

SECURITIES AND EXCHANGE COMMISSION

FORM 10-Q

Quarterly report pursuant to sections 13 or 15(d)

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FILER

TITAN PHARMACEUTICALS INC

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SIC: **2836** Biological products, (no disgnostic substances)

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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, 2020.

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. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

| | | | |
|---------------------------|-------------------------------------|-------------------------|--------------------------|
| Large accelerated filer | <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 November 10, 2020 |
|---------------------------------|---|
| Common Stock, par value \$0.001 | 196,763,180 |

Titan Pharmaceuticals, Inc.

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Part I. Financial Information

Item 1. Financial Statements

TITAN PHARMACEUTICALS, INC.

CONDENSED BALANCE SHEETS (in thousands, except per share data)

| | September 30, 2020 (unaudited) | December 31, 2019 (Note 1) |
|---|--------------------------------------|----------------------------------|
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 4,073 | \$ 5,223 |
| Receivables | 423 | 993 |
| Inventory | 1,073 | 998 |
| Prepaid expenses and other current assets | 1,080 | 1,094 |
| Total current assets | <u>6,649</u> | <u>8,308</u> |
| Property and equipment, net | 1,161 | 817 |
| Operating lease right-of-use asset | 208 | 397 |
| Total assets | <u>\$ 8,018</u> | <u>\$ 9,522</u> |
| Liabilities and Stockholders' Equity (Deficit) | | |
| Current liabilities: | | |
| Accounts payable | \$ 1,750 | \$ 1,401 |
| Accrued clinical trials expenses | 829 | 309 |
| Accrued sales allowances | 119 | 809 |
| Other accrued liabilities | 875 | 809 |
| Operating lease liability, current | 222 | 272 |
| Current portion of long-term debt | 2,082 | — |
| Total current liabilities | <u>5,877</u> | <u>3,600</u> |
| Operating lease liability, non-current | — | 150 |
| Long-term debt | 3,038 | 4,019 |
| Warrant liability | — | 320 |
| Total liabilities | <u>8,915</u> | <u>8,089</u> |
| Stockholders' equity (deficit): | | |
| Common stock, at amounts paid-in | 117 | 57 |
| Additional paid-in capital | 363,180 | 350,413 |
| Accumulated deficit | (364,194) | (349,037) |
| Total stockholders' equity (deficit) | <u>(897)</u> | <u>1,433</u> |
| Total liabilities and stockholders' equity (deficit) | <u>\$ 8,018</u> | <u>\$ 9,522</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 | | Nine Months Ended | |
|---|--------------------|------------|-------------------|-------------|
| | September 30, | | September 30, | |
| | 2020 | 2019 | 2020 | 2019 |
| Revenues: | | | | |
| License revenue | \$ — | \$ — | \$ 6 | \$ 313 |
| Product revenue | 102 | 190 | 427 | 811 |
| Grant revenue | 1,018 | 757 | 3,348 | 1,270 |
| Total revenues | 1,120 | 947 | 3,781 | 2,394 |
| Operating expenses: | | | | |
| Cost of goods sold | 683 | 188 | 1,081 | 738 |
| Research and development | 1,562 | 1,619 | 5,846 | 5,370 |
| Selling, general and administrative | 3,549 | 3,023 | 10,137 | 9,336 |
| Total operating expenses | 5,794 | 4,830 | 17,064 | 15,444 |
| Loss from operations | (4,674) | (3,883) | (13,283) | (13,050) |
| Other expense: | | | | |
| Interest expense, net | (246) | (238) | (718) | (737) |
| Non-cash gain (loss) on changes in the fair value of warrants | — | 1,041 | (923) | 1,066 |
| Gain on debt extinguishment | — | 291 | — | 226 |
| Other income (expense), net | (12) | (14) | (233) | (22) |
| Other income (expense), net | (258) | 1,080 | (1,874) | 533 |
| Net loss and comprehensive loss | \$ (4,932) | \$ (2,803) | \$ (15,157) | \$ (12,517) |
| Basic and diluted net loss per common share | \$ (0.05) | \$ (0.18) | \$ (0.17) | \$ (0.89) |
| Weighted average shares used in computing basic and diluted net loss per common share | 97,906 | 15,517 | 91,848 | 14,112 |

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 | Equity (Deficit) |
|--|--------------|--------|----------------------------------|------------------------|---------------------|
| | Shares | Amount | | | |
| Balances at December 31, 2019 | 57,379 | \$ 57 | \$ 350,413 | \$ (349,037) | \$ 1,433 |
| Net loss | — | — | — | (5,584) | (5,584) |
| Issuance of common stock, net | 8,700 | 9 | 443 | — | 452 |
| Issuance of common stock upon exercises of warrants, net | 27,388 | 27 | 6,135 | — | 6,162 |
| Reclassification of warrants from liability | — | — | 2,897 | — | 2,897 |
| Stock-based compensation | — | — | (84) | — | (84) |
| Balances at March 31, 2020 | 93,467 | \$ 93 | \$ 359,804 | \$ (354,621) | \$ 5,276 |
| Net loss | — | — | — | (4,641) | (4,641) |
| Issuance of common stock upon exercises of warrants, net | 3,756 | 4 | 842 | — | 846 |
| Stock-based compensation | — | — | 79 | — | 79 |
| Balances at June 30, 2020 | 97,223 | \$ 97 | \$ 360,725 | \$ (359,262) | \$ 1,560 |
| Net loss | — | — | — | (4,932) | (4,932) |
| Issuance of common stock, net | 19,440 | 20 | 2,424 | — | 2,444 |
| Issuance of common stock upon exercises of warrants, net | 100 | — | 22 | — | 22 |
| Stock-based compensation | — | — | 9 | — | 9 |
| Balances at September 30, 2020 | 116,763 | \$ 117 | \$ 363,180 | \$ (364,194) | \$ (897) |

| | Common Stock | | Additional Paid-In Capital | Accumulated Deficit | Equity (Deficit) |
|--|--------------|--------|----------------------------------|------------------------|---------------------|
| | Shares | Amount | | | |
| Balances at December 31, 2018 | 13,010 | \$ 13 | \$ 339,397 | \$ (332,579) | \$ 6,831 |
| Net loss | — | — | — | (4,517) | (4,517) |
| Issuance of common stock upon exercises of warrants, net | 404 | — | 605 | — | 605 |
| Stock-based compensation | — | — | 136 | — | 136 |
| Balances at March 31, 2019 | 13,414 | \$ 13 | \$ 340,138 | \$ (337,096) | \$ 3,055 |
| Net loss | — | — | — | (5,197) | (5,197) |
| Issuance of common stock upon exercises of warrants, net | 70 | — | 105 | — | 105 |
| Issuance of common stock upon conversion of convertible loan | 448 | 1 | 649 | — | 650 |
| Issuance of common stock in at-the-market offerings, net | 330 | — | 466 | — | 466 |
| Stock-based compensation | — | — | 350 | — | 350 |
| Balances at June 30, 2019 | 14,262 | \$ 14 | \$ 341,708 | \$ (342,293) | \$ (571) |
| Net loss | — | — | — | (2,803) | (2,803) |
| Issuance of common stock upon exercises of warrants, net | 1,372 | 1 | 12 | — | 13 |
| Issuance of common stock upon conversion of convertible loan | — | — | — | — | — |
| Issuance of common stock in at-the-market offerings, net | 1,480 | 2 | 571 | — | 573 |

| | | | | | | | | | |
|--------------------------------|---------------|----|-----------|----|----------------|----|------------------|----|----------------|
| Stock-based compensation | — | | — | | 128 | | — | | 128 |
| Balances at September 30, 2019 | <u>17,144</u> | \$ | <u>17</u> | \$ | <u>342,419</u> | \$ | <u>(345,096)</u> | \$ | <u>(2,660)</u> |

TITAN PHARMACEUTICALS, INC.

CONDENSED STATEMENTS OF CASH FLOWS
(in thousands)
(unaudited)

| | Nine Months Ended September 30, | |
|---|------------------------------------|-----------------|
| | 2020 | 2019 |
| Cash flows from operating activities: | | |
| Net loss | \$ (15,157) | \$ (12,517) |
| Adjustments to reconcile loss to net cash used in operating activities: | | |
| Depreciation and amortization | 227 | 186 |
| Non-cash interest expense | 447 | 467 |
| Non-cash (gain) loss on changes in fair value of warrants | 923 | (1,066) |
| Non-cash loss on asset impairment | 433 | — |
| Stock-based compensation | 4 | 614 |
| Finance costs attributable to issuance of warrants | 211 | — |
| Gain on debt extinguishment | — | (226) |
| Other | (11) | (36) |
| Changes in operating assets and liabilities: | | |
| Receivables | 570 | 962 |
| Inventory | (508) | — |
| Prepaid expenses and other assets | 14 | (492) |
| Accounts payable | 309 | (111) |
| Accrued sales allowances | (690) | 750 |
| Other accrued liabilities | 586 | — |
| Deferred revenue | — | (313) |
| Net cash used in operating activities | <u>(12,642)</u> | <u>(11,782)</u> |
| Cash flows from investing activities: | | |
| Purchases of property and equipment | (531) | (144) |
| Net cash used in investing activities | <u>(531)</u> | <u>(144)</u> |
| Cash flows from financing activities: | | |
| Net proceeds from equity offering | 4,339 | 2,467 |
| Net proceeds from the exercises of common stock warrants | 7,030 | 724 |
| Net loan proceeds | 654 | — |
| Net cash provided by financing activities | <u>12,023</u> | <u>3,191</u> |
| Net decrease in cash and cash equivalents | <u>(1,150)</u> | <u>(8,735)</u> |
| Cash, cash equivalents and restricted cash at beginning of period | 5,223 | 9,656 |
| Cash, cash equivalents and restricted cash at end of period | <u>\$ 4,073</u> | <u>\$ 921</u> |
| Supplemental disclosure of cash flow information: | | |
| Interest paid | \$ 295 | \$ 328 |
| Non-cash conversion of Molteni Convertible Loan | \$ — | \$ 650 |

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 provides the potential for an efficacy and/or safety benefit. Probuphine® (buprenorphine) implant is the first product based on our ProNeura technology approved in the U.S., Canada and the European Union, or EU, for the maintenance treatment of opioid use disorder, or OUD, in select patients. In October 2020, we made a determination to discontinue commercial activities associated with marketing Probuphine in the U.S. and we are now transitioning back to a development stage enterprise. We operate in only one business segment, the development of pharmaceutical products.

Basis of Presentation

The accompanying unaudited condensed financial statements have been prepared in accordance with U.S. generally accepted accounting principles (“GAAP”) for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by 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, 2020 are not necessarily indicative of the results that may be expected for the year ending December 31, 2020, or any future interim periods.

The balance sheet at December 31, 2019 is derived from the audited financial statements at that date, but does not include all of 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, 2019, as filed with the Securities and Exchange Commission (“SEC”).

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

At September 30, 2020, we had cash and cash equivalents of approximately \$4.1 million, which we believe along with the approximately \$5.7 million of net proceeds from our October 2020 public offering (the “2020 Public Offering”) is sufficient to complete the wind down of the U.S. Probuphine commercialization activities and fund our planned operations into the third quarter of 2021. We will require additional funds to finance our operations beyond such period. 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.

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 financial statements are issued or available to be issued, which is referred to as the “look-forward period” as defined by Accounting Standard Update (“ASU”) No. 2014-15. As part of this assessment, based on conditions that are known and reasonably knowable to us, we will consider various scenarios, forecasts, projections, estimates and will make certain key assumptions, including the timing and nature of projected cash expenditures or programs, and its ability to delay or curtail expenditures or programs, if necessary, among other factors. Based on this assessment, as necessary or applicable, we make certain assumptions around implementing curtailments or delays in the nature and timing of programs and expenditures to the extent we deem probable those implementations can be achieved and we have the proper authority to execute them within the look-forward period in accordance with ASU No. 2014-15.

Based upon the above assessment, we concluded that, at the date of filing the financial statements in this Quarterly Report on Form 10-Q for the nine months ended September 30, 2020, 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 financial statements were issued.

Use of Estimates

The preparation of these unaudited condensed financial statements requires that we make estimates and judgments that affect the reported amounts of assets, liabilities, revenues, expenses and related disclosures. On an ongoing basis, we evaluate our estimates, including critical accounting policies or estimates related to warrants issued in equity financing, research and development expenses, income taxes, inventories, revenues, accrued sales allowances, contingencies and litigation and share-based compensation. We base our estimates on historical experience, information received from third parties and on various market specific and other relevant assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results could differ significantly from those estimates under different assumptions or conditions.

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 | |
|----------------------------|---------------------------|--------------------------|
| | September 30, 2020 | December 31, 2019 |
| Raw materials and supplies | 442 | 563 |
| Finished goods | 631 | 435 |
| | <u>\$ 1,073</u> | <u>\$ 998</u> |

Revenue Recognition

We generate revenue principally from collaborative research and development arrangements, technology licenses and sales, government grants and, prior to the discontinuance of our commercial activities in October 2020, the sale of Probuphine in the U.S. Consideration received for revenue arrangements with multiple components is allocated among the separate performance obligations based upon their relative estimated standalone selling price.

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

Net Product Revenue

Until the discontinuance of our commercial activities in October 2020, we recognized revenue from product sales when control of the product transferred, 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, including 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 is typically at stated contractual rates. The actual outcome of this variable consideration may materially differ from our estimates.

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.

The following table provides a summary of activity with respect to our product returns, and discounts and rebates, which are included on our condensed balance sheets within accrued sales allowances (in thousands):

| | Accrued Sales Allowances | | | Allowance for Doubtful Accounts |
|-------------------------------|--------------------------------|--|---------------|--|
| | Product Return Allowance | Discounts and Rebates Allowance | Total | |
| Balance at December 31, 2019 | \$ 721 | \$ 88 | \$ 809 | \$ 63 |
| Provision | 94 | 40 | 134 | 22 |
| Payments/credits | (722) | (102) | (824) | (76) |
| Balance at September 30, 2020 | <u>\$ 93</u> | <u>\$ 26</u> | <u>\$ 119</u> | <u>\$ 8</u> |

During the nine months ended September 30, 2020, we received customer returns of approximately \$0.7 million that had been reserved for previously.

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.

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 activity is considered variable until such costs are reimbursed at which point they are considered fixed. We allocate the total transaction price to each performance obligation based on the relative estimated standalone selling prices of the promised goods or services for each performance obligation.

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

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

Allocation of Consideration

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

Timing of Recognition

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

Research and Development Costs and Related Accrual

Research and development expenses include internal and external costs. Internal costs include salaries and employment related expenses, facility costs, administrative expenses and allocations of corporate costs. External expenses consist of costs associated with outsourced contract research organization (“CRO”) activities, sponsored research studies, product registration and patent application and prosecution. We also record accruals for estimated ongoing non-clinical and clinical research 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 clinical research, 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

In February 2016, the Financial Accounting Standards Board (the “FASB”) issued ASU No. 2016-02, Leases (Topic 842), to enhance the transparency and comparability of financial reporting related to leasing arrangements.

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 sheet 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 sheet.

The following table presents obligation related to our operating lease:

| | | |
|--|----|------|
| 2020 | \$ | 78 |
| 2021 | | 155 |
| Total minimum lease payments (base rent) | | 233 |
| Less: imputed interest | | (11) |
| Total operating lease liabilities | \$ | 222 |

Recent Accounting Pronouncements

Accounting Standards Adopted

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

Accounting Standards Not Yet Adopted

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

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

Subsequent Events

We have evaluated events that have occurred after September 30, 2020 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. Our derivative liability is classified within Level 3 of the fair value hierarchy because the fair value is calculated using significant judgment based on our own assumptions in the valuation of this liability.

At September 30, 2020 and December 31, 2019, the fair value of our investments in money market funds were approximately \$3.8 million and approximately \$4.9 million, respectively, which are included within our cash and cash equivalents in our condensed balance sheets.

2. Stock Plans

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

(in thousands)

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|-------------------------------------|-------------------------------------|--------|------------------------------------|--------|
| | 2020 | 2019 | 2020 | 2019 |
| Research and development | \$ — | \$ — | \$ — | \$ 91 |
| Selling, general and administrative | 9 | 128 | 4 | 523 |
| Total stock-based compensation | \$ 9 | \$ 128 | \$ 4 | \$ 614 |

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, | |
|---|-------------------------------------|------|------------------------------------|------|
| | 2020 | 2019 | 2020 | 2019 |
| Weighted-average risk-free interest rate | 0.3% | — | 0.4% | 2.2% |
| Expected dividend payments | — | — | — | — |
| Expected holding period (years) ¹ | 5.7 | — | 5.8 | 5.4 |
| Weighted-average volatility factor ² | 1.07 | — | 1.04 | 0.94 |
| Estimated forfeiture rates for options granted ³ | 24% | — | 27% | 21% |

- (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.

