 Probuphine[®] (buprenorphine implant), which is 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 in the EU (as Sixmo[™]) by other companies that have either licensed or acquired the rights from Titan, we discontinued commercialization of the product in the U.S. during the fourth quarter of 2020. Discontinuation of our commercial operations has allowed us to focus our limited resources on product development programs.

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, 2022 are not necessarily indicative of the results that may be expected for the year ending December 31, 2022, or any future interim periods.

The balance sheet as of December 31, 2021 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, 2021, 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, 2022, we had cash and cash equivalents of \$8.1 million, which we believe is sufficient to fund our planned operations to the end of the third quarter of 2022. We will require additional funds to finance our operations. We are exploring several financing and strategic alternatives; however, there can be no assurance that our efforts to obtain the funding required to continue our operations will be successful. 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.

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The accompanying condensed 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 7). The accompanying condensed 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 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, 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 our 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 condensed financial statements in this Quarterly Report on Form 10-Q for the three months ended March 31, 2022, we did not have sufficient cash to fund our operations for the next 12 months without 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, 2022	December 31, 2021
Raw materials and supplies	227	227
Finished goods	66	66
	<u>\$ 293</u>	<u>\$ 293</u>

The approximately \$66,000 of finished goods inventory at March 31, 2022 and December 31, 2021 included materials held for potential sale.

Revenue Recognition

We generate revenue principally from collaborative research and development arrangements, sales or licenses of technology, government grants, sales of Probuphine materials to holders of the ex-U.S. product rights, 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.

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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.

Grant Revenue

We have contracts with National Institute on Drug Abuse or NIDA, within the U.S. Department of Health and Human Services, or HHS, the Bill & Melinda Gates Foundation, and other government-sponsored organizations for research and development related activities that provide for payments for reimbursed costs, which may include overhead and general and administrative costs. We recognize revenue from these contracts as we perform services under these arrangements when the funding is committed. Associated expenses are recognized when incurred as research and development expense. Revenues and related expenses are presented gross in the condensed statements of operations.

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 arriving 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 a distinct good or service 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.

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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.

Contract Assets and liabilities

The following table presents the activity related to our accounts receivable for the three months ended March 31, 2022.

	March 31, 2022
<i>(In thousands)</i>	
Balance at January 1, 2022	\$ 112
Additions	192
Deductions	(86)
Balance at March 31, 2022	<u>\$ 218</u>

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, 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.

Leases

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 condensed balance sheets as right-of-use assets, operating lease liabilities current and operating lease liabilities non-current.

The following table presents maturities of our operating lease:

2022	96
2023	130
2024	66
Total minimum lease payments (base rent)	292
Less: imputed interest	(20)
Total operating lease liabilities	\$ 272

Recent Accounting Pronouncements

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 beginning on January 1, 2023. We are currently assessing the impact of the adoption of Topic 326 on our condensed 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, or 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 condensed 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

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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 condensed financial statements and related disclosures.

In November 2021, the FASB issued ASU 2021-10, Disclosures by Business Entities about Government Assistance. The ASU codifies new requirements to disclose information about the nature of certain government assistance received, the accounting policy used to account for the transactions, the location in the financial statements where such transactions were recorded and significant terms and conditions associated with such transactions. The guidance is effective for annual periods beginning after December 15, 2021. We do not expect the adoption of ASU No. 2021-10 to have a material impact to our condensed financial statements and related disclosures.

Subsequent Events

We have evaluated events that have occurred after March 31, 2022 and through the date that our condensed financial statements are issued. See Note 8 Subsequent Events.

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.

At March 31, 2022 and December 31, 2021, the fair value of our investments in money market funds were approximately \$7.8 million and \$5.7 million, respectively, which are included within our cash and cash equivalents in our condensed balance sheets.

2. Stock Plans

The following table summarizes our 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, 2021	682	\$ 12.53	8.98	\$ —
Granted	310	1.18		
Forfeited or expired	(2)	531.11		
Outstanding at March 31, 2022	990	\$ 8.28	9.07	\$ —
Exercisable at March 31, 2022	511	\$ 14.01	8.71	\$ —

Approximately 310,000 options to purchase common shares were granted during the three-month period ended March 31, 2022.

