

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 September 30, 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)

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

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

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 Accelerated filer
Non-accelerated filer
Smaller reporting company Emerging growth company

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

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

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 November 9, 2021
Common Stock, par value \$0.001	9,914,158

Titan Pharmaceuticals, Inc.

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Part I. Financial Information

Item 1. Financial Statements

TITAN PHARMACEUTICALS, INC.

CONDENSED BALANCE SHEETS
(in thousands)

	September 30, 2021 (unaudited)	December 31, 2020 (Note 1)
Assets		
Current assets:		
Cash and cash equivalents	\$ 7,418	\$ 5,413
Receivables	265	884
Inventory	129	328
Prepaid expenses and other current assets	846	522
Discontinued operations - current assets	187	181
Total current assets	8,845	7,328
Property and equipment, net	468	618
Operating lease right-of-use assets	324	141
Total assets	<u>\$ 9,637</u>	<u>\$ 8,087</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 386	\$ 1,253
Accrued clinical trials expenses	14	214
Other accrued liabilities	303	319
Operating lease liability, current	109	150
Current portion of long-term debt	—	327
Discontinued operations – current liabilities	1,113	1,960
Total current liabilities	1,925	4,223
Operating lease liability, noncurrent	216	—
Long-term debt	—	332
Total liabilities	2,141	4,555
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Common stock, at amounts paid-in, \$0.001 par value per share; 225,000,000 shares authorized 9,864,158 and 7,139,068 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively.	10	7
Additional paid-in capital	381,001	370,804
Accumulated deficit	(373,515)	(367,279)
Total stockholders' equity	7,496	3,532
Total liabilities and stockholders' equity	<u>\$ 9,637</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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenues:				
License revenue	\$ 4	\$ —	\$ 9	\$ 6
Product revenue	36	—	236	39
Grant revenue	224	1,018	1,146	3,348
Total revenues	264	1,018	1,391	3,393
Operating expenses:				
Cost of goods sold	—	—	199	—
Research and development	1,193	887	4,716	4,343
Selling, general and administrative	979	1,327	3,341	4,052
Total operating expenses	2,172	2,214	8,256	8,395
Loss from operations	(1,908)	(1,196)	(6,865)	(5,002)
Other income (expense):				
Interest expense, net	—	(246)	(2)	(718)
Non-cash loss on changes in the fair value of warrants	—	—	—	(923)
Gain on debt extinguishment	—	—	661	—
Other expense, net	(7)	(13)	(30)	(233)
Other income (expense), net	(7)	(259)	629	(1,874)
Loss from continuing operations	(1,915)	(1,455)	(6,236)	(6,876)
Loss from discontinued operations	—	(3,477)	—	(8,281)
Net loss and comprehensive loss	\$ (1,915)	\$ (4,932)	\$ (6,236)	\$ (15,157)
Basic and diluted net loss per common share from continuing operations	\$ (0.19)	\$ (0.45)	\$ (0.64)	\$ (2.25)
Basic and diluted net loss per common share from discontinued operations	\$ —	\$ (1.07)	\$ —	\$ (2.70)
Weighted average shares used in computing basic and diluted net loss per common share	9,864	3,264	9,675	3,062

See Notes to Condensed Financial Statements

TITAN PHARMACEUTICALS, INC.

CONDENSED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
(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
Net loss	—	—	—	(1,680)	(1,680)
Stock-based compensation	—	—	447	—	447
Balances at June 30, 2021	9,864	\$ 10	\$ 380,337	\$ (371,600)	\$ 8,747
Net loss	—	—	—	(1,915)	(1,915)
Stock-based compensation	—	—	664	—	664
Balances at September 30, 2021	9,864	\$ 10	\$ 381,001	\$ (373,515)	\$ 7,496

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	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, net	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
Net loss	—	—	—	(4,641)	(4,641)
Issuance of common stock upon exercises of warrants, net	125	—	846	—	846
Stock-based compensation	—	—	79	—	79
Balances at June 30, 2020	3,241	\$ 3	\$ 360,819	\$ (359,262)	\$ 1,560
Net loss	—	—	—	(4,932)	(4,932)
Issuance of common stock, net	648	1	2,443	—	2,444
Issuance of common stock upon exercises of warrants, net	3	—	22	—	22
Stock-based compensation	—	—	9	—	9
Balances at September 30, 2020	3,892	\$ 4	\$ 363,293	\$ (364,194)	\$ (897)