The following table summarizes option activity:

(in thousands)

| | Options (in thousands) | Weighted Average Exercise Price per share | Weighted Average Remaining Option Term (in years) | Aggregate Intrinsic Value (in thousands) |
|-----------------------------------|---------------------------|---|--|---|
| Outstanding December 31, 2019 | 1,192 | \$ 6.23 | 7.9 | \$ — |
| Granted | 60 | 0.27 | | |
| Forfeited or expired | (334) | 1.88 | | |
| Outstanding at September 30, 2020 | 918 | 7.42 | 6.8 | — |
| Exercisable at September 30, 2020 | 827 | 8.16 | 6.6 | — |

Options to purchase 10,000 common shares were granted during the three month periods ended September 30, 2020.

As of September 30, 2020, there was approximately \$30,000 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 1.8 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 | | Nine Months Ended | |
|---|---------------------------|--------------|--------------------------|--------------|
| | September 30, | | September 30, | |
| | 2020 | 2019 | 2020 | 2019 |
| Weighted-average anti-dilutive common shares resulting from options | 913 | 1,282 | 934 | 1,027 |
| Weighted-average anti-dilutive common shares resulting from warrants | 8,342 | 5,961 | 8,342 | 1,222 |
| Weighted-average anti-dilutive common shares resulting from convertible loans | 3,243 | 330 | 3,243 | 332 |
| | <u>12,498</u> | <u>7,573</u> | <u>12,519</u> | <u>2,581</u> |

4. Molteni Purchase Agreement

On March 21, 2018, we entered into a purchase agreement (“Molteni Purchase Agreement”) with L. Molteni & C. Dei Fratelli Alitti Società Di Esercizio S.P.A. (“Molteni”) pursuant to which Molteni acquired the European intellectual property related to Probuphine, including the marketing authorization application under review by the European Medicines Agency (“EMA”), 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 (the “Molteni Territory”).

In connection with the Molteni Purchase Agreement, we received an initial payment of €2.0 million (approximately \$2.4 million), of which approximately \$1.0 million was allocated to the transfer of the intellectual property, which was recognized immediately, and approximately \$1.4 million to our efforts towards the approval by the EMA by using the expected cost-plus approach to estimate the standalone selling price of and other regulatory bodies (“Titan Services”), which was recorded as deferred revenue and amortized as the performance obligations associated with the Titan Services being satisfied over time. Titan Services included employee-related expenses as well as other manufacturing, regulatory and clinical costs. During the three months ended March 31, 2019, we fully amortized our deferred revenue and recognized approximately \$0.3 million of revenue associated with the completion of Titan Services.

In August 2018, we entered into an amendment to the Molteni Purchase Agreement, pursuant to which Molteni made an immediate payment of €950,000 (approximately \$1.1 million) and a convertible loan of €550,000 (approximately \$0.6 million) (“Molteni Convertible Loan”) (see Note 5) to us, both in exchange for the elimination of an aggregate of €2.0 million (approximately \$2.3 million) of regulatory milestones provided for in the Molteni Purchase Agreement.

In September 2019, we entered into an additional amendment to the Molteni Purchase Agreement, pursuant to which the percentage earn-out payments on net sales were reduced and payments of any earn-outs were delayed until the later of (i) January 1, 2021 or (ii) the one year anniversary of completion of compliance by our manufacturer with EU requirements (currently anticipated to occur during the second quarter of this year).

In October 2020, in connection with the settlement of our debt obligations, we forfeited our rights to any future payments under the Molteni Purchase Agreement. See Note 8 “Subsequent Events.”

5. Debt Agreements

Horizon and Molteni Loans

In March 2018, we entered into an Amended and Restated Venture Loan and Security Agreement (the “Loan Agreement”) with Horizon Credit II LLC (“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 \$7.20 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 6,667 shares of our common stock with an exercise price per share of \$7.20 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 \$0.225 and to cap the number of shares issuable upon conversion to 3,422,777, with any balance repayable in cash.

In accordance with ASC 470, the amendment to the loan from Molteni is accounted for under debt extinguishment accounting, which required us to extinguish the carrying amount of the loan prior to the amendment and reacquire the loan after the amendment. As a result, during the three months ended September 30, 2019, we recorded approximately \$0.3 million gain on debt extinguishment related to the write-off of the balance of the accreted final payment of the loan. The modification to the loan from Horizon did not constitute debt extinguishment and, therefore, did not have any impact to our condensed financial statements.

Repayment of the loans is on an interest-only basis, followed by monthly payments of principal and accrued interest for the balance of the 46-month term. The loans bear interest at a floating coupon rate of one-month LIBOR (floor of 1.10%) plus 8.40%. A final payment equal to 5.0% of each loan tranche will be due on the scheduled maturity date for such loan. In addition, if we repay all or a portion of the loan prior to the applicable maturity date, we will pay Horizon and Molteni prepayment penalty fees.

Debt discount associated with the Horizon and Molteni Loans was approximately \$0.3 million as of both September 30, 2020 and December 31, 2019.

In October 2020, we settled all of our outstanding debt obligations, to Horizon and Molteni. See Note 8 “Subsequent Events.”

Molteni Convertible Loan

In connection with the amendment to the Molteni Purchase Agreement (see Note 4), in June 2019, the Molteni Convertible Loan, together with unpaid accrued interest, was converted in full into 448,287 shares of our common stock at \$1.50 per share upon the receipt of EMA approval of Sixmo. As a result, we recorded approximately \$0.1 million loss on debt extinguishment.

Paycheck Protection Program Loan

On April 20, 2020, we received an approximately \$0.7 million loan (“PPP Loan”) pursuant to the Paycheck Protection Program of the CARES Act. The PPP Loan matures in April 2022 with an annual interest rate of 1.0%. The PPP Loan originally had a six month deferral of payments period which was extended to sixteen months during the third quarter of 2020 and may be prepaid at any time without penalty. All other terms remained the same. Forgiveness of the loan, when requested, is not automatic and is only available for principal that is used for the limited purposes that expressly qualify for forgiveness under SBA requirements. The proceeds of the PPP Loan are to be used to retain workers and maintain payroll and make mortgage interest, lease and utility payments. Approximately \$0.1 million of the PPP loan is included in current portion of long-term debt and approximately \$0.6 million is included in long-term debt on our condensed balance sheet at September 30, 2020.

6. Stockholders’ Equity

Our common stock outstanding as of September 30, 2020 and December 31, 2019 was 116,763,180 shares and 57,378,794 shares, respectively.

January 2020 Offering

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 8,700,000 shares of our common stock with an exercise price of \$0.25 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. During the three months ended March 31, 2020, financing costs of \$211,000 allocated to the January 2020 warrant liability were expensed and included in other income (expense) 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 19,440,000 shares of our common stock at a price of \$0.14 per share. We received net cash proceeds of approximately \$2.4 million, after deduction of underwriting fees and other offering expenses.

Common Stock Warrants

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 31,244,386 shares of our common stock.

7. Warrant Liabilities

On March 3, 2020, we amended certain outstanding warrants to purchase an aggregate of 11,552,314 shares of common stock, including the January 2020 Warrants and warrants we issued in connection with a financing in August 2019 (the “August 2019 Warrants”), to modify certain provisions that had required them to be previously classified as liabilities and to enable them to now be classified as equity under the relevant accounting standards. As a result, during the three months ended March 31, 2020, we reclassified the fair value of the warrants on the date of the amendment from warrant liabilities to additional paid-in capital in the condensed balance sheet and recognized a non-cash loss on changes in the fair value of warrants in the condensed statement of operations and comprehensive loss.

The following table provides a roll forward of the fair value of our warrant liabilities, the fair value of which was determined by Level 3 inputs for the nine months ended September 30, 2020 (in thousands):

| | | |
|--|----|----------------|
| Fair value, December 31, 2019 | \$ | 320 |
| Issuance of the January 2020 Warrants | | 1,654 |
| Change in fair value ⁽¹⁾ | | 923 |
| Reclassification of warrants to additional paid-in capital | | <u>(2,897)</u> |

Fair value, September 30, 2020

\$ —

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

The warrant liability associated with the January 2020 Warrants was classified within Level 3 of the fair value hierarchy. The following table presents the weighted-average key assumptions used to calculate the fair value of the January 2020 Warrants:

| | As of | |
|---|------------------|--------------------|
| | March 3, 2020 | January 7, 2020 |
| Expected volatility | 124% | 121% |
| Risk-free interest rate | 0.8% | 1.6% |
| Dividend yield | — | — |
| Expected term (in years) | 4.9 | 5.0 |
| Weighted-average fair value per share warrant | \$ 0.26 | \$ 0.19 |

The warrant liability associated with the August 2019 Warrants was classified within Level 3 of the fair value hierarchy. The following table presents the weighted-average key assumptions used to calculate the fair value of the August 2019 Warrants:

| | As of | |
|---|------------------|----------------------|
| | March 3, 2020 | December 31, 2019 |
| Expected volatility | 124% | 125% |
| Risk-free interest rate | 0.8% | 1.7% |
| Dividend yield | — | — |
| Expected term (in years) | 4.5 | 4.6 |
| Weighted-average fair value per share warrant | \$ 0.21 | \$ 0.11 |

8. Subsequent Events

In October 2020, we announced our decision to discontinue selling our Probuphine® (buprenorphine) implant and wind-down our commercialization activities and pursue a plan that will enable us to focus on our ProNeura-based product development efforts.

In October 2020, we entered into a Debt Settlement and Release Agreement (the “DSRA Agreement”) with Molteni and Horizon pursuant to which the parties agreed to settle the approximately \$5.2 million of outstanding indebtedness to Molteni and Horizon (\$4.0 million principal amount and approximately \$1.2 million in final payments) in exchange for the payment of \$1.6 million in cash, the transfer of certain Probuphine assets to Molteni, including manufacturing equipment, certain inventory and non-U.S. Probuphine intellectual property, and the termination of our rights to future payments under the Molteni Purchase Agreement.

In October 2020, we entered into an Asset Purchase Agreement (the “JT Agreement”) with JT Pharmaceuticals, Inc. (“JT Pharma”) to acquire JT Pharma’s kappa opioid agonist peptide, JT-09, for use in combination with our ProNeura® long-term, continuous drug delivery technology, for the treatment of chronic pruritus. Under the terms of the JT Agreement, JT Pharma received a \$15,000 closing payment and is entitled to receive future milestone payments, payable in cash or in stock, based on the achievement of regulatory milestones, and single-digit percentage earn-out payments on net sales of the product if successfully developed and approved for commercialization.

In October 2020, we completed the 2020 Public Offering pursuant to which we sold 80,000,000 units at a price of \$0.10 per unit, with each unit consisting of (i) one share of common stock and (ii) one warrant (the “October 2020 Warrants”) to purchase one share of common stock, resulting in gross proceeds of approximately \$8.0 million. The net proceeds of the 2020 Public Offering, after deduction of underwriting discounts and commissions and other offering expenses and the \$1.6 million payment pursuant to the DSRA Agreement, were approximately \$5.7 million. The October 2020 Warrants have an exercise price of \$0.10, will be exercisable commencing on the effective date of an increase in our authorized shares of common stock or a reverse split in an amount sufficient to permit the exercise in full of the October 2020 Warrants and will expire on the fifth anniversary of the initial exercise date.

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

Forward-Looking Statements

Statements in the following discussion and throughout this report that are not historical in nature are “forward-looking statements” within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act. You can identify forward-looking statements by the use of words such as “expect,” “anticipate,” “estimate,” “may,” “will,” “should,” “intend,” “believe,” and similar expressions. Although we believe the expectations reflected in these forward-looking statements are reasonable, such statements are inherently subject to risk and we can give no assurances that our expectations will prove to be correct. Actual results could differ from those described in this report because of numerous factors, many of which are beyond our control. These factors include, without limitation, those described under Item 1A “Risk Factors.” We undertake no obligation to update these forward-looking statements to reflect events or circumstances after the date of this report or to reflect actual outcomes.

References herein to “we,” “us,” “Titan,” and “our company” refer to Titan Pharmaceuticals, Inc. and its subsidiaries unless the context otherwise requires.

Overview

Company 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 EVA (ethylene-vinyl acetate) and a drug substance. The resulting product is a solid matrix that is administered subdermally, normally in the inner upper arm, or potentially in alternative sites, 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.

Probuphine was the first product based on our ProNeura technology approved in the U.S., 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. On October 15, 2020, we issued a press release announcing our decision to discontinue selling Probuphine (buprenorphine) implant in the U.S., wind down our commercialization activities and focus on our ProNeura-based product development programs. We based this decision on several factors; most notably that commercializing Probuphine with the requirements of the current product label and the Risk Evaluation and Mitigation Strategy, or REMS, program has proven to be onerous, leading to minimal utilization despite our significant efforts to overcome these obstacles. Other factors that have negatively impacted Titan’s ability to effectively commercialize Probuphine include the financial constraints that have limited our sales and marketing capabilities; suboptimal reimbursement rates; and the complexity of the distribution channel. The continually changing environment due to the COVID-19 pandemic has further exacerbated these issues. As a result, sales of Probuphine have been, and would likely continue for the foreseeable future to be, extremely limited. After careful review of the recent sales and marketing results, the hurdles that Titan has and will continue to face, and the substantial additional expenditures and resources that would be required, our board of directors made a determination to advise the U.S. Food and Drug Administration (“FDA”) of its decision to cease commercialization of Probuphine. A wind-down plan taking into considerations FDA and state regulatory requirements, as well as business considerations is underway.

In October 2020, we entered into the DSRA Agreement with Molteni and Horizon, the holders of our approximately \$5.2 million of outstanding secured debt (\$4.0 million principal amount and approximately \$1.2 million in payoff amounts) 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 Purchase Agreement with Molteni. The DSRA Agreement, which closed on October 30, 2020, provide for the release to us of the remaining collateral to enable us to continue operating as a research and development company.

Development Programs

Kappa Opioid Agonist Peptide Program

In October 2020, we entered into the JT Agreement with JT Pharma, for the acquisition and development of JT Pharma's kappa opioid agonist peptide, or JT 09, for use in combination with our ProNeura technology. James McNab, a member of our board of directors, is a principal of JT Pharma. Several years ago, we began limited laboratory work in collaboration with JT Pharma to assess the feasibility of delivering JT 09 through peptide-infused ProNeura implants in animal models. Our initial work focused on JT-09's ability to activate peripheral kappa opioid receptors, with the JT-09 ProNeura implants potentially providing a non-addictive treatment for certain types of pain. Recently, our collaboration with JT Pharma has pivoted to explore the feasibility of also using JT -09 implants in the treatment of chronic pruritus, a debilitating condition defined as itching of the skin lasting longer than six weeks. In 2015, an estimated 23 – 44 million Americans suffered from chronic pruritus in the setting of both cutaneous and systemic conditions. The antipruritic effect of kappa opioid agonists is thought to be related to their binding to kappa opioid receptors on keratinocytes, immune cells and peripheral itch neurons. We believe, based on our early animal data, that subcutaneous placement of the JT -09 implants could potentially deliver therapeutic concentrations of JT--09 for six months or longer following a single in-office procedure. The initial non-clinical studies designed to establish proof of concept in an animal model will be completed during Q2 2021, and, if successful, we will need to conduct Investigational New Drug, or IND, enabling safety and pharmacology studies. The efficacy of a kappa opioid agonist was first demonstrated in humans by Toray Industries, Inc., or Toray, using a highly potent small molecule kappa agonist, nalfurafine. Toray's application for nalfurafine was approved in Japan for the treatment of pruritus in end stage kidney disease, or ESKD, and chronic liver disease. More recently, Cara Therapeutics Inc., or Cara, has demonstrated in phase 2 and phase 3 clinical trials the efficacy of a selective kappa opioid receptor agonist peptide, CR845, in the treatment of pruritus associated with ESKD in patients undergoing dialysis, and Cara has announced plans to submit a New Drug Application in the U.S. in the second half of 2020. According to published reports, the prevalence of ESKD has been rising continuously, and reached approximately 750,000 in 2017. Pruritus affects approximately 40% of patients with ESKD and has been associated with poor quality of life, poor sleep, depression, and mortality. We believe a ProNeura rod containing JT- 09 could potentially eliminate the need for multiple weekly injections by delivering therapeutic levels of medication for six months or longer following implant.