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

	Three Months Ended March 31,	
	2022	2021
Research and development	\$ 123	\$ 120
Selling, general and administrative	103	128
Total stock-based compensation expense	\$ 226	\$ 248

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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,	
	2022	2021
Weighted-average risk-free interest rate	1.47 %	0.54 %
Expected dividend payments	—	—
Expected holding period (years) ⁽¹⁾	5.4	5.5
Weighted-average volatility factor ⁽²⁾	113.2	113.9
Estimated forfeiture rates for options granted ⁽³⁾	5.14 %	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, 2022, there was approximately \$0.6 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 1.0 years.

3. Net Loss Per Share

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:

(in thousands)	Three months ended March 31,	
	2022	2021
Weighted-average anti-dilutive common shares resulting from options	977	399
Weighted-average anti-dilutive common shares resulting from warrants	5,442	719
Total	6,419	1,118

4. JT Pharmaceuticals Asset Purchase Agreement

In October 2020, we entered into an Asset Purchase Agreement, or JT Agreement, with JT Pharmaceuticals, Inc., or 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 certain developmental and regulatory milestones, and single-digit percentage earn-out payments on net sales of the product if successfully developed and approved for commercialization. In January 2022, we entered into an agreement with JT Pharma to clarify certain provisions of the JT Agreement pursuant to which we agreed that the proof-of-concept milestone provided for in the JT Agreement was achieved and made a payment of \$100,000 and issued 51,021 shares of our common stock to JT Pharma. The related expense was included in research and development expenses in our condensed statements of operations.

5. Commitments and Contingencies

Lease Commitments

We lease our office facility under an operating lease that expires in June 2024. Rent expense associated with this lease was approximately \$32,000 for the three-month period ended March 31, 2022.

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 (which we have compelled into arbitration); 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.

6. Stockholders' Equity

Our common stock outstanding as of March 31, 2022 and December 31, 2021 was 12,039,421 shares and 9,914,158 shares, respectively.

February 2022 Offerings

In February 2022, we completed a registered direct offering with an accredited investor pursuant to which we issued an aggregate of 1,100,000 shares of our common stock and 2,274,242 pre-funded warrants to purchase shares of our common stock, with an exercise price of \$0.001 per share. In a concurrent private placement, we sold unregistered pre-funded warrants to purchase an aggregate of 1,289,796 shares of common stock with an exercise price of \$0.001 per share and issued unregistered five year and six month warrants to purchase an aggregate of 4,664,038 shares of common stock with an exercise price of \$1.14. The net cash proceeds from these offerings were approximately \$5.0 million after deduction of underwriting fees and other offering expenses.

Warrant Exercises

In March 2022, we received approximately \$1,000 from the exercise of 974,242 pre-funded warrants issued in the February 2022 registered direct offering.

JT Pharma Milestone

In January 2022, we entered into an agreement with JT Pharma to clarify certain provisions of the JT Agreement pursuant to which we agreed that the proof-of-concept milestone provided for in the JT Agreement was achieved and made a payment of \$100,000 and issued 51,021 shares of our common stock to JT Pharma.

Restricted Shares

In August 2021, we agreed to issue 50,000 shares of our common stock pursuant to a restricted stock agreement with Maxim Partners, LLC in connection with the entry into an amendment to our existing advisory agreement. The shares vest monthly over 12 months. We recorded approximately \$27,000 of stock-based compensation expense during the three months ended March 31, 2022.

The following table summarizes our restricted stock activity:

	<u>March 31,</u> <u>2022</u>
Outstanding at January 1, 2022	50,000
Issued	—
Forfeited or expired	—
Outstanding at March 31, 2022	<u>50,000</u>

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.

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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.

7. Discontinued Operations

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

	March 31, 2022	December 31, 2021
<i>(In thousands)</i>		
Prepaid expenses and other current assets	\$ 24	\$ 12
Discontinued operations – current assets	<u>\$ 24</u>	<u>\$ 12</u>
Accounts payable	\$ 758	\$ 782
Accrued clinical trials expenses	6	—
Other accrued liabilities	362	362
Discontinued operations – current liabilities	<u>\$ 1,126</u>	<u>\$ 1,144</u>

8. Subsequent Events

Warrant Exercises

In April 2022, we received approximately \$1,300 from the exercise of 1,300,000 pre-funded warrants issued in the February 2022 registered direct offering.