See Notes to Condensed Financial Statements

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

	Nine Months Ended September 30,	
	2021	2020
Cash flows from operating activities:		
Net loss	\$ (6,236)	\$ (15,157)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	168	227
Non-cash interest expense	2	447
Non-cash loss on changes in fair value of warrants	—	923
Non-cash loss on asset impairment	—	433
Non-cash gain on debt extinguishment	(661)	—
Stock-based compensation	1,359	4
Finance costs attributable to issuance of warrants	—	211
Other	(8)	(11)
Changes in operating assets and liabilities:		
Receivables	459	570
Inventory	199	(508)
Prepaid expenses and other assets	(170)	14
Accounts payable	(1,628)	309
Accrued sales allowances	—	(690)
Other accrued liabilities	(302)	586
Net cash used in operating activities	<u>(6,818)</u>	<u>(12,642)</u>
Cash flows from investing activities:		
Purchases of property and equipment	(18)	(531)
Net cash used in investing activities	<u>(18)</u>	<u>(531)</u>
Cash flows from financing activities:		
Net proceeds from equity offering	8,841	4,339
Net proceeds from the exercises of common stock warrants	—	7,030
Net loan proceeds	—	654
Net cash provided by financing activities	<u>8,841</u>	<u>12,023</u>
Net increase (decrease) in cash and cash equivalents	<u>2,005</u>	<u>(1,150)</u>
Cash and cash equivalents at beginning of period	5,413	5,223
Cash and cash equivalents at end of period	<u>\$ 7,418</u>	<u>\$ 4,073</u>
Supplemental disclosure of cash flow information:		
Interest paid	<u>\$ —</u>	<u>\$ 295</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 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 (known as Sixmo[™]) by other companies who 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. The disappointing commercial performance of Probuphine was multifactorial in origin, as previously enumerated in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020, or 2020 10-K, as filed with the Securities and Exchange Commission, or SEC. 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.

We continue to monitor the impact of the COVID-19 pandemic on all aspects of our business, including how it has and will continue to impact our operations and the operations of our vendors and contractors, and may take further precautionary and preemptive action as may be required by federal, state or local authorities. The full extent and duration of the impact of COVID-19 on our operations and financial performance is currently unknown and depends on future developments that are uncertain and unpredictable.

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 30 shares then outstanding.

The accompanying condensed 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, or 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 and nine months ended September 30, 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 2020 10-K.

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.

As of September 30, 2021, we had cash and cash equivalents of approximately \$7.4 million, which we believe is sufficient to fund our planned operations into the second 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 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 9). 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 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, which is referred to as the “look-forward period” as defined by Accounting Standard Update, or 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 and nine months ended September 30, 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:

<i>(in thousands)</i>	<i>As of</i>	
	September 30, 2021	December 31, 2020
Raw materials and supplies	\$ 60	\$ 170
Finished goods	69	158
	<u>\$ 129</u>	<u>\$ 328</u>

The approximately \$69,000 of finished goods inventory at September 30, 2021 included materials held for potential 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.

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 and comprehensive loss.

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.

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 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.

Contract Assets and liabilities

There were no contract assets or liabilities in our condensed financial statements at September 30, 2021. The following table presents the activity related to our accounts receivable for the nine-month period ended September 30, 2021.

<i>(In thousands)</i>	September 30, 2021
Balance at January 1, 2021	\$ 884
Additions	1,391
Deductions	(2,010)
Balance at September 30, 2021	<u>\$ 265</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, 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 compliance with ASU No. 2016-02, Leases (Topic 842), 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. We no longer recognize deferred rent on our condensed balance sheets.

The following table presents the minimum lease payments of our operating lease:

2021	\$ 31
2022	127
2023	130
2024	66
Total minimum lease payments (base rent)	<u>354</u>
Less: imputed interest	(29)
Total operating lease liabilities	<u>\$ 325</u>

Recent Accounting Pronouncements

Recently Adopted Accounting Pronouncements

In December 2019, the FASB issued ASU 2019-12, *Income Taxes - Simplifying the Accounting for Income Taxes* ("Topic 740"), which simplifies the accounting for income taxes, eliminates certain exceptions to the general principles in Topic 740 and clarifies and amends existing guidance to improve consistent application. The new guidance, effective January 1, 2021, did not have an impact on our condensed financial statements.

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 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 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 September 30, 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, and 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 was 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 September 30, 2021 and December 31, 2020, the fair value of our investments in money market funds were approximately \$.1 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 September 30, 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 nine-month period ended September 30, 2020 (in thousands):

	September 30, 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 condensed statements 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	(6)	137.74		
Outstanding at September 30, 2021	<u>692</u>	<u>\$ 12.46</u>	<u>9.23</u>	<u>\$ —</u>
Exercisable at September 30, 2021	<u>415</u>	<u>\$ 18.08</u>	<u>9.15</u>	<u>\$ —</u>

No options to purchase common stock were granted during the three-month period ended September 30, 2021.