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. An injectable formulation of nalmefene was approved by the FDA in 1995 for the management and reversal of opioid overdose, including respiratory depression. Oral nalmefene was approved by the European Medicines Agency in 2013 for treating alcohol dependence. The NIDA grant provides funds for the completion of implant formulation development, cGMP manufacturing and non-clinical studies required for filing an IND. During the first quarter of 2020 we met with the FDA to review our non-clinical development plans and obtain guidance regarding filing an IND. The FDA provided clear guidance on the type of development plan that we should follow, specifically that this product development should follow the 505(b)(i) regulatory pathway due to the lack of safety data on nalmefene for a long acting formulation, and the non-clinical studies that will be required to file an IND. Based on this input, collecting all the non-clinical chronic toxicology data will require an additional study as well as increasing the duration of an ongoing study that will delay filing of the IND to mid-2021. We have discussed the change in development plan with NIDA and they have accepted our plan to reallocate previously approved funds for conduct of the studies.

Management Restructuring

As previously disclosed, Sunil Bhonsle, our President and Chief Executive Officer, advised us of his desire to retire before the end of the year. Effective October 18, 2020, Kate DeVarney, Ph.D., our Executive Vice President and Chief Scientific Officer and a member of the board of directors, was promoted to the position of President and Chief Operating Officer. Effective October 31, 2020, Mr. Bhonsle stepped down from his executive role.

Dr. Marc Rubin, our Executive Chairman, together with Dr. DeVarney, will oversee our product development activities.

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 September 30, 2020 and 2019

Revenues

| | Three Months Ended September 30, | | | Nine Months Ended September 30, | | |
|-----------------|-------------------------------------|---------------|---------------|------------------------------------|-----------------|-----------------|
| | 2020 | 2019 | Change | 2020 | 2019 | Change |
| | (In thousands) | | | | | |
| Revenues: | | | | | | |
| License revenue | \$ — | \$ — | \$ — | \$ 6 | \$ 313 | \$ (307) |
| Product revenue | 102 | 190 | (88) | 427 | 811 | (384) |
| Grant revenue | 1,018 | 757 | 261 | 3,348 | 1,270 | 2,078 |
| Total revenues | <u>\$ 1,120</u> | <u>\$ 947</u> | <u>\$ 173</u> | <u>\$ 3,781</u> | <u>\$ 2,394</u> | <u>\$ 1,387</u> |

The increase in total revenues for the three and nine months ended September 30, 2020 compared to the same period in 2019 was primarily due to increases in grant revenue, partially offset by decreases in license and product revenue. Product revenue during the three and nine month periods ended September 30, 2020 declined substantially from the comparable periods in 2019 due to a substantial decrease in unit sales volumes, increased utilization of our patient assistance programs and the effects of the COVID-19 pandemic and the related shelter in place restrictions and clinic closures. Also, the first half of 2019 unit sales volume included initial purchases by specialty pharmacies. License revenue recognized for the nine months ended September 30, 2019 was related to the amortization of deferred revenue associated with the sale of our European intellectual property rights to Molteni.

Operating Expenses

| | Three Months Ended September 30, | | | Nine Months Ended September 30, | | |
|-------------------------------------|-------------------------------------|-----------------|---------------|------------------------------------|------------------|-----------------|
| | 2020 | 2019 | Change | 2020 | 2019 | Change |
| | (In thousands) | | | | | |
| Operating expenses: | | | | | | |
| Cost of goods sold | \$ 683 | \$ 188 | \$ 495 | \$ 1,081 | \$ 738 | \$ 343 |
| Research and development | 1,562 | 1,619 | (57) | 5,846 | 5,370 | 476 |
| Selling, general and administrative | 3,549 | 3,023 | 526 | 10,137 | 9,336 | 801 |
| Total operating expenses | <u>\$ 5,794</u> | <u>\$ 4,830</u> | <u>\$ 964</u> | <u>\$ 17,064</u> | <u>\$ 15,444</u> | <u>\$ 1,620</u> |

Cost of goods sold reflects costs and expenses associated with sales of our Probuphine product. The increase in cost of goods sold for the three and nine month periods ended September 30, 2020 was primarily related to an approximately \$0.4 million non-cash loss related to the impairment of inventory.

The increase in research and development costs for the nine months ended September 30, 2020 was primarily associated with increased activities related to our NIDA grant for the development of a nalmefene implant. 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 at such time as we are able to undertake the required Probuphine Phase 4 clinical studies and continue our current or any future ProNeura development programs to the extent these costs are not supported through grants or partners.

The increase in selling, general and administrative expenses for the three and nine months ended September 30, 2020 was primarily due to expenses associated with the commercialization of Probuphine, which resulted in increases in employee related expenses, consulting and professional fees, other outside services, travel costs and facilities related expenses.

Other Expense, Net

| | Three Months Ended September 30, | | | Nine Months Ended September 30, | | |
|---|-------------------------------------|-----------------|-------------------|------------------------------------|---------------|-------------------|
| | 2020 | 2019 | Change | 2020 | 2019 | Change |
| | (In thousands) | | | | | |
| Other expense: | | | | | | |
| Interest expense, net | \$ (246) | \$ (238) | \$ (8) | \$ (718) | \$ (737) | \$ 19 |
| Non-cash gain (loss) on changes in fair value of warrants | — | 1,041 | (1,041) | (923) | 1,066 | (1,989) |
| Gain (loss) on debt extinguishment | — | 291 | (291) | — | 226 | (226) |
| Other income, net | (12) | (14) | 2 | (233) | (22) | (211) |
| Other income (expense), net | <u>\$ (258)</u> | <u>\$ 1,080</u> | <u>\$ (1,338)</u> | <u>\$ (1,874)</u> | <u>\$ 533</u> | <u>\$ (2,407)</u> |

The decrease in other income (expense), net for the three months ended September 30, 2020 was primarily due to an approximately \$1.0 million non-cash gain on changes in the fair value of our warrants issued in connection with our August 2019 offering and an approximately \$0.3 million non-cash gain on debt extinguishment related to the modification of our loan from Molteni. The decrease in other income (expense), net for the nine months ended September 30, 2020 was primarily attributable to non-cash losses of approximately \$2.0 million related to changes in the fair value of our warrants and approximately \$0.2 million in costs attributable to the issuance of warrants.

Net Loss and Net Loss per Share

Our net loss for the three months ended September 30, 2020 was approximately \$4.9 million, or approximately \$0.05 per share, compared to our net loss of approximately \$2.8 million, or approximately \$0.18 per share, for the comparable period in 2019. Our net loss for the nine months ended September 30, 2020 was approximately \$15.2 million, or approximately \$0.17 per share, compared to our net loss of approximately \$12.5 million, or approximately \$0.89 per share, for the comparable period in 2019.

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, 2020, we had working capital of approximately \$0.8 million compared to working capital of approximately \$4.7 million at December 31, 2019.

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 8,700,000 shares of our common stock with an exercise price of \$0.25 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.

On April 20, 2020, we received an approximately \$0.7 million PPP Loan under the Paycheck Protection Program (“PPP”) of the CARES Act. Under the terms of the CARES Act and the PPP Flexibility Act, we may apply for and be granted forgiveness for all or a portion of loan granted under the PPP, with such forgiveness to be determined, subject to limitations (including where our employees have been terminated and not re-hired by a certain date), based on the use of the loan proceeds for payment of payroll costs and any payments of mortgage interest, rent, and utilities. The terms of any forgiveness may also be subject to further requirements in regulations and guidelines adopted by the SBA. While we currently believe that the majority of the use of the PPP loan proceeds will meet the conditions for forgiveness under the PPP, no assurance is provided that we will obtain partial forgiveness of the loan.

In June 2020, we established a co-promotion partnership with Indegene to establish multichannel digital marketing programs throughout the United States and expand the capabilities for the engagement of HCPs who can be certified to prescribe Probuphine. Under the terms of the co-promotion partnership, we are required to contribute approximately \$0.8 million during the first year and approximately \$0.4 million during the second year of the agreement.

In September 2020, we completed a registered direct offering with several institutional investors pursuant to which we issued 19,440,000 shares of our common stock with an exercise price of \$0.14 per share. As a result, we received net cash proceeds of approximately \$2.4 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 31,244,386 shares of our common stock.

In October 2020, we announced our decision to discontinue selling our Probuphine® (buprenorphine) implant and wind-down our commercialization activities and pursue a plan that will enable us to focus on our ProNeura-based product development efforts. Activities associated with the wind-down of our U.S. commercialization activities will continue through the second quarter of 2021.

In October 2020, we entered the DSRA Agreement with Molteni and Horizon pursuant to which the parties agreed to settle all of our obligations under the Loan Agreement. Under the terms of the DSRA Agreement, Molteni and Horizon agreed to settle the approximately \$5.2 million of outstanding indebtedness in exchange for the payment of \$1.6 million in cash, the transfer of certain Probuphine assets to Molteni, including manufacturing equipment, certain inventory and non-U.S. Probuphine intellectual property, and the termination of our rights to future payments under the Molteni Purchase Agreement.

In October 2020, we completed the 2020 Public Offering pursuant to which we received net proceeds of approximately \$5.7 million, after deduction of underwriting discounts and commissions and other offering expenses and the \$1.6 million payment pursuant to the DSRA Agreement.

At September 30, 2020, we had cash and cash equivalents of approximately \$4.1 million, which we believe along with the proceeds of the 2020 Public Offering is sufficient to fund our planned operations into the third quarter of 2021. We will require additional funds to finance our operations beyond such period. 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, | |
|---|------------------------------------|----------|
| | 2020 | 2019 |
| | (In thousands) | |
| Net cash used in operating activities | (12,642) | (11,782) |
| Net cash used in investing activities | (531) | (144) |
| Net cash provided by financing activities | 12,023 | 3,191 |
| Net decrease in cash and cash equivalents | (1,150) | (8,735) |

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, 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, non-cash losses on impairment of assets, interest expense, stock based compensation and depreciation and amortization, and approximately \$0.2 million in costs attributable to the issuance of warrants. Net cash used in operating activities for the nine months ended September 30, 2019 consisted primarily of our net loss of approximately \$12.5 million, approximately \$1.1 million non-cash gain on changes in the fair value of warrant liability and approximately \$0.3 million of other non-cash charges. This was partially offset by approximately \$0.8 million related to net changes in operating assets and liabilities and non-cash charges of approximately \$0.6 million related to stock-based compensation, approximately \$0.5 million related to interest expense and approximately \$0.2 million related to depreciation and amortization.

Cash used in investing activities was primarily related to purchases of equipment for both the nine months ended September 30, 2020 and 2019.

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 PPP Loan. Net cash provided by financing activities for the nine months ended September 30, 2019 consisted of approximately \$0.7 million of net proceeds from the exercises of warrants to purchase our common stock and approximately \$2.5 million of net proceeds from equity offerings.

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, 2019 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, 2020, the end of the period covered by this report, and has concluded that our disclosure controls and procedures were effective to ensure that the information required to be disclosed by us in reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC, and that such information is accumulated and communicated to our principal executive and principal financial officer as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the nine months ended September 30, 2020 that materially affected, or were reasonably likely to materially affect, our internal controls over financial reporting.

PART II

Item 1. Legal Proceedings

We have received notice that 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 such individual's allegations was conducted and concluded that such allegations were without merit. We intend to vigorously defend the lawsuit; however, in light of our cash position, there can be no assurance that the defense and/or settlement of this matter will not have a material adverse impact on our business.

Item 1A. Risk Factors

In addition to the other information set forth in this report, you should carefully consider the factors discussed in Part I, "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2019, 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.

The winding down of our commercial operations may be more costly and time-consuming than we anticipate.

The cessation of our Probuphine related commercial activities requires us to comply with FDA and state regulatory requirements, including those related to notifications to various stakeholders and the continuation of adverse event reporting, as well as to address a number of business considerations, such as termination of third-party agreements and transfer of manufacturing equipment. The costs and timing associated with the wind down of our commercial operations may exceed our current estimates, requiring a reallocation of proceeds that may limit what we can accomplish in our product development programs unless additional financing is procured sooner than we currently anticipate.

There are risks associated with a reverse split.

We have filed a proxy statement relating to a special meeting of stockholders that is being held to seek approval of a reverse stock split in the range of one-for-15 and one-for-30 (the "Reverse Split"). There are numerous factors and contingencies that could affect our stock price if the proposed Reverse Split is approved, including the status of the market for our stock at the time, our reported results of operations in future periods, and general economic, market and industry conditions. Accordingly, the market price of our common stock may not be sustainable at the direct arithmetic result of the Reverse Split. If the market price of our common stock declines after the Reverse Split, our total market capitalization (the aggregate value of all of our outstanding common stock at the then existing market price) after the split will be lower than before the split. The Reverse Split may also result in some stockholders owning "odd lots" of less than 100 shares of our common stock on a post-split basis. Odd lots may be more difficult to sell, or require greater transaction costs per share to sell, than shares in "round lots" of even multiples of 100 shares.

Our failure to meet the continued listing requirements of Nasdaq could result in a delisting of our common stock.

On August 18, 2020, we received a notice from the Nasdaq Capital Market, or Nasdaq, that because our stockholders' equity was less than \$2,500,000, we were no longer in compliance with the minimum stockholders' equity requirement for continued listing pursuant to Nasdaq Listing Rule 5550(b)(1). As a result of the closing of the 2020 Public Offering and the DSRA Agreement, we believe that we regained compliance with the minimum stockholders' equity requirement. Nasdaq will continue to monitor our ongoing compliance with Nasdaq Listing Rule 5550(b)(1) and, if at the time of our next periodic report or thereafter we do not evidence compliance with the stockholders' equity requirement or otherwise fail to comply with Nasdaq's requirements for continued listing, Nasdaq may take steps to de-list the common stock. Importantly, the Company is not currently in compliance with the \$1.00 minimum bid price requirement for continued listing and has until November 30, 2020 to regain compliance. We are seeking stockholder approval of a Reverse Split at a special meeting that has been rescheduled from November 16, 2020 to November 30, 2020. While the Reverse

Split, if approved, should have the result of increasing the closing bid price of our common stock to above \$1.00, we will not be able to regain compliance with the minimum bid price requirement within the time frame set by Nasdaq. Our prior efforts to obtain stockholder approval of a reverse stock split of our outstanding shares of common stock were not successful and there can be no assurance that stockholders will approve the Reverse Split proposal at the scheduled special meeting or that Nasdaq will provide us with an extension of time within which to regain compliance.

If our common stock is delisted from Nasdaq, our common stock would likely then trade only in the over-the-counter market. If our common stock were to trade on the over-the-counter market, selling our common stock could be more difficult because smaller quantities of shares would likely be bought and sold, transactions could be delayed, and we could face significant material adverse consequences, including: a limited availability of market quotations for our securities; reduced liquidity with respect to our securities; a determination that our shares are a “penny stock,” which will require brokers trading in our securities to adhere to more stringent rules, possibly resulting in a reduced level of trading activity in the secondary trading market for our securities; a reduced amount of news and analyst coverage for our Company; and a decreased ability to issue additional securities or obtain additional financing in the future. These factors could result in lower prices and larger spreads in the bid and ask prices for our common stock and would substantially impair our ability to raise additional funds and could result in a loss of institutional investor interest and fewer development opportunities for us.

In addition to the foregoing, if our common stock is delisted from Nasdaq and it trades on the over-the-counter market, the application of the “penny stock” rules could adversely affect the market price of our common stock and increase the transaction costs to sell those shares. The SEC has adopted regulations which generally define a “penny stock” as an equity security that has a market price of less than \$5.00 per share, subject to specific exemptions. If our common stock is delisted from Nasdaq and it trades on the over-the-counter market at a price of less than \$5.00 per share, our common stock would be considered a penny stock. The SEC’s penny stock rules require a broker-dealer, before a transaction in a penny stock not otherwise exempt from the rules, to deliver a standardized risk disclosure document that provides information about penny stocks and the risks in the penny stock market. The broker-dealer must also provide the customer with current bid and offer quotations for the penny stock, the compensation of the broker-dealer and the salesperson in the transaction, and monthly account statements showing the market value of each penny stock held in the customer’s account. In addition, the penny stock rules generally require that before a transaction in a penny stock occurs, the broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser’s agreement to the transaction. If applicable in the future, these rules may restrict the ability of brokers-dealers to sell our common stock and may affect the ability of investors to sell their shares, until our common stock no longer is considered a penny stock.

We have used almost all of our unreserved, authorized shares.