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:

- our ability to raise capital when needed;
- difficulties or delays in the product development process, including the results of preclinical studies or clinical trials;
- financing and strategic agreements and relationships;
- difficulties or delays in the regulatory approval process;
- 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;
- manufacturing, sales, marketing and distribution of any of our drug candidates that may be successfully developed and approved for commercialization;
- 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 Quarterly Report on Form 10-Q also includes trade names and trademarks of companies other than Titan.

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 Probuphine® (buprenorphine implant), which is 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 in the EU (as Sixmo™) by other companies that have either licensed or acquired the rights from Titan, we discontinued commercialization of the product in the U.S. during the fourth quarter of 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.

ProNeura Continuous Drug Delivery Platform

Our ProNeura continuous drug delivery system consists of a small, solid rod-shaped implant made from a mixture of EVA and a given drug substance. The resulting product is a solid matrix that is placed subdermally, normally in the inside part of the upper arm in a brief procedure using a local anesthetic and is removed in a similar manner at the end of the treatment period. The drug substance is released continuously through the process of dissolution-controlled diffusion. This results in a continuous, steady rate of release generally similar to intravenous administration. We believe that such long-term, near linear release characteristics are desirable as they avoid the fluctuating peak and trough drug levels seen with oral dosing that often poses treatment problems in a range of diseases.

The ProNeura platform was developed to address the need for a simple, practical method to achieve continuous long-term drug delivery, and, depending on the characteristics of the compound to be delivered, can potentially provide treatment on an outpatient basis over extended periods of up to 12 months. We believe that the benefits of this technology have been demonstrated by the clinical results seen to date with Probuphine, and, in addition, that the development and regulatory process have been affirmed by the U.S. Food and Drug Administration, or FDA, the European Medicines Agency, or EMA, and Health Canada approvals of this product. We have further demonstrated the feasibility of the ProNeura platform with small molecules, hormones, and bio-active peptides. The delivery system works with both hydrophobic and hydrophilic molecules. We have also shown the flexibility of the platform by experimenting with the release characteristics of the EVA implants, layering the implants with varying concentrations of drug, and generating implants of different sizes and porosity to achieve a desired delivery profile. We have received a grant from the Bill and Melinda Gates Foundation to undertake preliminary work on a long-acting implant capable of delivering two compounds- a human immunodeficiency virus, or HIV, preventative therapeutic and a contraceptive for women and girls in developing countries.

Development Programs

According to a 2015 review by Mollanazar, N., et al., an estimated 23 – 44 million Americans suffer from chronic pruritus, a severe and debilitating condition defined as itching of the skin lasting longer than six weeks, of both cutaneous and systemic etiologies. Current treatments include antihistamines, corticosteroids, and over-the-counter lotions, all of which are relatively ineffective and/or 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.

In February 2021, we announced that early non-clinical studies of our kappa opioid agonist peptide, TP-2021, showed very high affinity and specificity for the human kappa opioid receptor and demonstrated potent antipruritic activity when injected subcutaneously in a mouse model for moderate to severe pruritus. TP-2021 - ProNeura implants were then formulated and tested in this model. In November 2021, data presented at the annual meeting of the Society for Neuroscience demonstrated that significant reduction in scratching behavior in this proven animal model for pruritus was maintained in mice who received the TP-2021 - ProNeura implant through Day 56 post-implantation, when compared with control untreated mice, with no safety issues observed for the implanted animals over the three-month duration of treatment. Subsequently, efficacy in this pruritus model has been extended through Day 84 post-implantation. In addition, the TP-2021 - ProNeura implant provided sustained supra-therapeutic plasma levels of the peptide through Day 84 post-implantation in a separate pharmacokinetic study in mice. We believe that subdermal implantation of TP-2021 - ProNeura could potentially deliver therapeutic concentrations of TP-2021 in human subjects for up to six months or longer following a single in-office procedure. We will need to conduct Investigational New Drug, or IND, enabling non-clinical safety and pharmacology studies in preparation for regulatory approval to enter human clinical studies. We estimate that the IND submission can be accomplished within 18 to 24 months.