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

<i>(in thousands)</i>	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Research and development	\$ 325	\$ —	\$ 659	\$ —
Selling, general and administrative	330	9	691	4
Total stock-based compensation	<u>\$ 655</u>	<u>\$ 9</u>	<u>\$ 1,350</u>	<u>\$ 4</u>

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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Weighted-average risk-free interest rate	— %	0.3 %	0.5 %	0.4 %
Expected dividend payments	—	—	—	—
Expected holding period (years) ¹	—	5.7	5.5	5.8
Weighted-average volatility factor ²	—	1.07	1.14	1.04
Estimated forfeiture rates for options granted ³	— %	24 %	30 %	27 %

- (1) Expected holding period is based on historical experience of similar awards, giving consideration to the contractual terms of the stock-based awards, vesting schedules and the expectations of future employee behavior.
- (2) Weighted average volatility is based on the historical volatility of our common stock.
- (3) Estimated forfeiture rates are based on historical data.

As of September 30, 2021, 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 1.3 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:

<i>(in thousands)</i>	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Weighted-average anti-dilutive common shares resulting from options	692	30	596	31
Weighted-average anti-dilutive common shares resulting from warrants	2,949	279	1,651	279
Restricted stock	19	—	6	—
Convertible debt	—	108	—	108
	<u>3,660</u>	<u>417</u>	<u>2,253</u>	<u>418</u>

4. Molteni Purchase Agreement

On March 21, 2018, we entered into a purchase agreement, or Molteni Purchase Agreement, with L. Molteni & C. Dei Frattelli Alitti Società Di Esercizio S.P.A., or 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, or DSRA, with Molteni and Horizon Technology Finance Corporation, or 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 provided for the release to us of the remaining collateral.

5. 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. 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 Laboratories, Ltd., or DPT, our contract manufacturer for our Probuphine product, provided for a minimum annual manufacturing fee of \$1.0 million. In the event we did not have DPT manufacture sufficient quantities of product to exceed the minimum annual manufacturing fee, DPT may 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 (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.

7. Debt Agreements

Horizon and Molteni Loans

In March 2018, we entered into an Amended and Restated Venture Loan and Security Agreement, or 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 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 located at DPT, 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, or PPP Loan, pursuant to the Paycheck Protection Program of the CARES Act that bore interest at the annual rate of 1.0% and matured in April 2022. The proceeds of the PPP Loan were to be used to retain workers and maintain payroll and make mortgage interest, lease and utility payments and were subject to forgiveness in accordance with requirements of the Small Business Administration. The PPP Loan originally had a six-month deferral of payments period which was extended to sixteen months during the third quarter of 2020. In May 2021, the entire balance of the PPP loan along with accrued interest was forgiven and the approximately \$0.7 million gain on extinguishment of the debt was included in other income (expense) in our condensed statements of operations and comprehensive loss.

8. Stockholders' Equity

Our common stock outstanding as of September 30, 2021 and December 31, 2020 was 9,864,158 shares and 7,139,068 shares, respectively.

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 \$9,000 of stock-based compensation expense during the three-month period ended September 30, 2021.

The following table summarizes restricted stock activity:

	<u>September 30, 2021</u>
Outstanding at December 31, 2020	—
Issued	50,000
Forfeited or expired	—
Outstanding at September 30, 2021	<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.

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 classified as equity, were exercisable immediately and will expire in July 2026. The net cash proceeds from this offering were approximately \$8.8 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 condensed statements of operations and comprehensive loss. The January 2020 Warrants were originally recorded as liabilities. In March 2020, we amended the January 2020 Warrants and warrants we issued in connection with a financing in August 2019 to modify certain provisions that had required them to be previously classified as liabilities and to enable them to be classified as equity under the relevant accounting standards. As a result, we reclassified the fair value of such warrants on the date of the amendment from warrant liabilities to additional paid-in capital in the balance sheet and recognized an approximately \$0.9 million non-cash loss on changes in the fair value of warrants in the condensed statements of operations and comprehensive loss.

September 2020 Offering

In September 2020, we completed a registered direct offering with several institutional investors pursuant to which we issued 648,000 shares of our common stock at a price of \$4.20 per share. We received net cash proceeds of approximately \$2.4 million, after deduction of underwriting fees and other offering expenses.