We have used almost all of our unreserved authorized shares and will need stockholder approval to implement an increase in our authorized shares of common stock or a reverse stock split. Our certificate of incorporation and the Delaware General Corporation Law, or the DGCL, currently require the approval of stockholders holding not less than a majority of all outstanding shares of capital stock entitled to vote in order to approve an increase in our authorized shares of common stock or a reverse stock split. There are no assurances that stockholder approval will be obtained, in which event will be unable to raise additional capital through the issuance of shares of common stock to fund our future operations.

We face risks related to health epidemics, such as the current COVID-19 global pandemic, that could adversely affect our operations or financial results.

The spread of COVID-19, the novel coronavirus, including restrictions on travel, “shelter in place” orders, and quarantine policies put into place by businesses and state and local governments to mitigate its transmission, had a material adverse effect on our business and contributed to our decision to discontinue our commercial operations,. As the pandemic continues, it may result in a sustained economic downturn that could affect our ability to access capital on reasonable terms, or at all, beyond the third quarter of this year, which could have a material adverse effect on our business, operating results and financial condition.

We received a loan under the Paycheck Protection Program of the CARES Act, and all or a portion of the loan may not be forgivable.

On April 20, 2020, we received an approximately \$0.7 million PPP Loan pursuant to the Paycheck Protection Program of the CARES Act. The PPP Loan matures in April 2022 with an annual interest rate of 1.0%. The PPP Loan originally had a six month deferral of payments period which was extended to sixteen months during the third quarter of 2020 and may be prepaid at any time without penalty. The proceeds of the PPP Loan are to be used to retain workers and maintain payroll and make mortgage interest, lease and utility payments. Under the CARES Act, we will be eligible to apply for forgiveness of all loan proceeds used to pay payroll costs, rent, utilities and other qualifying expenses during the 24-week period following receipt of the loan, provided that we maintain our number of employees and compensation within certain parameters during such period. Not more than 40% of the forgiven amount may be for non-payroll costs. If the conditions outlined in the PPP loan program are adhered to by us, all or part of such loan could be forgiven. However, we cannot provide any assurance that we will be eligible for loan forgiveness or that any amount of the PPP loan will ultimately be forgiven by the SBA. Any forgiven amounts will not be included in our taxable income.

Item 6. Exhibits

(b) Exhibits

| Exhibit No. | Description |
|-----------------------|---|
| 1.1 | Underwriting Agreement dated October 28, 2020 between Titan Pharmaceuticals, Inc. and Maxim Group LLC⁽²⁶⁾ |
| 3.1.1 | Amended and Restated Certificate of Incorporation of the Registrant, as amended⁽⁴⁾ |
| 3.1.2 | Certificate of Amendment to the Restated Certificate of Incorporation dated September 24, 2015⁽⁶⁾ |
| 3.1.3 | Certificate of Amendment to the Restated Certificate of Incorporation dated January 23, 2019⁽¹⁶⁾ |
| 3.1.4 | Certificate of Amendment to the Restated Certificate of Incorporation dated September 24, 2020⁽¹⁶⁾ |
| 3.2 | By-laws of the Registrant⁽¹⁾ |
| 4.1 | Form of Lender Warrant⁽⁸⁾ |
| 4.2 | Form of Rights Agreement Warrant⁽¹⁰⁾ |
| 4.3 | Warrant Agency Agreement between Titan Pharmaceuticals, Inc. and Continental Stock Transfer & Trust Company and Form of Offering Warrant⁽¹⁵⁾ |
| 4.4 | Representative's Purchase Warrant⁽¹⁵⁾ |
| 4.5 | Form of August 2019 Private Placement Warrant⁽¹⁷⁾ |
| 4.6 | Class B Warrant Agency Agreement dated October 16, 2019 between Titan Pharmaceuticals, Inc. and Maxim Group LLC Form of January 2020 Private Placement Warrant⁽¹⁸⁾ |
| 4.7 | Form of January 2020 Private Placement Warrant⁽¹⁹⁾ |
| 4.8 | Form of March 3, 2020 Warrant Amendment Agreement⁽²³⁾ |
| 4.9 | Description of the Registrant's Common Stock |
| 4.10 | Warrant Agency Agreement between Titan Pharmaceuticals, Inc. and Continental Stock Transfer & Trust Company and Form of Warrant⁽²⁵⁾ |
| 4.11 | Form of Lock-Up and Voting Agreement⁽²⁵⁾ |
| 10.1 | 2001 Non-Qualified Employee Stock Option Plan⁽²⁾ |

- [10.2](#) [2002 Stock Option Plan^{\(3\)}](#)
- [10.3](#) [Titan Pharmaceuticals, Inc. 2014 Incentive Plan^{\(5\)}](#)
- [10.4](#) [Titan Pharmaceuticals, Inc. Third Amended and Restated 2015 Omnibus Equity Incentive Plan^{\(16\)}](#)
- [10.5](#) [Employment Agreement between Titan Pharmaceuticals, Inc. and Sunil Bhonsle^{\(7\)}](#)
- [10.6](#) [Employment Agreement between Titan Pharmaceuticals, Inc. and Marc Rubin^{\(7\)}](#)
- [10.7](#) [Venture Loan and Security Agreement, dated July 27, 2017, by and between Titan Pharmaceuticals, Inc. and Horizon Technology Finance Corporation^{\(8\)}](#)
- [10.8](#) [Amendment of Venture Loan and Security Agreement, dated February 2, 2018, by and between Titan Pharmaceuticals, Inc. and Horizon Technology Finance Corporation^{\(9\)}](#)
- [10.9](#) [Amended and Restated Venture Loan and Security Agreement, dated March 21, 2018, by and between Titan Pharmaceuticals, Inc., Horizon Technology Finance Corporation and L. Molteni & C. Dei Frattelli Alitti Società Di Esercizio S.P.A.^{\(10\)}](#)
- [10.10 ±](#) [Asset Purchase, Supply and Support Agreement dated March 21, 2018, by and between Titan Pharmaceuticals, Inc. and L. Molteni & C. Dei Frattelli Alitti Società Di Esercizio S.P.A.^{\(10\)}](#)
- [10.11](#) [Rights Agreement dated March 21, 2018, by and between Titan Pharmaceuticals, Inc. and L. Molteni & C. Dei Frattelli Alitti Società Di Esercizio S.P.A.^{\(10\)}](#)
- [10.12 ±](#) [Termination and Transition Services Agreement dated May 25, 2018 by and between Titan Pharmaceuticals, Inc. and Braeburn Pharmaceuticals, Inc.^{\(11\)}](#)
- [10.13 ±](#) [Amendment to Asset Purchase, Supply and Support Agreement dated August 3, 2018, by and between Titan Pharmaceuticals, Inc. and L. Molteni & C. Dei Frattelli Alitti Società Di Esercizio S.P.A.^{\(12\)}](#)
- [10.14 ±](#) [Distribution and Sublicense Agreement dated February 1, 2016 as amended by agreement dated August 2, 2018 between Titan Pharmaceuticals, Inc. and Knight Therapeutics Inc.^{\(13\)}](#)
- [10.15](#) [Amendment to lease for Registrant's facility dated March 21, 2016^{\(13\)}](#)
- [10.16](#) [Unsecured Convertible Loan Agreement dated September 18, 2018^{\(14\)}](#)
- [10.17](#) [Employment Agreement between the Registrant and Katherine Beebe DeVarney^{\(20\)}](#)
- [10.18](#) [Employment Agreement between the Registrant and Dane Hallberg^{\(20\)}](#)
- [10.19](#) [Securities Purchase Agreement, dated August 7, 2019, by and between Titan Pharmaceuticals, Inc. and the investors named therein^{\(17\)}](#)
- [10.20](#) [Securities Purchase Agreement, dated January 7, 2020, by and between Titan Pharmaceuticals, Inc. and the investors named therein^{\(19\)}](#)
- [10.21](#) [Placement Agency Agreement, dated August 7, 2019, by and between Titan Pharmaceuticals, Inc. and Maxim Group LLC^{\(17\)}](#)
- [10.22](#) [Placement Agency Agreement, dated January 7, 2020, by and between Titan Pharmaceuticals, Inc. and Maxim Group LLC^{\(19\)}](#)
- [10.23](#) [Amendment dated September 10, 2019 to Amended and Restated Venture Loan and Security Agreement, dated March 21, 2018, by and between Titan Pharmaceuticals, Inc., Horizon Technology Finance Corporation and L. Molteni & C. Dei Frattelli Alitti Società Di Esercizio S.P.A.^{\(21\)}](#)
- [10.24 ±](#) [Amendment No. 2 dated September 10, 2019 to Asset Purchase, Supply and Support Agreement by and between Titan Pharmaceuticals, Inc. and L. Molteni & C. Dei Frattelli Alitti Società Di Esercizio S.P.A.^{\(21\)}](#)
- [10.25](#) [Amendment No. 2 dated March 12, 2020 to Amended and Restated Venture Loan and Security Agreement, dated March 21, 2018, by and between Titan Pharmaceuticals, Inc., Horizon Technology Finance Corporation and L. Molteni & C. Dei Frattelli Alitti Società Di Esercizio S.P.A.^{\(22\)}](#)

- 10.26 ±± [Agreement for Co-Promotion Partnership, dated June 23, 2020, by and between Titan Pharmaceuticals, Inc. and Indegene, Inc.](#)⁽²³⁾
- 10.27 [Debt Settlement and Release Agreement by and between Titan Pharmaceuticals, Inc., Horizon Technology Finance Corporation and L. Molteni & C. Dei Fratelli Alitti Società Di Esercizio S.P.A.](#)⁽²⁴⁾
- 10.28±± [Asset Purchase Agreement dated October 27, 2020 between Titan Pharmaceuticals, Inc. and JT Pharmaceuticals, Inc.](#)
- 14.1 [Code of Business Conduct and Ethics](#)⁽⁵⁾
- 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](#)

± Confidential treatment has been granted as to certain portions of this exhibit.

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

- (1) Incorporated by reference from the Registrant's Registration Statement on Form S-3 (File No. 333-221126).
- (2) Incorporated by reference from the Registrant's Annual Report on Form 10-K for the year ended December 31, 2001.
- (3) Incorporated by reference from the Registrant's Annual Report on Form 10-K for the year ended December 31, 2002.
- (4) Incorporated by reference from the Registrant's Registration Statement on Form 10 filed on January 14, 2010.
- (5) Incorporated by reference from the Registrant's Annual Report on Form 10-K for the year ended December 31, 2013.
- (6) Incorporated by reference from the Registrant's Current Report on Form 8-K filed on September 28, 2015.
- (7) Incorporated by reference from the Registrant's Current Report on Form 8-K filed on April 3, 2019.
- (8) Incorporated by reference from the Registrant's Current Report on Form 8-K filed on July 27, 2017.
- (9) Incorporated by reference from the Registrant's Current Report on Form 8-K filed on February 7, 2018.
- (10) Incorporated by reference from the Registrant's Current Report on Form 8-K filed on March 26, 2018.
- (11) Incorporated by reference from the Registrant's Current Report on Form 8-K filed on May 30, 2018.
- (12) Incorporated by reference from the Registrant's Current Report on Form 8-K filed on August 3, 2018.
- (13) Incorporated by reference from the Registrant's Quarterly Report on Form 10-Q for the period ended June 30, 2018.
- (14) Incorporated by reference from the Registrant's Current Report on Form 8-K dated September 20, 2018.
- (15) Incorporated by reference from the Registrant's Current Report on Form 8-K dated September 25, 2018.
- (16) Incorporated by reference from the Registrant's Current Report on Form 8-K dated January 25, 2019.
- (17) Incorporated by reference from the Registrant's Current Report on Form 8-K dated August 8, 2019.
- (18) Incorporated by reference from the Registrant's Current Report on Form 8-K dated October 18, 2019.
- (19) Incorporated by reference from the Registrant's Current Report on Form 8-K dated January 7, 2020.
- (20) Incorporated by reference from the Registrant's Annual Report on Form 10-K dated April 1, 2019.
- (21) Incorporated by reference from the Registrant's Registration Statement on Form S-1 dated September 12, 2019.
- (22) Incorporated by reference from the Registrant's Annual Report on Form 10-K dated March 30, 2020.
- (23) Incorporated by reference from the Registrant's Quarterly Report on Form 10-Q for the period ended June 30, 2020.
- (24) Incorporated by reference from the Registrant's Current Report on Form 8-K dated October 26, 2020.
- (25) Incorporated by reference from the Registrant's Registration Statement on Form S-1/A dated October 27, 2020.
- (26) Incorporated by reference from the Registrant's Current Report on Form 8-K dated November 2, 2020.

SIGNATURES

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

TITAN PHARMACEUTICALS, INC.

Dated: November 16, 2020

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

Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

THIS ASSET PURCHASE AGREEMENT (the “**Agreement**”) is made as of October 27, 2020 (the “**Effective Date**”), by and between **TITAN PHARMACEUTICALS, INC.**, a Delaware corporation (“**Titan**”), and **JT PHARMACEUTICALS, INC.**, a Delaware corporation (“**JT**”).

RECITALS

WHEREAS, JT owns the Purchased Assets (as defined herein);

WHEREAS, JT desires to sell to Titan, and Titan desires to purchase from JT, the Purchased Assets, upon the terms and conditions hereinafter set forth;

NOW, THEREFORE, in consideration of the foregoing statements and the mutual agreements and covenants herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Titan and JT hereby agree as follows:

1. Definitions

Unless specifically set forth to the contrary herein, the following terms, where used in the singular or plural, shall have the respective meanings set forth below:

1.1 “**Affiliate**” of a Party means (i) any corporation or business entity of which at least fifty percent (50%) of the securities or other ownership interests representing the equity, the voting stock or general partnership interest are owned, controlled or held, directly or indirectly, by a Party; (ii) any corporation or business entity which, directly or indirectly, owns, controls or holds at least fifty percent (50%) (or the maximum ownership interest permitted by law) of the securities or other ownership interests representing the equity, voting stock or general partnership interest of a Party; (iii) any corporation or business entity of which, directly or indirectly, an entity described in the immediately preceding subsection (ii) controls or holds at least fifty percent (50%) (or the maximum ownership interest permitted by law) of the securities or other ownership interests representing the equity, voting stock or general partnership interest of such corporation or entity; or (iv) any corporation or business entity of which a Party has the right to acquire, directly or indirectly, at least fifty percent (50%) of the securities or other ownership interests representing the equity, voting stock or general partnership interest thereof.

1.2 “**Agreement Term**” has the meaning set forth in Section 6.1.

1.3 “**Ancillary Agreements**” means (a) the short-form patent assignments to be executed by JT (or the applicable Affiliates thereof) and Titan at or after the Closing, providing for the assignment of the Registered IP from JT to Titan, in substantially the form of the assignments set forth as Exhibit A hereto (the “**IP Assignment Agreements**”), and (b) the Bill of Sale, dated as of the date hereof, by and between Titan and JT, in substantially the form set forth as Exhibit B hereto.

1.4 “**Applicable Law**” means the laws, rules, and regulations, including any statutes, rules, regulations, guidelines, or other requirements that may be in effect from time to time and apply to the activities contemplated by this Agreement.

1.5 “**Business Day**” means any day that is not (i) a Saturday or a Sunday or (ii) any other day on which banks in New York, New York, United States, the United Kingdom or Italy are permitted or required to be closed.

1.6 “**Commercialize**” or “**Commercialization**” means all activities that are undertaken after Regulatory Approval of a Product and that relate to the commercial marketing, sale, and/or distribution of such Product, including but not limited to advertising, marketing, promotion, distribution, and/or sales.

1.7 “**Commercially Reasonable Efforts**” means the carrying out of obligations or tasks in a manner consistent with the exercise, by a pharmaceutical company of comparable size and resources to Titan, of reasonable, customary, scientific and business practices within the pharmaceutical industry, and of a level no less than consistent with the efforts Titan and its Affiliates devote to marketing of another pharmaceutical product, in each case of similar market potential, profit potential, competitiveness, and strategic value, taking into account technical, regulatory, and intellectual property factors, target product profiles, product labeling, past performance, costs, economic return, the regulatory environment and competitive market conditions in the therapeutic or market niche, all based on conditions then prevailing.

1.8 “**Compound**” means the kappa opioid agonists described in Schedule 1, including, but not limited to the kappa opioid agonist known as JT-09.

1.9 “**Contract**” means any contract, agreement, lease, sublease, license, sublicense or other legally binding commitment or arrangement, whether written or oral.

1.10 “**Earn-Out Payments**” means any payment contemplated by Section 3.3 herein.

1.11 “**Effective Date**” has the meaning set forth in the Preamble.