Pursuant to a research and option license agreement with the Medical University of South Carolina Foundation for Research Development, we have also synthesized a limited number of new peptides designed, like TP-2021, to bind with high selectivity to

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peripheral kappa opioid receptors. We will consider further development of any of these newly synthesized compounds that meet the criteria for high-affinity receptor bonding and antipruritic activity to enhance our intellectual property position.

We are also assessing the feasibility of non-implant biodegradable depot formulations of these kappa opioid receptor agonist peptides to provide antipruritic activity for shorter sustained periods (e.g., 1 – 3 months).

Nalmefene Development Program

In September 2019, the National Institute for Drug Addiction, or NIDA, awarded us an approximately \$8.7 million grant over two years for our nalmefene implant development program for the prevention of opioid relapse following detoxification of patients suffering opioid use disorder, or OUD. 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. Other formulations, including a nasal formulation of nalmefene are currently in clinical development by another company for the 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. In early 2020, following a meeting with the FDA to review our non-clinical development plans and obtain guidance regarding filing an IND, the FDA provided clear guidance on the type of development plan that we should follow. Specifically, that this product development should follow the more expansive 505(b)(1) regulatory pathway rather than the shorter, more streamlined 505(b)(2) regulatory pathway we had been pursuing. Based on this input, we determined that collection of all the requisite non-clinical chronic toxicology data would require an additional six-month rodent chronic toxicity study and a three-month extension to the duration of an ongoing six-month non-rodent chronic toxicity study, resulting in a delay of the IND filing. We discussed the change in development plan with NIDA and they accepted our plan to reallocate previously approved funds for conduct of such studies and extended the existing grant term through August 2022. In September 2021, the FDA advised that it was reconsidering the regulatory pathway for the nalmefene implant and could ultimately determine that the 505(b)(2) process is potentially appropriate. We expect to submit the IND for this program in Q2 2022. If accepted, we could be eligible for the additional third through fifth year grant funding of approximately \$6.3 million from NIDA. However, this funding availability is dependent on a progress review at NIDA. Additional funding from external sources for progression of the clinical program will be separately sought but will be dependent on finding a suitable partner.

Other Programs

In October 2021, we received an approximately \$500,000 grant from the Bill and Melinda Gates Foundation to demonstrate the ability to deliver a combination HIV preventative therapeutic and a contraceptive from a single ProNeura implant for women and adolescent girls in low- and middle-income countries.

In October 2021, we entered into a research and option license agreement, or MUSC Agreement, with the MUSC Foundation for Research Development, or MUSC FRD. Under the terms of the MUSC Agreement, we will conduct certain research, evaluation, proof of concept development and testing of at least three tetrapeptide kappa-opioid receptor agonist compounds related to the provisional U.S. patent application previously assigned to FRD by the Medical University of South Carolina (“MUSC”) and entitled “Opioid Agonists and Methods of Use Thereof.” In exchange, FRD has granted Titan the option to acquire an exclusive worldwide, commercial license to the inventions related to MUSC’s compounds.

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, 2022 and March 31, 2021

Revenues

	Three Months Ended March 31,		
	2022	2021 (In thousands)	Change
Revenues:			
License revenue	\$ 3	\$ 2	\$ 1
Product revenue	—	111	(111)
Grant revenue	189	569	(380)
Total revenues	<u>\$ 192</u>	<u>\$ 682</u>	<u>\$ (490)</u>

The decrease in total revenues for the three months ended March 31, 2022 was primarily due to a decrease in grant revenues and product revenues. Product revenues for the three months ended March 31, 2021 consisted of sales of Probuphine product materials to the holder of the EU rights.

Operating Expenses

	Three Months Ended March 31,		
	2022	2021	Change
Operating expenses:			
Cost of goods sold	\$ —	\$ 110	\$ (110)
Research and development	1,409	1,877	(468)
General and administrative	1,322	1,327	(5)
Total operating expenses	<u>\$ 2,731</u>	<u>\$ 3,314</u>	<u>\$ (583)</u>

Cost of goods sold reflects costs and expenses associated with sales of our Probuphine product to the holder of the EU rights.

The decrease in research and development costs was primarily associated with reduced 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. This was partially offset by initial non-clinical proof of concept studies related to our TP-2021 implant program and increases in research and development personnel-related expenses. 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. 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.