9. Discontinued Operations

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

	Three Months Ended September 30, 2020	Nine Months Ended September 30, 2020
	(In thousands, except per share data)	
Revenue:		
Product revenue	\$ 102	\$ 388
Costs and expenses:		
Cost of goods sold	683	1,082
Research and development	675	1,503
Selling, general and administrative	2,221	6,084
Total costs and expenses	3,579	8,669
Loss from discontinued operations	(3,477)	(8,281)
Other expense, net	—	—
Net loss from discontinued operations	\$ (3,477)	\$ (8,281)
Basic and diluted net loss per common share from discontinued operations	\$ (1.07)	\$ (2.70)
Weighted average shares used in computing basic and diluted net loss per common share	3,264	3,062

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

	September 30, 2021	December 31, 2020
<i>(In thousands)</i>		
Receivables	\$ 160	\$ —
Prepaid expenses and other current assets	27	181
Discontinued operations – current assets	\$ 187	\$ 181
Accounts payable	\$ 752	\$ 1,515
Accrued clinical trials expenses	9	80
Accrued sales allowances	—	61
Other accrued liabilities	352	304
Discontinued operations – current liabilities	\$ 1,113	\$ 1,960

During the three and nine months ended September 30, 2020 we recognized non-cash stock-based compensation expenses of approximately \$9,000 and \$110,000, respectively, 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, or 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 SEC include, but are not necessarily limited to, those relating to uncertainties relating to:

- the 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;
- 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 and uncertainties referred to in this Quarterly Report on Form 10-Q or included in our other public disclosures or our other periodic reports or documents filed with or furnished to the SEC 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.

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.

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 and Nine Months ended September 30, 2021 and 2020

Revenues

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2021	2020	Change	2021	2020	Change
	(In thousands)					
Revenues:						
License revenue	\$ 4	\$ —	\$ 4	\$ 9	\$ 6	\$ 3
Product revenue	36	—	36	236	39	197
Grant revenue	224	1,018	(794)	1,146	3,348	(2,202)
Total revenues	<u>\$ 264</u>	<u>\$ 1,018</u>	<u>\$ (754)</u>	<u>\$ 1,391</u>	<u>\$ 3,393</u>	<u>\$ (2,002)</u>

The decrease in total revenues from continuing operations for the three and nine months ended September 30, 2021 was primarily due to decreases in grant revenues primarily related to the type and timing of development activities performed during the periods presented, which were partially offset by an increase in product revenues. Product revenues from continuing operations for the three and nine months ended September 30, 2021 consisted of sales of Probuphine related product materials to Molteni for the EU. Revenue from the sale of Probuphine in the U.S. during the three and nine months ended September 30, 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 September 30,			Nine Months Ended September 30,		
	2021	2020	Change	2021	2020	Change
	(In thousands)					
Operating expenses:						
Cost of goods sold	\$ —	\$ —	\$ —	\$ 199	\$ —	\$ 199
Research and development	1,193	887	306	4,716	4,343	373
Selling, general and administrative	979	1,327	(348)	3,341	4,052	(711)
Total operating expenses	<u>\$ 2,172</u>	<u>\$ 2,214</u>	<u>\$ (42)</u>	<u>\$ 8,256</u>	<u>\$ 8,395</u>	<u>\$ (139)</u>

Cost of goods sold from continuing operations reflects costs and expenses associated with sales of Probuphine related product materials to Molteni for the EU. Cost of goods sold related to the sale of Probuphine in the U.S. during the three and nine months ended September 30, 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 for the three and nine months ended September 30, 2021 was primarily associated with activities related to non-clinical studies required for the planned Investigational New Drug 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 and nine months ended September 30, 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.

The decrease in general and administrative expenses from continuing operations for the three and nine months was primarily related to the substantial non-recurring consulting, legal and other professional fees incurred in connection with the stockholder meetings held in 2020 which were partially offset by increases in non-cash stock-based compensation. Selling and marketing expenses related to the sale of Probuphine in the U.S. during the three and nine months ended September 30, 2020 have been reclassified to discontinued operations (see Note 9 to the condensed financial statements included in this report for more information).

Other Income (Expense), Net

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2021	2020	Change	2021	2020	Change
	(In thousands)					
Other income (expense):						
Interest expense, net	\$ —	\$ (246)	\$ 246	\$ (2)	\$ (718)	\$ 716
Non-cash loss on changes in fair value of warrants	—	—	—	—	(923)	923
Gain on debt extinguishment	—	—	—	661	—	661
Other expense, net	(7)	(13)	6	(30)	(233)	203
Other income (expense), net	<u>\$ (7)</u>	<u>\$ (259)</u>	<u>\$ 252</u>	<u>\$ 629</u>	<u>\$ (1,874)</u>	<u>\$ 2,503</u>

The decrease in other expense, net for the three months ended September 30, 2021 was primarily due to decreases in interest expense resulting from the settlement of debt in October 2020. The increase in other income, net for the nine months ended September 30, 2021 was primarily due to a gain on debt extinguishment resulting from the May 2021 forgiveness of our outstanding PPP Loan and decreases in interest expense resulting from the settlement of debt in October 2020. During the nine months ended September 30, 2020, we incurred approximately \$0.9 million in non-cash losses on changes in the fair value of warrants, approximately \$0.7 million of interest expense related to our debt, and approximately \$0.2 million in costs attributable to the issuance of warrants.