1.12 “**Encumbrance**” means any mortgage, lien (statutory or otherwise), license, pledge, security interest, charge, hypothecation, restriction, claim of ownership, preference, encroachment, right of first refusal, title defect, covenant not to sue, release of claims or other encumbrance.

1.13 “**FDA**” means the United States Food and Drug Administration and any successor agency having substantially the same functions and authority.

1.14 “**Force Majeure**” means, with respect to a Party, any fire, flood, earthquake, explosion, storm, blockage, embargo, war, acts of war (whether war be declared or not), terrorism, insurrection, riot, civil commotion, strike, lockout or other labor disturbance, failure of public utilities or common carriers, act of God or act, omission or delay in acting by any Governmental Authority.

1.15 “**GAAP**” means generally accepted accounting principles in the United States, consistently applied.

1.16 “**Governmental Authority**” means any domestic or foreign entity exercising executive, legislative, judicial, regulatory or administrative functions of or pertaining to government, including any governmental authority, agency, department, board, commission, court, tribunal, judicial body or instrumentality of any union of nations, federation, nation, state, municipality, county, locality or other political subdivision thereof.

1.17 “**JT**” has the meaning set forth in the Preamble.

1.18 “**JT Indemnified Parties**” has the meaning set forth in Section 7.1.

1.19 “**Know-How**” means any non-public information, ideas, data, inventions, works of authorship, trade secrets, technology, or materials, including formulations, molecules, assays, reagents, compounds, compositions, human or animal tissue, samples or specimens, and combinations or components thereof, whether or not proprietary or patentable, and whether stored or transmitted in oral, documentary, electronic or other form.

1.20 “**Launch**” means, following Regulatory Approval of the Product, the date on which a Product is first sold by Titan, any Affiliate thereof, or any Licensee to a Third Party; provided, however, that the following shall not be considered a Launch: (a) sales or other dispositions of a Product for use in clinical studies or other scientific testing purposes, as free samples or (b) dispositions at or below Product cost for early access or compassionate use programs.

1.21 “**Law(s)**” means all laws, statutes, rules, regulations, ordinances and other pronouncements having the binding effect of law of any Governmental Authority.

1.22 “**Liabilities**” means any debts, liabilities, obligations, commitments, claims or complaints, whether absolute or contingent, accrued or unaccrued, asserted or unasserted, known or unknown, fixed or contingent, matured or unmatured, determined or determinable or otherwise, whether arising under any Law, Contract or otherwise, and whether or not the same would be required to be reflected in financial statements or disclosed in the notes thereto.

1.23 “**Licensee**” means a Third Party granted any right or license to develop, manufacture or sell Products, including, without limitation, a Third Party granted a license or rights under any of the Transferred Patent Rights.

1.24 “**Losses**” means any and all damages of any kind whatsoever (including all incidental, consequential, statutory and treble damages), awards, deficiencies, settlement amounts, defaults, assessments, fines, dues, penalties, judgments (including penalties imposed by any Governmental Authority), costs, fees, liabilities, obligations, taxes, liens, losses, lost profits and expenses (including court costs, interest and reasonable fees of attorneys, accountants and other experts) and other monetary obligations arising out of or resulting from claims or judgments, arbitral awards, including amounts paid in settlement of claims, judgments, legal (including judicial, arbitral and administrative) proceedings and the like, incurred or otherwise payable to Third Parties.

1.25 “**Net Sales**” means:

(a) means the gross amounts invoiced or otherwise received for Titan’s, its Affiliates’, and its and their Licensees’ (collectively, Titan, its Affiliates, and Licensees, the “**Net Sales Parties**”) sales or other transfers of Products to a Third Party, reduced by the following deductions actually allowed or reserved in accordance with GAAP (collectively, “**Permitted Deductions**”):

(i) discounts actually granted and returns credited;

(ii) any tax imposed on the sale, delivery or use of such Product, including sales, use, excise or value added taxes, tariffs or duties, but only to the extent set forth separately in the applicable invoices; and

(iii) rebates granted to governments or managed health care organizations (including their agencies, purchasers, and/or reimbursers) under programs available or required by Applicable Law.

Notwithstanding the foregoing, Net Sales shall not include, (i) Products provided, prior to Regulatory Approval, for clinical trials or research purposes at a price equal to or less than the cost to manufacture or procure such Products, or (ii) Products provided by a Net Sales Party to a Net Sales Party for purposes of resale thereby, provided that such Products’ resale shall be subject to the Earn-Out Payments due to JT under Section 3.3.

1.26 “**Party**” means Titan or JT, as applicable.

1.27 “**Patent Rights**” means any of the following, whether existing now or in the future: (i) patents and patent applications (including provisional applications); (ii) all patent applications filed either from such patents or patent applications or from an application claiming priority from either of these, including continuations, continuations-in-part, divisionals, converted provisionals, continued prosecution applications, and substitute applications; (iii) any patents issued (A) based on or claiming priority to any such patent applications in (i) and (ii), or (B) which are subject to a terminal disclaimer with any such patent applications in (i) and (ii); (iv) any and all extensions or restorations by existing or future extension or restoration mechanisms, including adjustments, revalidations, renewals, reissues, re-examinations and extensions (including any supplementary protection certificates and the like) of the foregoing patents or patent applications in (i), (ii) and (iii); and (v) any similar rights, including rights provided by multinational treaties or conventions, so-called pipeline protection, or any importation, revalidation, confirmation or introduction patent or registration patent or patents of addition to any of such foregoing patents or patent applications.

1.28 “**Permitted Deductions**” has the meaning set forth in Section 1.26.

1.29 “**Person**” means any individual, partnership, limited partnership, limited liability company, joint venture, syndicate, sole proprietorship, corporation, unincorporated association, trust, trustee, executor, administrator or other legal personal representative, or any other legal entity, including a Governmental Authority.

1.30 “**Phase II Clinical Trial**” means a human clinical trial of a Product, including possibly pharmacokinetic studies, the principal purpose of which is to make a preliminary determination that such Product is safe for its intended use and to obtain sufficient information about such Product’s efficacy to permit the design of further clinical trials, and generally consistent with 21 CFR § 312.21(b).

1.31 “**Phase III Clinical Trial**” means a human clinical trial that provides for a pivotal human clinical trial of a Product, which trial is designed to: (a) establish that a Product is safe and efficacious for its intended use; (b) define warnings, precautions and adverse reactions that are associated with the Product in the dosage range to be prescribed; (c) support Regulatory Approval of such Product; and (d) generally consistent with 21 CFR § 312.21(c).

1.32 “**Product**” means a product consisting of a Compound and a biocompatible polymeric matrix set forth in Schedule 2, including, but not limited to, ethylene vinyl acetate (EVA) copolymer, alone or in combination with other active ingredients.

1.33 “**Proprietary Information**” means any and all Know-How, scientific, clinical, regulatory, marketing, financial, technical, non-technical, commercial or other confidential information or data of a confidential nature, whether communicated in writing, orally or by any other means, that is under the protection of one Party and is provided by that Party to the other Party in connection with this Agreement.

1.34 “**Regulatory Approval**” means with respect to a pharmaceutical or biological product or medical device in a country or regulatory jurisdiction, any and all approvals, licenses, permits, certifications, registrations or authorizations from the relevant Regulatory Authority in such regulatory jurisdiction that is specific to such product and necessary for the marketing and commercial sale of such product in such country or regulatory jurisdiction (including pricing and/or reimbursement approval in any country in which pricing and/or reimbursement approval is required by Applicable Laws).

1.35 “**Regulatory Authority**” means, in a particular country or regulatory jurisdiction, any applicable Governmental Authority involved in granting Regulatory Approval and/or, to the extent required in such country or regulatory jurisdiction, pricing or reimbursement approval of a product in such country or regulatory jurisdiction.

1.36 “**SEC**” has the meaning set forth in Section 5.3.

1.37 “**Successful Completion**” means, with respect to a clinical study or clinical trial, the meeting of the primary endpoints of such clinical study or clinical trial.

1.38 “**Third Party(ies)**” means a person or entity who or which is not a Party or Affiliate of a Party.

1.39 “**Titan**” has the meaning set forth in the Preamble.

1.40 “**Titan Indemnified Parties**” has the meaning set forth in Section 7.1.

1.41 “**Titan Stock**” means the common stock, \$.001 per share, of Titan.

1.42 “**Transferred Patent Rights**” means the Patent Rights listed on Schedule 3 hereto.

2. Sale of Purchased Assets.

2.1 **Purchase and Sale of Purchased Assets.** Upon the terms and subject to the conditions of this Agreement, at and effective as of the Closing, JT shall (or shall cause the applicable Affiliate thereof to) sell, transfer, convey, assign and deliver to Titan, and Titan shall purchase and accept from JT (or such Affiliate thereof), all of the following assets, properties and rights (collectively, the “**Purchased Assets**”), in each case free and clear of any Encumbrances:

(a) the Transferred Patent Rights;

(b) any and all other rights and privileges relating to the Transferred Patent Rights, or arising therefrom, including (i) the right to register or apply in any and all countries and regions in Titan’s name for patents, utility models, design registrations and like rights of exclusion and for inventors’ certificates and improvements, in each case in respect of the Transferred Patent Rights, (ii) the right to prosecute, maintain and defend such Transferred Patent Rights before any public or private agency, office, registrar or other applicable Governmental Authority or other Person, (iii) the right to claim priority based on the filing dates of any of the Transferred Patent Rights under any applicable treaty, Law or otherwise, (iv) any and all causes of action and enforcement rights, whether currently pending, filed, threatened or otherwise, for or in respect of the Transferred Patent Rights, (v) without limiting the foregoing, the right to sue and recover damages, other compensation and/or equitable relief (including injunctive relief) for past, present or future infringements in respect of the Transferred Patent Rights, and (vi) the right to fully and entirely stand in the place of the JT or any Affiliate thereof in all matters related to the Transferred Patent Rights; and

(c) all deferred and prepaid charges, fees, recoverable deposits, advances and expenses paid by or on behalf of JT or any Affiliate thereof in respect of the other Purchased Assets.

2.2 Liabilities.

(a) **Assumed Liabilities.** Upon the terms and subject to the conditions of this Agreement, at the Closing, JT shall assign to Titan, and Titan shall assume from JT and agree to pay and discharge when due, (i) all Liabilities arising due to actions or omissions taken (or not taken) by JT in respect of the Purchased Assets following the Closing Date; and (ii) all Liabilities arising after the Closing Date with respect to Product or the other Purchased Assets to the extent related to the conduct of Titan and its Affiliates, including using, promoting, marketing or selling Product (collectively, but excluding the Excluded Liabilities, the “**Assumed Liabilities**”).

(b) **Excluded Liabilities.** Notwithstanding anything to the contrary in this Agreement or any Ancillary Agreement, neither Titan nor any of its Affiliates shall assume, nor shall they be or become responsible for, any Liabilities of JT or any of its Affiliates, other than the Assumed Liabilities (all such Liabilities other than the Assumed Liabilities being referred to herein as the “**Excluded Liabilities**”), and the Excluded Liabilities shall remain the sole obligation and responsibility of JT and its Affiliates. For the avoidance of doubt, the Excluded Liabilities include all Liabilities of JT and its Affiliates in respect of or otherwise relating to the Purchased Assets that arise at any time (including after the Closing) from any actions, omissions or any state of facts or circumstances that were taken (or not taken) or that existed on or prior to the Closing Date, including (A) any such Liabilities arising at any time (including after the Closing) from the ownership, use or exploitation of the Purchased Assets by JT or its Affiliates on or prior to the Closing Date, (B) prosecution costs with any intellectual property offices related to the Transferred Patent Rights associated with the ownership or exploitation by or through the JT or its Affiliates, in each case that are attributable to periods occurring on or prior to the Closing Date.

2.3 **Closing.**

(a) **Closing.** The closing of the transactions contemplated by this Agreement (the “**Closing**”) shall take place at the New York City office of Loeb & Loeb LLP, at 10:00 a.m. local time, on the date hereof (the date on which the Closing occurs is referred to as the “**Closing Date**”). The Closing shall be deemed to have occurred at 12:00 a.m., Eastern time, on the Closing Date and Titan shall be deemed the owner of the Purchased Assets on and after the Closing Date.

(b) At the Closing, JT shall deliver (or cause to be delivered) the following:

(i) each of the Ancillary Agreements, validly executed by a duly authorized representative of JT and each required Affiliate of JT.

(c) At the Closing, Titan shall deliver (or cause to be delivered) the following:

(i) each of the Ancillary Agreements, validly executed by a duly authorized representative of Titan; and

(ii) the Closing Payment by electronic funds transfer of immediately available funds to an account or accounts designated in writing by JT.

2.4 **Further Assurances; Access to Information.** Each Party shall, and shall cause any Affiliate thereof to, at any time or from time to time after the Closing, at the expense of the other Party, execute and deliver to the other all such instruments and documents or further assurances as the other may reasonably request, in each case that are consistent with the terms of this Agreement, in order to vest in Titan all of JT’s and its Affiliates’ right, title and interest in and to the Purchased Assets as contemplated hereby, including execution, acknowledgment, and recordation of other such papers, and using commercially reasonable efforts to obtain the same from the respective inventors, as necessary or desirable for fully perfecting and conveying unto Titan the benefit of the transactions contemplated hereby. Effective upon the Closing, JT hereby irrevocably appoints Titan and its successors, agents and assigns as its true and lawful attorney, in its name, place and stead, with power of substitution, to (a) execute, acknowledge, deliver, swear to, file and record any IP Assignment Agreement, or (b) otherwise take any action necessary to vest in Titan all of JT’s and its respective Affiliates’ right, title and interest in and to the Purchased Assets as contemplated hereby. The foregoing power of attorney is a special power of attorney coupled with an interest and is irrevocable. In addition, JT shall provide Titan all data obtained by JT related to the Compound.

3. Payments and Statements.

3.1 **Purchase Price.** Subject to the terms and conditions set forth herein, in consideration of the sale, assignment, conveyance and delivery of the Purchased Assets and assumption of the Assumed Liabilities, Titan will irrevocably pay to JT:

(a) Fifteen Thousand Dollars (\$15,000) at Closing (the “**Closing Payment**”);

(b) If applicable, the Milestone Payments as provided in Section 3.2; and

(c) If applicable, the Earn-Out Payments as provided in Section 3.3 (the Closing Payment, Milestone Payments and Earn-Out Payments being collectively referred to herein as the “**Purchase Price**”).

3.2 **Milestone Payments.** In partial consideration for the transactions contemplated by this Agreement, Titan shall pay to JT the applicable non-refundable, non-creditable, one-time Milestone Payment after achievement by Titan, its Affiliates or a Licensee of each corresponding Milestone Event as set forth below. Each Milestone Payment listed in the table below shall be due within five Business Days after achievement of the corresponding Milestone Event. Other than as specifically provided below, Milestone Payments may be made, at Titan’s sole discretion, either in cash or in Titan Stock valued at the closing price on the first trading day following the public announcement of the applicable Milestone Event. If a Milestone Payment, or any portion of a Milestone Payment, is made in Titan Stock, such shares of Titan Stock issued to JT must be validly issued, fully paid, non-assessable and registered for resale with the SEC within forty-five (45) days of the achievement of the applicable Milestone Event.

| “Milestone Event”: | “Milestone Payment”: |
|--|---|
| Upon Successful Completion of a proof of concept study of the Product in an animal model | \$100,000 in cash and \$50,000 in shares of Titan Stock |
| Enrollment of the first patient in a Phase II Clinical Trial of the Product | [\$****] |
| Successful Completion of a Phase III Clinical Trial of the Product | [\$*****] |
| Regulatory Approval of the Product by the FDA | [\$*****] |

3.3 **Earn-Out Payments.**

(a) Subject to the terms of this Agreement, Titan shall pay to JT Earn-Out Payments based on annual Net Sales of the Product at the following rates:

| | From (\$) | To (\$) | Earn-Out Payment (%) on Net Sales |
|--------|------------------|----------------|--|
| Tier 1 | 0 | [*] | [*]% |
| Tier 2 | [*] | [*] | [*]% |
| Tier 3 | [*] | [*] | [*]% |
| Tier 4 | [*] | [*] | [*]% |
| Tier 5 | [*] | beyond | [*]% |

3.4 **Reports and Payments.**

(a) Within thirty (30) days after the end of each calendar quarter following Launch that begins or ends during the Agreement Term, Titan shall furnish to JT a written report showing:

(i) all Net Sales during (A) such calendar quarter, including a reconciliation to Net Sales and a breakdown of all estimated Permitted Deductions from the gross amount invoiced to arrive at Net Sales, and (B) the calendar year to date through the end of such calendar quarter; and

(ii) a calculation of Earn-Out Payments for such calendar quarter.