Other Expense, Net

	Three Months Ended March 31,		
	2022	2021	Change
Other expense:			
Interest expense, net	\$ —	\$ (1)	\$ 1
Other expense, net	(1)	(8)	7
Total other expense, net	<u>\$ (1)</u>	<u>\$ (9)</u>	<u>\$ 8</u>

Net Loss and Net Loss per Share

Our net loss for the three-month period ended March 31, 2022 was approximately \$2.5 million, or approximately \$0.24 per share, compared to our net loss of approximately \$2.6 million, or approximately \$0.28 per share, for the comparable period in 2021.

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, 2022, we had working capital of approximately \$7.4 million compared to working capital of approximately \$4.6 million at December 31, 2021.

In February 2022, we completed a registered direct offering with an accredited investor pursuant to which we issued an aggregate of 1,100,000 shares of our common stock and 2,274,242 pre-funded warrants to purchase shares of our common stock, with an exercise price of \$0.001 per share. In a concurrent private placement, we sold unregistered pre-funded warrants to purchase an aggregate of 1,289,796 shares of common stock with an exercise price of \$0.001 per share and issued unregistered five year and six month warrants to purchase an aggregate of 4,664,038 shares of common stock with an exercise price of \$1.14. The net cash proceeds from these offerings were approximately \$5.0 million after deduction of underwriting fees and other offering expenses.

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.

As of March 31, 2022, we had cash and cash equivalents of \$8.1 million, which we believe is sufficient to fund our planned operations to the end of the third quarter of 2022. We will require additional funds to advance our kappa opioid agonist program beyond the proof-of-concept stage, and to fund any of our ProNeura development programs, including nalmefene, into the clinic and to complete the regulatory approval process necessary to commercialize any products we might develop. While we are currently evaluating the financing and strategic alternatives available to us, our efforts to address our liquidity requirements may not be successful. Furthermore, there can be no assurance that any source of capital will be available to us on acceptable terms, or will not involve substantial dilution to our stockholders. Our failure to obtain substantial funds in the next several months would likely result in the cessation of one or more of our development programs or the wind-down of our business.

Sources and Uses of Cash

	Three Months Ended March 31,	
	2022	2021
	(in thousands)	
Net cash used in operating activities	(2,964)	(2,625)
Net cash provided by financing activities	4,981	8,841
Change in cash, cash equivalents and restricted cash	<u>2,017</u>	<u>6,216</u>

Net cash used in operating activities for the three months ended March 31, 2022 consisted primarily of our net loss of approximately \$2.5 million and approximately \$0.8 million related to net changes in operating assets and liabilities, partially offset by approximately \$0.4 million of non-cash charges primarily related to non-cash stock-based compensation and depreciation and amortization. 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. Uses of cash in operating activities were primarily to fund product development programs and administrative expenses.

Net cash provided by financing activities for the three months ended March 31, 2022 consisted primarily of net cash proceeds from the February 2022 offering. Net cash provided by financing activities for the three months ended March 31, 2021 consisted of net cash proceeds from the January 2021 offering.

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, 2021 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, 2022, 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, 2022 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 (which we have compelled into arbitration); 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, 2021, 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.

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.

In February 2022, we completed a registered direct offering with an accredited investor pursuant to which we issued an aggregate of 1,100,000 shares of our common stock and 2,274,242 pre-funded warrants to purchase shares of our common stock, with an exercise price of \$0.001 per share. In a concurrent private placement, we sold unregistered pre-funded warrants to purchase an aggregate of 1,289,796 shares of common stock with an exercise price of \$0.001 per share and issued unregistered five year and six month warrants to purchase an aggregate of 4,664,038 shares of common stock with an exercise price of \$1.14. On April 4, 2022 we registered the shares underlying the warrants for resale under the Securities Act.

Item 6. Exhibits

(b) Exhibits

No.	Description
31.1	Certification of the Principal Executive and Financial Officer pursuant to Rule 13(a)-14(a) of the Securities Exchange Act of 1934 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
32.1	
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
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

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.

Dated: May 16, 2022

TITAN PHARMACEUTICALS, INC.

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

Name: **Marc Rubin, M.D.**

Title: **Executive Chairman**

(Principal Executive 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, 2022, 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 16, 2022

/s/ Marc Rubin, M.D.

Name: Marc Rubin, M.D.

Title: Executive Chairman

(Principal Executive Officer and Principal Financial Officer)