Net Loss and Net Loss per Share

Our net loss from continuing operations for the three-month period ended September 30, 2021 was approximately \$1.9 million, or approximately \$0.19 per share, compared to our net loss from continuing operations of approximately \$1.5 million, or approximately \$0.45 per share, for the comparable period in 2020. Our net loss from discontinued operations for the three-month period ended September 30, 2020 was approximately \$3.5 million, or approximately \$1.07 per share. Our net loss from continuing operations for the nine-month period ended September 30, 2021 was approximately \$6.2 million, or approximately \$0.64 per share, compared to our net loss from continuing operations of approximately \$6.9 million, or approximately \$2.25 per share, for the comparable period in 2020. Our net loss from discontinued operations for the nine-month period ended September 30, 2020 was approximately \$8.3 million, or approximately \$2.70 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 September 30, 2021, we had working capital of approximately \$6.9 million compared to working capital of approximately \$3.1 million at December 31, 2020.

In May 2021, the approximately \$0.7 million of outstanding debt related to our April 2020 PPP Loan was forgiven.

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 \$8.8 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 nine months ended September 30, 2020, we received an aggregate of approximately \$7.0 million in cash proceeds from the exercises of warrants to purchase approximately 1,038,147 shares of our common stock.

At September 30, 2021, we had cash and cash equivalents of approximately \$7.4 million, which we believe is sufficient to fund our planned operations into the second 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

	Nine Months Ended September 30,	
	2021	2020
	(In thousands)	
Net cash used in operating activities	(6,818)	(12,642)
Net cash used in investing activities	(18)	(531)
Net cash provided by financing activities	8,841	12,023
Net increase (decrease) in cash and cash equivalents	2,005	(1,150)

Net cash used in operating activities for the nine months ended September 30, 2021 consisted primarily of our net loss of approximately \$6.2 million, approximately \$0.7 million related to a gain on debt extinguishment, and approximately \$1.4 million related to net changes in operating assets and liabilities, partially offset by approximately \$1.5 million of non-cash charges primarily related to stock-based compensation and depreciation and amortization. Net cash used in operating activities for the nine months ended September 30, 2020 consisted primarily of our net loss of approximately \$15.2 million, partially offset by approximately \$0.3 million related to net changes in operating assets and liabilities, approximately \$2.0 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.

Net cash provided by financing activities for the nine months ended September 30, 2021 consisted of net cash proceeds from the January 2021 offering. Net cash provided by financing activities for the nine months ended September 30, 2020 consisted of approximately \$4.3 million of net cash proceeds from equity offerings, approximately \$7.0 million of net cash proceeds from the exercises of warrants to purchase our common stock and approximately \$0.7 million from our April 2020 PPP Loan.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our market risk disclosures set forth in our 2020 10-K 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 September 30, 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 and nine months ended September 30, 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 (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.

We recently became aware of the legal matter filed by FirstString Research, Inc. against several parties, including James McNab, Jr. and JT Pharma, currently pending in the United States District Court for the District of South Carolina. We are not a party to the lawsuit. Among the numerous allegations contained in the FirstString complaint are claims of allegedly unlawful actions taken by Mr. McNab, JT Pharma and others surrounding the TP-2021 asset that was sold to us in October 2020. Based on a preliminary evaluation of the matters described in the complaint, we do not believe there is any material risk to our company or our TP-2021 development program associated with this matter.

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 2020 10-K, which could materially affect our business, financial condition or future results. The risks described in our 2020 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 electronically stored 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 electronically stored 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

<u>No.</u>	<u>Description</u>
10.1	Amendment to Employment Agreement between the Registrant and Marc Rubin⁽¹⁾
31.1	Certification of the Principal Executive and Financial Officer pursuant to Rule 13(a)-14(a) of the Securities Exchange Act of 1934
32.1	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
101.INS	XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL 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 - The cover page interactive data file does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document

(1) Incorporated by reference from the Registrant's Current Report on Form 8-K dated October 28, 2021.