(b) Each such report shall be accompanied by payment of the Earn-Out Payments due under Section 3.3 and subject to the terms herein.

(c) Except as otherwise defined herein, all financial calculations by Titan under this Agreement shall be calculated in accordance with GAAP.

(d) Currency Exchange. For the purpose of converting the local currency in which any Earn-Out Payments or other payments arise into US dollars, the rate of exchange to be applied shall be the rate of exchange in effect on the last Business Day of the calendar quarter to which the payment relates as reported in the Wall Street Journal (New York Edition).

(e) Late Payment. If JT does not receive payment of any Milestone Payment or Earn-Out Payment due to it hereunder on or before the thirtieth (30th) day following the due date therefor, simple interest shall thereafter accrue on the sum from the due date until the date of payment at a per month rate of one percent (1%) or the maximum rate allowable by Law, whichever is less.

Audits. During the Agreement Term, Titan, upon thirty (30) days' prior written notice from JT during normal business hours, but in no event more than once in any 12- month period, shall permit an independent certified public accounting firm of nationally recognized standing, selected by JT and reasonably acceptable to Titan, to have access during normal business hours to the records of Titan, its Affiliates and its and their Licensees as may be reasonably necessary to verify the accuracy of Titan's payment obligations hereunder; provided however, that any audit conducted under this Section 3.5 may only be for any year ending not more than thirty-six (36) months prior to the date of such request. Titan shall reasonably cooperate with the accounting firm. The accounting firm shall disclose to JT only whether the reports are correct or incorrect, the specific details concerning any discrepancies (including, if applicable, the accuracy of the calculation of Net Sales, and the resulting effect of such calculations on the amounts payable by Titan under this Agreement), but no other information shall be disclosed to JT. If the accountant's report shows, in respect of any period then being reviewed, an underpayment of amounts due to JT hereunder for such period by more than five percent (5%), then Titan shall be responsible all costs and expenses incurred by JT in connection with such audit. If the report shows an underpayment of amounts due to JT hereunder, then Titan will pay JT an amount equal to such underpayment, plus interest on such amounts in accordance with Section 3.4(e), within thirty (30) calendar days after receipt of notice of such underpayment and copy of the relevant portion of the audit report.

4. Representations and Warranties

4.1 **General Representations.** Each Party hereby represents and warrants to the other Party as of the Effective Date and Closing Date as follows:

(a) Such Party is an entity duly organized, validly existing and in good standing under the Laws of the jurisdiction of its incorporation or formation, is qualified to do business and is in good standing as a foreign entity in each jurisdiction in which the conduct of its business or the ownership of its properties requires such qualification and failure to have such would prevent it from performing its obligations under this Agreement and the Ancillary Agreements;

(b) The execution, delivery and performance by such Party of this Agreement and the Ancillary Agreements have been duly authorized by all necessary corporate action and does not and will not (i) violate any provision of any Law, rule, regulation, order, writ, judgment, injunction, decree, determination or award presently in effect having applicability to it or any provision of its charter or bylaws or other organizational or governing documents; or (ii) conflict with or constitute a default under any other agreement to which such Party is a party;

(c) This Agreement and the Ancillary Agreements have been duly executed and are legal, valid and binding obligations of such Party, enforceable against it in accordance with the terms and conditions hereof, except as enforceability may be limited by (i) any applicable bankruptcy, insolvency, reorganization, moratorium or similar law affecting creditor's rights generally, or (ii) general principles of equity, whether considered in a proceeding in equity or at Law;

(d) Such Party is not under any obligation to any person or entity, contractual or otherwise, that is in conflict with the terms of this Agreement or any Ancillary Agreement, nor will such Party undertake any such obligation during the Agreement Term;

(e) Such Party has obtained all material authorizations, consents and approvals, governmental or otherwise, necessary for the execution and delivery of this Agreement and the Ancillary Agreements, and to otherwise perform such Party's obligations under this Agreement and the Ancillary Agreements;

(f) Such Party, and each of its Affiliates, is not a party to, or are otherwise bound by, any oral or written contract that will result in any Third Party obtaining any interest in, or that would give to any Third Party any right to assert any claim in or with respect to, any of such Party's or the other Party's rights under this Agreement or any Ancillary Agreement; and

(g) Such Party shall perform its obligations hereunder in accordance with all Laws in all material respects.

4.2 **Additional Representations and Warranties of JT as of the Effective Date and the Closing Date.** JT represents and warrants to Titan that as of the Effective Date and as of the Closing Date:

(a) Schedule 3 sets forth, for each issued patent and patent application, included in the Transferred Patent Rights (the "**Registered IP**"), a true and complete list of (i) the title of such Registered IP, (ii) the name or names of the registered and beneficial owner of such Registered IP, (iii) in the case of patents and patent applications, the inventor or inventors of such Registered IP, (iv) the jurisdiction of issuance, application or registration of such Registered IP, and (v) the patent number and application or publication number of such Registered IP, as applicable.

(b) JT exclusively owns the Purchased Assets and the Purchased Assets are not subject to any Encumbrance.

(c) JT has not entered into any agreements, either oral or written, with any Third Party relating to the development of the Compound or commercialization, manufacture or promotion of the Product, including any agreement granting rights under the Transferred Patent Rights, that are in conflict with the rights granted to Titan under this Agreement;

(d) JT has not received any written notice from any Third Party asserting or alleging that the development, manufacture, use or sale of the Product infringed, violated or misappropriated any rights of such Third Party and, to JT's actual knowledge as of the Effective Date, without duty or obligation of investigation or inquiry, the development, manufacture, use or sale of the Product has not, infringed, violated or misappropriated any rights of any Third Party.

(e) There are no pending legal suits or proceedings (other than standard prosecution before a Governmental Authority) involving the Transferred Patent Rights or the Product, and to JT's actual knowledge, there are no threatened legal suits or proceedings involving the Transferred Patent Rights or the Product.

(f) Neither JT nor any of its Affiliates has commenced any action, suit, claim, investigation, legal or administrative proceeding against any other Person asserting the infringement by such Person or any Affiliate thereof of the Transferred Patent Rights or claims set forth therein or otherwise relating to the Transferred Patent Rights.

(g) The Registered IP is subsisting and, if issued or registered, is believed to be enforceable. All fees required to be paid to the applicable Governmental Authority prior to the Effective Date to prosecute or maintain the Registered IP have been filed and have been paid.

(h) There are no trademarks associated with the Compound or Product.

4.3 Titan Covenants.

(a) Titan shall use Commercially Reasonable Efforts to Commercialize the Product following Regulatory Approval of the Product.

(b) Titan shall not take any action or agree to any obligation with any Person, contractual or otherwise, that is in conflict with the terms of this Agreement.

4.4 **Disclaimer of Additional Warranties.** EXCEPT AS SET FORTH HEREIN, EACH PARTY HEREBY EXPRESSLY DISCLAIMS ANY WARRANTIES OR CONDITIONS, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, WITH RESPECT TO THE SUBJECT MATTER OF THIS AGREEMENT, INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE, EVEN IF EITHER PARTY HAS BEEN ADVISED OF SUCH PURPOSE.

4.5 **Limitation of Liability.** EXCEPT IN CIRCUMSTANCES OF GROSS NEGLIGENCE, FRAUD OR WILLFUL MISCONDUCT BY A PARTY, NEITHER PARTY SHALL BE LIABLE TO THE OTHER WITH RESPECT TO ANY SUBJECT MATTER OF THIS AGREEMENT, WHETHER UNDER ANY CONTRACT, NEGLIGENCE, STRICT LIABILITY OR OTHER LEGAL OR EQUITABLE THEORY, FOR ANY INCIDENTAL, INDIRECT, SPECIAL, EXEMPLARY, PUNITIVE, MULTIPLE, OR CONSEQUENTIAL DAMAGES (INCLUDING LOST PROFITS, LOSS OF USE, DAMAGE TO GOODWILL, OR LOSS OF BUSINESS AND WITH RESPECT TO TITAN AS THE PARTY SEEKING DAMAGES, LOST MILESTONES OR LOST ROYALTIES).

5. Confidentiality and Publicity

5.1 **Non-Disclosure and Non-Use Obligations.** All Proprietary Information disclosed by one Party to the other Party hereunder shall be maintained in confidence and shall not be disclosed to any Third Party or used for any purpose except as expressly permitted herein without the prior written consent of the Party that disclosed the Proprietary Information to the other Party during the Agreement Term and thereafter. The foregoing non-disclosure and non-use obligations shall not apply to the extent that such Proprietary Information:

(a) is known by the receiving Party at the time of its receipt, and not through a prior disclosure by the disclosing Party or subject to any confidentiality obligation, as documented by business records;

(b) is or becomes properly in the public domain or knowledge without breach by either Party or such Party's Affiliates or their respective employees, officers, directors, agents or representatives; or

(c) is subsequently disclosed to a receiving Party by a Third Party who, to the knowledge of the receiving Party, is lawfully able to do so and, to the knowledge of the receiving Party, is not under an obligation of confidentiality to the disclosing Party.

5.2 Permitted Disclosure of Proprietary Information. Notwithstanding Section 5.1, a Party receiving Proprietary Information of another Party may disclose such Proprietary Information:

(a) to governmental or other regulatory agencies in order to obtain Patent Rights pursuant to this Agreement, or to gain approval to conduct clinical trials or to market the Product, but such disclosure may be made only to the extent reasonably necessary to obtain such Patent Rights or authorizations and in accordance with the terms of this Agreement or as otherwise requested by the FDA or another Regulatory Authority;

(b) in connection with the performance of this Agreement and solely on a need-to-know basis, to Affiliates; potential or actual collaborators (including potential Licensees); potential or actual investment bankers, accountants, investors, lenders, or acquirers; or employees, independent contractors (including consultants and clinical investigators) or agents, each of whom prior to disclosure must be bound by written obligations of confidentiality and non-use no less restrictive than the obligations set forth in this Section 5 or to counsel for such Party; provided, however, that the receiving Party shall (i) undertake reasonable precautions to safeguard and protect the confidentiality of the Proprietary Information; (ii) remain responsible for any failure by any Person who receives Proprietary Information pursuant to this Section 5 to treat such Proprietary Information as required under this Section 5; and (iii) take all reasonable measures to restrain the receiving Party and any such Persons from prohibited or unauthorized disclosure or use in violation of this Section 5; or

(c) if required to be disclosed by Law or court order, provided that notice is promptly delivered to the non-disclosing Party in order to provide an opportunity to challenge or limit the disclosure obligations.

If and whenever any Proprietary Information is disclosed in accordance with this Section 5.2, such disclosure shall not cause any such information to cease to be Proprietary Information except to the extent that such disclosure results in an authorized public disclosure of such information (other than in breach of this Agreement). Where reasonably possible and subject to Section 5.3, the receiving Party shall promptly notify the disclosing Party of the receiving Party's intent to make such disclosure pursuant to Sections 5.2(a)–5.2(c) sufficiently prior to making such disclosure so as to allow the disclosing Party adequate time to take whatever action it may deem appropriate to protect the confidentiality of the information, and the receiving Party shall cooperate with the disclosing Party in such efforts.

5.3 **Disclosure of Agreement to Governmental Authority.** Without limiting any of the foregoing, it is understood that the Parties or their Affiliates may make disclosure of this Agreement and the terms hereof in any filings required by the United States Securities and Exchange Commission and any successor agency having substantially the same functions (the “SEC”), other Governmental Authority or securities exchange, may file this Agreement as an exhibit to any filing with the SEC, other governmental authority or securities exchange, and may distribute any such filing in the ordinary course of its business.

5.4 **Other Public Statements.** The parties will agree on the content of any press release relating to this Agreement, and neither party shall make public the parties’ relationship, or any of the terms herein except as required by applicable securities or regulatory laws (as set forth in Section 5.3) without the prior written consent of the other party.

5.5 **No Rights to Use Name of Other Party.** Except as provided herein, neither Party shall use the name, trademark, trade name or logo of the other Party in any publicity, promotion, news release or disclosure relating to this Agreement or its subject matter, without the prior express written permission of the other Party, except as may be required by Law.

6. Term

6.1 **Term.** This Agreement shall be effective as of the Effective Date until seventeen (17) years from the Effective Date (the “**Agreement Term**”).

6.2 **Expiration.** Upon expiration of the Agreement Term, Titan will no longer be liable for any Earn-Out Payments or Milestone Payments.

6.3 **Survival.** Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing prior to such expiration or termination. In addition, any other provisions required to interpret and enforce the Parties’ rights and obligations under this Agreement shall also survive, but only to the extent required for the full observation and performance of this Agreement. Any expiration or early termination of this Agreement shall be without prejudice to the rights of any Party against the other accrued or accruing under this Agreement prior to termination. Except as expressly set forth herein, the rights to terminate as set forth herein shall be in addition to all other rights and remedies available under this Agreement, at Law, or in equity, or otherwise.

7. Indemnification

7.1 **Parties.** For purposes of this Section 7, “**Titan Indemnified Parties**” refers to Titan, its Affiliates and the officers, directors, employees, shareholders, agents and successors and assigns of Titan and its Affiliates, and “**JT Indemnified Parties**” refers to JT, its Affiliates and officers, directors, employees, shareholders, members, partners, agents and successors and assigns of JT and its Affiliates.

7.2 **Indemnification by JT.** Subject to the limitations set forth in Section 7.4, JT shall indemnify, reimburse, defend, save and hold the Titan Indemnified Parties harmless from and against all losses, costs, damages and expenses, including reasonable attorneys' fees and expenses and reasonable fees and expenses of other professionals and experts, but excluding unforeseeable, speculative, special, indirect, consequential, exemplary and punitive damages ("**Damages**") (but net of the amount of (x) any insurance proceeds realized by such Titan Indemnified Parties from insurance policies with respect to such matters or (y) any recoveries by any Titan Indemnified Parties from any third party, without duplication) resulting proximately from:

- (a) JT's breach of any representation or warranty of JT contained in this Agreement and the Ancillary Agreement;
- (b) JT's breach or nonfulfillment of any covenant or agreement made by JT in or pursuant to this Agreement or in any Ancillary Agreement; or
- (c) JT's failure to satisfy any Excluded Liabilities.

7.3 **Indemnification by Titan.** Subject to the limitations set forth in Section 7.4, Titan shall indemnify, reimburse, defend, save and hold the JT Indemnified Parties harmless from and against all Damages (but net of the amount of (a) any insurance proceeds realized by such JT Indemnified Parties from insurance policies with respect to such matters or (b) any recoveries by any JT Indemnified Parties from any third party, without duplication) resulting proximately from:

- (a) Titan's breach of any representation or warranty of Titan contained in this Agreement;
- (b) Titan's breach or nonfulfillment of any covenant or agreement made by Titan in or pursuant to this Agreement; and
- (c) Any Liability related to or arising from the ownership of the Purchased Assets following the Closing.

7.4 **Limitations.** In no event shall either Party be liable for or have any obligation to compensate or indemnify the other Party's indemnified Parties for any indirect or consequential damages claimed by such other Party other than in connection with their respective indemnification obligations set forth in this Section 7, including the loss of opportunity, loss of use, or loss of revenue or profit, in connection with or arising out of this Agreement or breach thereof.

8. Miscellaneous

8.1 **Force Majeure.** Neither Party shall be held liable or responsible to the other Party nor be deemed to have defaulted under or breached the Agreement for failure or delay in fulfilling or performing any term of the Agreement during the period of time when such failure or delay is caused by or results from a Force Majeure event or act, omission or delay in acting by the other Party. The affected Party shall notify the other Party of such Force Majeure circumstances as soon as reasonably practicable.

8.2 **Assignment.** This Agreement may not be assigned or otherwise transferred without the prior written consent of the other Party; provided, however, that either Party may assign this Agreement to (i) an Affiliate of such Party or (ii) in connection with the transfer or sale of its business or all or substantially all of its assets or in the event of a merger, consolidation, change in control or similar corporate transaction, without such consent, provided that all of Titan's obligations hereunder are assumed by the assignee. This Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the Parties. Any purported assignment not in accordance with this Agreement shall be void.

8.3 **Severability.** In the event that any of the provisions contained in this Agreement are held invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein shall not in any way be affected or impaired thereby, unless the absence of the invalidated provision(s) adversely affects the substantive rights of the Parties.

8.4 **Notices.**

(a) Notices and communications shall be in writing and shall be deemed to have been given when delivered in person, or sent by overnight courier service, postage prepaid, or by facsimile confirmed by prepaid registered or certified air mail letter or by overnight express mail, or sent by prepaid certified or registered air mail, return receipt requested, to the following addresses of the parties (or to such other address or addresses as may be specified from time to time in a written notice), and shall be deemed to have been properly served to the addressee upon receipt of such written communication, to the following addresses of the Parties:

if to Titan to:

Titan Pharmaceuticals, Inc.
400 Oyster Point Blvd., Suite 505
South San Francisco, CA 94080-1921
Attention: President
Fax No.: 650-244-4956

with a copy to:

Fran M. Stoller, Esq.
Loeb & Loeb LLP
345 Park Avenue
New York, NY 10154
Fax No.: 212-214-0706

if to JT to:

JT Pharmaceuticals, Inc.
300 West Coleman Boulevard, Suite 203
Mt. Pleasant, SC 29464
Attention: James R. McNab, Jr.
Fax No.:

with a copy to:

David L. Wilke
Wyrick Robbins Yates & Ponton LLP
4101 Lake Boone Trail, Suite 300
Raleigh, NC 27607
Fax No.: 919-781-4865

or to such other address as the Party to whom notice is to be given may have furnished to the other Parties in writing in accordance herewith. Any such communication shall be deemed to have been given when delivered if personally delivered or sent by facsimile on a Business Day, upon confirmed delivery by nationally-recognized overnight courier if so delivered and on the third Business Day following the date of mailing if sent by registered or certified mail.

8.5 Remedies.

(a) Cumulative Remedies. All rights and remedies provided in this Agreement are cumulative and not exclusive, and the exercise by either Party of any right or remedy does not preclude the exercise of any other rights or remedies that may now or subsequently be available at Law, in equity, by statute, in any other agreement between the Parties or otherwise.

(b) Specific Performance. Each of the Parties acknowledges and agrees that the other Party would be damaged irreparably in the event any of the provisions of this Agreement are not performed in all material respects or otherwise are breached. Accordingly, and notwithstanding anything herein to the contrary, each of the Parties agree that the other Party shall be entitled to injunctive relief to prevent breaches of the provisions of this Agreement, or to enforce specifically this Agreement and the terms and provisions hereof, in any action instituted in any court or tribunal having jurisdiction over the Parties and the matter, without posting any bond or other security, and that such injunctive relief shall be in addition to any other remedies to which such Party may be entitled, at Law or in equity.

8.6 **Applicable Law and Venue.** This Agreement shall be governed and construed by the Laws of the State of Delaware without regard to principles of conflicts of laws and any dispute arising out of, or in connection with, this Agreement, shall be subject to the exclusive jurisdiction of any Delaware State or federal court.

8.7 **Entire Agreement.** This Agreement, including the Schedules hereto, contains the entire understanding of the Parties with respect to the subject matter of this Agreement. All express or implied agreements and understandings, either oral or written, made on or before the Effective Date, including any offering letters or term sheets, are expressly superseded by this Agreement. This Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by all Parties.

8.8 **Independent Contractors.** It is expressly agreed that the Parties shall be independent contractors and that the relationship between the Parties shall not constitute a partnership, joint venture or agency. Neither Party shall have the authority to make any statements, representations or commitments of any kind, or to take any action, that shall be binding on the other Party, without the prior consent of such other Party.

8.9 **Waiver.** The waiver by a Party hereto of any right hereunder or the failure to perform or of a breach by another Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by said other Party whether of a similar nature or otherwise.

8.10 **Headings; References; Interpretation.** The captions to the several Schedules or Sections of this Agreement are not a part of the Agreement, but are merely guides or labels to assist in locating and reading the several Schedules or Sections of this Agreement. Where words and phrases are used herein in the singular, such usage is intended to include the plural forms where appropriate to the context, and vice versa. The words “including”, “includes” and “such as” are used in their non-limiting sense and have the same meaning as “including without limitation” and “including but not limited to”. Any reference in this Agreement to a Schedule or Section shall, unless otherwise specifically provided, be to a Schedule or Section of this Agreement. “Herein” means anywhere in this Agreement. “Hereunder”, “herein”, “hereinafter”, “hereby”, “hereunder”, “hereto” and words of similar import means under or pursuant to any provision of this Agreement, and not to any particular provision of this Agreement, unless the context clearly requires otherwise. Whenever the context requires, any pronoun includes the corresponding masculine, feminine and neuter forms. All references to “party” and “parties” are deemed references to parties to this Agreement, unless the context requires otherwise. The term “or” is used in its inclusive sense and is deemed to have the meaning “and/or”, and, together with the terms “either” and “any” is not exclusive. The term “any” is deemed to have the meaning “any and/or all”. Any reference to any contract or other document or instrument or to any law is to it as amended and supplemented from time to time unless the context requires otherwise. Any reference to a Person includes the permitted successors and assigns of such Person. Any reference to any materials, including any document, report, record, file or other data, include, in each case, any form or medium of such materials (including electronic form).

8.11 **Counterparts.** The Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Signatures to the Agreement transmitted by fax, by pdf or by any other electronic means intended to preserve the original graphic and pictorial appearance of the Agreement shall have the same effect as physical delivery of the paper document bearing original signature.

[Remainder of this page intentionally left blank]

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the Effective Date.

TITAN PHARMACEUTICALS, INC.

By: /s/ Marc Rubin

Name: Marc Rubin

Title: Executive Chairman

JT PHARMACEUTICALS, INC.

By: /s/ James R. McNab, Jr

Name: James R. McNab, Jr.

Title: President

CERTIFICATION

I, Marc Rubin, certify that:

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

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

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

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

Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my
(a) supervision, to ensure that material information relating to the registrant is made known to me by others within those entities, particularly during the period in which this report is being prepared;

Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed
(b) under my supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions
(c) about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the
(d) registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting
(a) which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 16, 2020

/s/ Marc Rubin, M.D.

Name: Marc Rubin, M.D.

Title: Executive Chairman

(Principal Executive Officer and Principal Financial Officer)

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

In connection with this quarterly report on Form 10-Q of Titan Pharmaceuticals, Inc. (the "Company") for the period ended September 30, 2020, 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: November 16, 2020

/s/ Marc Rubin, M.D.

Name: Marc Rubin, M.D.

Title: Executive Chairman

(Principal Executive Officer and Principal Financial Officer)

**Document and Entity
Information - shares**

**9 Months Ended
Sep. 30, 2020**

Nov. 10, 2020

Document and Entity Information

| | | |
|--|---------------------------------|-------------|
| <u>Document Type</u> | 10-Q | |
| <u>Document Period End Date</u> | Sep. 30, 2020 | |
| <u>Entity Registrant Name</u> | TITAN PHARMACEUTICALS INC | |
| <u>Entity Current Reporting Status</u> | Yes | |
| <u>Entity Interactive Data Current</u> | Yes | |
| <u>Entity Filer Category</u> | Non-accelerated Filer | |
| <u>Entity Small Business</u> | true | |
| <u>Entity Emerging Growth Company</u> | false | |
| <u>Entity Shell Company</u> | false | |
| <u>Title of 12(b) Security</u> | Common Stock, par value \$0.001 | |
| <u>Trading Symbol</u> | TTNP | |
| <u>Security Exchange Name</u> | NASDAQ | |
| <u>Entity Common Stock, Shares Outstanding</u> | | 196,763,180 |
| <u>Entity Central Index Key</u> | 0000910267 | |
| <u>Current Fiscal Year End Date</u> | --12-31 | |
| <u>Document Fiscal Year Focus</u> | 2020 | |
| <u>Document Fiscal Period Focus</u> | Q3 | |
| <u>Amendment Flag</u> | false | |

**CONDENSED BALANCE
SHEETS - USD (\$)
\$ in Thousands**

Sep. 30, 2020 Dec. 31, 2019

Current assets:

| | | |
|--|----------|----------|
| <u>Cash and cash equivalents</u> | \$ 4,073 | \$ 5,223 |
| <u>Receivables</u> | 423 | 993 |
| <u>Inventory</u> | 1,073 | 998 |
| <u>Prepaid expenses and other current assets</u> | 1,080 | 1,094 |
| <u>Total current assets</u> | 6,649 | 8,308 |
| <u>Property and equipment, net</u> | 1,161 | 817 |
| <u>Operating lease right-of-use asset</u> | 208 | 397 |
| <u>Total assets</u> | 8,018 | 9,522 |

Current liabilities:

| | | |
|---|-------|-------|
| <u>Accounts payable</u> | 1,750 | 1,401 |
| <u>Accrued clinical trials expenses</u> | 829 | 309 |
| <u>Accrued sales allowances</u> | 119 | 809 |
| <u>Other accrued liabilities</u> | 875 | 809 |
| <u>Operating lease liability, current</u> | 222 | 272 |
| <u>Current portion of long-term debt</u> | 2,082 | 0 |
| <u>Total current liabilities</u> | 5,877 | 3,600 |
| <u>Operating lease liability, non-current</u> | 0 | 150 |
| <u>Long-term debt</u> | 3,038 | 4,019 |
| <u>Warrant liability</u> | 0 | 320 |
| <u>Total liabilities</u> | 8,915 | 8,089 |

Stockholders' equity (deficit):

| | | |
|---|-----------|-----------|
| <u>Common stock, at amounts paid-in</u> | 117 | 57 |
| <u>Additional paid-in capital</u> | 363,180 | 350,413 |
| <u>Accumulated deficit</u> | (364,194) | (349,037) |
| <u>Total stockholders' equity (deficit)</u> | (897) | 1,433 |
| <u>Total liabilities and stockholders' equity (deficit)</u> | \$ 8,018 | \$ 9,522 |

**CONDENSED
STATEMENTS OF
OPERATIONS AND
COMPREHENSIVE LOSS -
USD (\$)
shares in Thousands, \$ in
Thousands**

| | 3 Months Ended | | 9 Months Ended | |
|--|--------------------------|--------------------------|--------------------------|--------------------------|
| | Sep. 30, 2020 | Sep. 30, 2019 | Sep. 30, 2020 | Sep. 30, 2019 |
| Revenues: | | | | |
| <u>Total revenues</u> | \$ 1,120 | \$ 947 | \$ 3,781 | \$ 2,394 |
| Operating expenses: | | | | |
| <u>Cost of goods sold</u> | 683 | 188 | 1,081 | 738 |
| <u>Research and development</u> | 1,562 | 1,619 | 5,846 | 5,370 |
| <u>Selling, general and administrative</u> | 3,549 | 3,023 | 10,137 | 9,336 |
| <u>Total operating expenses</u> | 5,794 | 4,830 | 17,064 | 15,444 |
| <u>Loss from operations</u> | (4,674) | (3,883) | (13,283) | (13,050) |
| Other expense: | | | | |
| <u>Interest expense, net</u> | (246) | (238) | (718) | (737) |
| <u>Non-cash gain (loss) on changes in the fair value of warrants</u> | 0 | 1,041 | (923) | 1,066 |
| <u>Gain on debt extinguishment</u> | 0 | 291 | 0 | 226 |
| <u>Other income (expense), net</u> | (12) | (14) | (233) | (22) |
| <u>Other income (expense), net</u> | (258) | 1,080 | (1,874) | 533 |
| <u>Net loss and comprehensive loss</u> | \$ (4,932) | \$ (2,803) | \$ (15,157) | \$ (12,517) |
| <u>Basic and diluted net loss per common share</u> | \$ (0.05) | \$ (0.18) | \$ (0.17) | \$ (0.89) |
| <u>Weighted average shares used in computing basic and diluted net loss per common share</u> | 97,906 | 15,517 | 91,848 | 14,112 |
| <u>License revenue</u> | | | | |
| Revenues: | | | | |
| <u>Total revenues</u> | \$ 0 | \$ 0 | \$ 6 | \$ 313 |
| <u>Product revenue</u> | | | | |
| Revenues: | | | | |
| <u>Total revenues</u> | 102 | 190 | 427 | 811 |
| <u>Grant revenue</u> | | | | |
| Revenues: | | | | |
| <u>Total revenues</u> | \$ 1,018 | \$ 757 | \$ 3,348 | \$ 1,270 |

| CONDENSED STATEMENTS OF STOCKHOLDERS' EQUITY - USD (\$) shares in Thousands, \$ in Thousands | At-the- market offerings [Member] Common Stock [Member] | At-the- market offerings [Member] Additional Paid-In Capital [Member] | At-the- market offerings [Member] | Common Stock [Member] | Additional Paid-In Capital [Member] | Accumulated Deficit [Member] | Total |
|---|--|--|--|--------------------------------------|--|---|--------------|
| Balance at Dec. 31, 2018 | | | | \$ 13 | \$ 339,397 | \$ (332,579) | \$ 6,831 |
| Balance (in shares) at Dec. 31, 2018 | | | | 13,010 | | | |
| Net loss | | | | \$ 0 | | (4,517) | (4,517) |
| Issuance of common stock upon exercises of warrants, net | | | | \$ 0 | 605 | | 605 |
| Issuance of common stock upon exercises of warrants, net (in shares) | | | | 404 | | | |
| Stock-based compensation | | | | \$ 0 | 136 | | 136 |
| Balance at Mar. 31, 2019 | | | | \$ 13 | 340,138 | (337,096) | 3,055 |
| Balance (in shares) at Mar. 31, 2019 | | | | 13,414 | | | |
| Balance at Dec. 31, 2018 | | | | \$ 13 | 339,397 | (332,579) | 6,831 |
| Balance (in shares) at Dec. 31, 2018 | | | | 13,010 | | | |
| Net loss | | | | | | | (12,517) |
| Balance at Sep. 30, 2019 | | | | \$ 17 | 342,419 | (345,096) | (2,660) |
| Balance (in shares) at Sep. 30, 2019 | | | | 17,144 | | | |
| Balance at Mar. 31, 2019 | | | | \$ 13 | 340,138 | (337,096) | 3,055 |
| Balance (in shares) at Mar. 31, 2019 | | | | 13,414 | | | |
| Net loss | | | | \$ 0 | | (5,197) | (5,197) |
| Issuance of common stock, net | \$ 0 | \$ 466 | \$ 466 | | | | |
| Issuance of common stock, net (in shares) | 330 | | | | | | |
| Issuance of common stock upon exercises of warrants, net | | | | \$ 0 | 105 | | 105 |
| Issuance of common stock upon exercises of warrants, net (in shares) | | | | 70 | | | |
| Issuance of common stock upon conversion of convertible loan | | | | \$ 1 | 649 | | 650 |

| | | | | | | | |
|--|-------|--------|--------|--------|---------|-----------|----------|
| <u>Issuance of common stock upon conversion of convertible loan, (in shares)</u> | | | | 448 | | | |
| <u>Stock-based compensation</u> | | | | \$ 0 | 350 | | 350 |
| <u>Balance at Jun. 30, 2019</u> | | | | \$ 14 | 341,708 | (342,293) | (571) |
| <u>Balance (in shares) at Jun. 30, 2019</u> | | | | 14,262 | | | |
| <u>Net loss</u> | | | | \$ 0 | | (2,803) | (2,803) |
| <u>Issuance of common stock, net</u> | \$ 2 | \$ 571 | \$ 573 | | | | |
| <u>Issuance of common stock, net (in shares)</u> | 1,480 | | | | | | |
| <u>Issuance of common stock upon exercises of warrants, net</u> | | | | \$ 1 | 12 | | 13 |
| <u>Issuance of common stock upon exercises of warrants, net (in shares)</u> | | | | 1,372 | | | |
| <u>Issuance of common stock upon conversion of convertible loan</u> | | | | \$ 0 | | | |
| <u>Stock-based compensation</u> | | | | 0 | 128 | | 128 |
| <u>Balance at Sep. 30, 2019</u> | | | | \$ 17 | 342,419 | (345,096) | (2,660) |
| <u>Balance (in shares) at Sep. 30, 2019</u> | | | | 17,144 | | | |
| <u>Balance at Dec. 31, 2019</u> | | | | \$ 57 | 350,413 | (349,037) | 1,433 |
| <u>Balance (in shares) at Dec. 31, 2019</u> | | | | 57,379 | | | |
| <u>Net loss</u> | | | | | | (5,584) | (5,584) |
| <u>Issuance of common stock, net</u> | | | | \$ 9 | 443 | | 452 |
| <u>Issuance of common stock, net (in shares)</u> | | | | 8,700 | | | |
| <u>Issuance of common stock upon exercises of warrants, net</u> | | | | \$ 27 | 6,135 | | 6,162 |
| <u>Issuance of common stock upon exercises of warrants, net (in shares)</u> | | | | 27,388 | | | |
| <u>Reclassification of warrants from liability</u> | | | | \$ 0 | 2,897 | 0 | 2,897 |
| <u>Stock-based compensation</u> | | | | | (84) | | (84) |
| <u>Balance at Mar. 31, 2020</u> | | | | \$ 93 | 359,804 | (354,621) | 5,276 |
| <u>Balance (in shares) at Mar. 31, 2020</u> | | | | 93,467 | | | |
| <u>Balance at Dec. 31, 2019</u> | | | | \$ 57 | 350,413 | (349,037) | 1,433 |
| <u>Balance (in shares) at Dec. 31, 2019</u> | | | | 57,379 | | | |
| <u>Net loss</u> | | | | | | | (15,157) |
| <u>Balance at Sep. 30, 2020</u> | | | | \$ 117 | 363,180 | (364,194) | (897) |

| | | | | |
|---|---------|------------|--------------|----------|
| <u>Balance (in shares) at Sep. 30, 2020</u> | 116,763 | | | |
| <u>Balance at Mar. 31, 2020</u> | \$ 93 | 359,804 | (354,621) | 5,276 |
| <u>Balance (in shares) at Mar. 31, 2020</u> | 93,467 | | | |
| <u>Net loss</u> | | | (4,641) | (4,641) |
| <u>Issuance of common stock upon exercises of warrants, net</u> | \$ 4 | 842 | | 846 |
| <u>Issuance of common stock upon exercises of warrants, net (in shares)</u> | 3,756 | | | |
| <u>Stock-based compensation</u> | | 79 | | 79 |
| <u>Balance at Jun. 30, 2020</u> | \$ 97 | 360,725 | (359,262) | 1,560 |
| <u>Balance (in shares) at Jun. 30, 2020</u> | 97,223 | | | |
| <u>Net loss</u> | | | (4,932) | (4,932) |
| <u>Issuance of common stock, net</u> | \$ 20 | 2,424 | | 2,444 |
| <u>Issuance of common stock, net (in shares)</u> | 19,440 | | | |
| <u>Issuance of common stock upon exercises of warrants, net</u> | | 22 | | 22 |
| <u>Issuance of common stock upon exercises of warrants, net (in shares)</u> | 100 | | | |
| <u>Stock-based compensation</u> | | 9 | | 9 |
| <u>Balance at Sep. 30, 2020</u> | \$ 117 | \$ 363,180 | \$ (364,194) | \$ (897) |
| <u>Balance (in shares) at Sep. 30, 2020</u> | 116,763 | | | |

**CONDENSED
STATEMENTS OF CASH
FLOWS - USD (\$)
\$ in Thousands**

9 Months Ended

Sep. 30, 2020 Sep. 30, 2019

Cash flows from operating activities:

Net loss \$ (15,157) \$ (12,517)

Adjustments to reconcile loss to net cash used in operating activities:

Depreciation and amortization 227 186

Non-cash interest expense 447 467

Non-cash (gain) loss on changes in fair value of warrants 923 (1,066)

Non-cash loss on asset impairment 433 0

Stock-based compensation 4 614

Finance costs attributable to issuance of warrants 211 0

Gain on debt extinguishment 0 (226)

Other (11) (36)

Changes in operating assets and liabilities:

Receivables 570 962

Inventory (508) 0

Prepaid expenses and other assets 14 (492)

Accounts payable 309 (111)

Accrued sales allowances (690) 750

Other accrued liabilities 586 0

Deferred revenue 0 (313)

Net cash used in operating activities (12,642) (11,782)

Cash flows from investing activities:

Purchases of property and equipment (531) (144)

Net cash used in investing activities (531) (144)

Cash flows from financing activities:

Net proceeds from equity offering 4,339 2,467

Net proceeds from the exercises of common stock warrants 7,030 724

Net loan proceeds 654 0

Net cash provided by financing activities 12,023 3,191

Net decrease in cash and cash equivalents (1,150) (8,735)

Cash, cash equivalents and restricted cash at beginning of period 5,223 9,656

Cash, cash equivalents and restricted cash at end of period 4,073 921

Supplemental disclosure of cash flow information:

Interest paid 295 328

Non-cash conversion of Molteni Convertible Loan \$ 0 \$ 650

**Organization and Summary
of Significant Accounting
Policies**

9 Months Ended

Sep. 30, 2020

**Organization and Summary
of Significant Accounting
Policies**

**Organization and Summary of
Significant Accounting
Policies**

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 provides the potential for an efficacy and/or safety benefit. Probuphine® (buprenorphine) implant is the first product based on our ProNeura technology approved in the U.S., Canada and the European Union, or EU, for the maintenance treatment of opioid use disorder, or OUD, in select patients. In October 2020, we made a determination to discontinue commercial activities associated with marketing Probuphine in the U.S. and we are now transitioning back to a development stage enterprise. We operate in only one business segment, the development of pharmaceutical products.

Basis of Presentation

The accompanying unaudited condensed financial statements have been prepared in accordance with U.S. generally accepted accounting principles (“GAAP”) for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by 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, 2020 are not necessarily indicative of the results that may be expected for the year ending December 31, 2020, or any future interim periods.

The balance sheet at December 31, 2019 is derived from the audited financial statements at that date, but does not include all of 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, 2019, as filed with the Securities and Exchange Commission (“SEC”).

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

At September 30, 2020, we had cash and cash equivalents of approximately \$4.1 million, which we believe along with the approximately \$5.7 million of net proceeds from our October 2020 public offering (the “2020 Public Offering”) is sufficient to complete the wind down of the U.S. Probuphine commercialization activities and fund our planned operations into the third quarter of 2021. We will require additional funds to finance our operations beyond such period. 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.

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 financial statements are issued or available to be issued, which is referred to as the “look-forward period” as defined by Accounting Standard Update (“ASU”) No. 2014-15. As part of this assessment, based on conditions that are known and reasonably knowable to us, we will consider various scenarios, forecasts, projections, estimates and will make certain key assumptions, including the timing and nature of projected cash expenditures or programs, and its ability to delay or curtail expenditures or programs, if necessary, among other factors. Based on this assessment, as necessary or applicable, we make certain assumptions around implementing curtailments or delays in the nature and timing of programs and expenditures to the extent we deem probable those implementations can be achieved and we have the proper authority to execute them within the look-forward period in accordance with ASU No. 2014-15.

Based upon the above assessment, we concluded that, at the date of filing the financial statements in this Quarterly Report on Form 10-Q for the nine months ended September 30, 2020, 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 financial statements were issued.

Use of Estimates

The preparation of these unaudited condensed financial statements requires that we make estimates and judgments that affect the reported amounts of assets, liabilities, revenues, expenses and related disclosures. On an ongoing basis, we evaluate our estimates, including critical accounting policies or estimates related to warrants issued in equity financing, research and development expenses, income taxes, inventories, revenues, accrued sales allowances, contingencies and litigation and share-based compensation. We base our estimates on historical experience, information received from third parties and on various market specific and other relevant assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results could differ significantly from those estimates under different assumptions or conditions.

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>As of</i> | |
|----------------------------|---------------------------|--------------------------|
| | <u>September 30, 2020</u> | <u>December 31, 2019</u> |
| Raw materials and supplies | 442 | 563 |
| Finished goods | 631 | 435 |
| | <u>\$ 1,073</u> | <u>\$ 998</u> |

Revenue Recognition

We generate revenue principally from collaborative research and development arrangements, technology licenses and sales, government grants and, prior to the discontinuance of our commercial activities in October 2020, the sale of Probuphine in the U.S. Consideration received for revenue arrangements with multiple components is allocated among the separate performance obligations based upon their relative estimated standalone selling price.

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

Net Product Revenue

Until the discontinuance of our commercial activities in October 2020, we recognized revenue from product sales when control of the product transferred, 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, including 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 is typically at stated contractual rates. The actual outcome of this variable consideration may materially differ from our estimates.

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.

The following table provides a summary of activity with respect to our product returns, and discounts and rebates, which are included on our condensed balance sheets within accrued sales allowances (in thousands):

| | Accrued Sales Allowances | | | Allowance for Doubtful Accounts |
|-------------------------------|--------------------------------|---------------------------------------|--------|--|
| | Product Return Allowance | Discounts and Rebates Allowance | Total | |
| Balance at December 31, 2019 | \$ 721 | \$ 88 | \$ 809 | \$ 63 |
| Provision | 94 | 40 | 134 | 22 |
| Payments/credits | (722) | (102) | (824) | (76) |
| Balance at September 30, 2020 | \$ 93 | \$ 26 | \$ 119 | \$ 8 |

During the nine months ended September 30, 2020, we received customer returns of approximately \$0.7 million that had been reserved for previously.

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.

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 activity is considered variable until such costs are reimbursed at which point they are considered fixed. We allocate the total transaction price to each performance obligation based on the relative estimated standalone selling prices of the promised goods or services for each performance obligation.

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

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

Allocation of Consideration

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

Timing of Recognition

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

Research and Development Costs and Related Accrual

Research and development expenses include internal and external costs. Internal costs include salaries and employment related expenses, facility costs, administrative expenses and allocations of corporate costs. External expenses consist of costs associated with outsourced

contract research organization (“CRO”) activities, sponsored research studies, product registration and patent application and prosecution. We also record accruals for estimated ongoing non-clinical and clinical research 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 clinical research, 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

In February 2016, the Financial Accounting Standards Board (the “FASB”) issued ASU No. 2016-02, Leases (Topic 842), to enhance the transparency and comparability of financial reporting related to leasing arrangements.

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 sheet 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 sheet.

The following table presents obligation related to our operating lease:

| | |
|--|---------------|
| 2020 | \$ 78 |
| 2021 | 155 |
| Total minimum lease payments (base rent) | 233 |
| Less: imputed interest | (11) |
| Total operating lease liabilities | <u>\$ 222</u> |

Recent Accounting Pronouncements

Accounting Standards Adopted

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

Accounting Standards Not Yet Adopted

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

31, 2023. We are currently assessing the impact of the adoption of Topic 326 on our financial statements and disclosures.

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

Subsequent Events

We have evaluated events that have occurred after September 30, 2020 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. Our derivative liability is classified within Level 3 of the fair value hierarchy because the fair value is calculated using significant judgment based on our own assumptions in the valuation of this liability.

At September 30, 2020 and December 31, 2019, the fair value of our investments in money market funds were approximately \$3.8 million and approximately \$4.9 million, respectively, which are included within our cash and cash equivalents in our condensed balance sheets.

Stock Plans

9 Months Ended Sep. 30, 2020

[Stock Plans](#)

[Stock Plans](#)

2. Stock Plans

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

| | Three Months Ended | | Nine Months Ended | |
|---------------------------------------|--------------------|---------------|-------------------|---------------|
| | September 30, | | September 30, | |
| | 2020 | 2019 | 2020 | 2019 |
| Research and development | \$ — | \$ — | \$ — | \$ 91 |
| Selling, general and administrative | 9 | 128 | 4 | 523 |
| Total stock-based compensation | \$ 9 | \$ 128 | \$ 4 | \$ 614 |

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 | | Nine Months Ended | |
|---|--------------------|------|-------------------|-------|
| | September 30, | | September 30, | |
| | 2020 | 2019 | 2020 | 2019 |
| Weighted-average risk-free interest rate | 0.3 % | — | 0.4 % | 2.2 % |
| Expected dividend payments | — | — | — | — |
| Expected holding period (years) ¹ | 5.7 | — | 5.8 | 5.4 |
| Weighted-average volatility factor ² | 1.07 | — | 1.04 | 0.94 |
| Estimated forfeiture rates for options granted ³ | 24 % | — | 27 % | 21 % |

- (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.

The following table summarizes option activity:

| | Options (in thousands) | Weighted Average Exercise Price per share | Weighted | Aggregate Intrinsic Value (in thousands) |
|-----------------------------------|------------------------|---|--|--|
| | | | Average Remaining Option Term (in years) | |
| <i>(in thousands)</i> | | | | |
| Outstanding December 31, 2019 | 1,192 | \$ 6.23 | 7.9 | \$ — |
| Granted | 60 | 0.27 | | |
| Forfeited or expired | (334) | 1.88 | | |
| Outstanding at September 30, 2020 | 918 | 7.42 | 6.8 | — |
| Exercisable at September 30, 2020 | 827 | 8.16 | 6.6 | — |

Options to purchase 10,000 common shares were granted during the three month periods ended September 30, 2020.

As of September 30, 2020, there was approximately \$30,000 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 1.8 years.

Net Loss Per Share

**9 Months Ended
Sep. 30, 2020**

[Net Loss Per Share](#)

[Net Loss Per Share](#)

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:

| | Three Months Ended | | Nine Months Ended | |
|---|--------------------|--------------|--------------------|--------------|
| | September 30, 2020 | 2019 | September 30, 2020 | 2019 |
| <i>(in thousands)</i> | | | | |
| Weighted-average anti-dilutive common shares resulting from options | 913 | 1,282 | 934 | 1,027 |
| Weighted-average anti-dilutive common shares resulting from warrants | 8,342 | 5,961 | 8,342 | 1,222 |
| Weighted-average anti-dilutive common shares resulting from convertible loans | 3,243 | 330 | 3,243 | 332 |
| | <u>12,498</u> | <u>7,573</u> | <u>12,519</u> | <u>2,581</u> |

4. Molteni Purchase Agreement

On March 21, 2018, we entered into a purchase agreement (“Molteni Purchase Agreement”) with L. Molteni & C. Dei Frattelli Alitti Società Di Esercizio S.P.A. (“Molteni”) pursuant to which Molteni acquired the European intellectual property related to Probuphine, including the marketing authorization application under review by the European Medicines Agency (“EMA”), 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 (the “Molteni Territory”).

In connection with the Molteni Purchase Agreement, we received an initial payment of €2.0 million (approximately \$2.4 million), of which approximately \$1.0 million was allocated to the transfer of the intellectual property, which was recognized immediately, and approximately \$1.4 million to our efforts towards the approval by the EMA by using the expected cost-plus approach to estimate the standalone selling price of and other regulatory bodies (“Titan Services”), which was recorded as deferred revenue and amortized as the performance obligations associated with the Titan Services being satisfied over time. Titan Services included employee-related expenses as well as other manufacturing, regulatory and clinical costs. During the three months ended March 31, 2019, we fully amortized our deferred revenue and recognized approximately \$0.3 million of revenue associated with the completion of Titan Services.

In August 2018, we entered into an amendment to the Molteni Purchase Agreement, pursuant to which Molteni made an immediate payment of €950,000 (approximately \$1.1 million) and a convertible loan of €550,000 (approximately \$0.6 million) (“Molteni Convertible Loan”) (see Note 5) to us, both in exchange for the elimination of an aggregate of €2.0 million (approximately \$2.3 million) of regulatory milestones provided for in the Molteni Purchase Agreement.

In September 2019, we entered into an additional amendment to the Molteni Purchase Agreement, pursuant to which the percentage earn-out payments on net sales were reduced and payments of any earn-outs were delayed until the later of (i) January 1, 2021 or (ii) the one year anniversary of completion of compliance by our manufacturer with EU requirements (currently anticipated to occur during the second quarter of this year).

In October 2020, in connection with the settlement of our debt obligations, we forfeited our rights to any future payments under the Molteni Purchase Agreement. See Note 8 “Subsequent Events.”

[Debt Agreements](#)

[Debt Agreements](#)

5. Debt Agreements

Horizon and Molteni Loans

In March 2018, we entered into an Amended and Restated Venture Loan and Security Agreement (the "Loan Agreement") with Horizon Credit II LLC ("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 \$7.20 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 6,667 shares of our common stock with an exercise price per share of \$7.20 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 \$0.225 and to cap the number of shares issuable upon conversion to 3,422,777, with any balance repayable in cash.

In accordance with ASC 470, the amendment to the loan from Molteni is accounted for under debt extinguishment accounting, which required us to extinguish the carrying amount of the loan prior to the amendment and reacquire the loan after the amendment. As a result, during the three months ended September 30, 2019, we recorded approximately \$0.3 million gain on debt extinguishment related to the write-off of the balance of the accreted final payment of the loan. The modification to the loan from Horizon did not constitute debt extinguishment and, therefore, did not have any impact to our condensed financial statements.

Repayment of the loans is on an interest-only basis, followed by monthly payments of principal and accrued interest for the balance of the 46-month term. The loans bear interest at a floating coupon rate of one-month LIBOR (floor of 1.10%) plus 8.40%. A final payment equal to 5.0% of each loan tranche will be due on the scheduled maturity date for such loan. In addition, if we repay all or a portion of the loan prior to the applicable maturity date, we will pay Horizon and Molteni prepayment penalty fees.

Debt discount associated with the Horizon and Molteni Loans was approximately \$0.3 million as of both September 30, 2020 and December 31, 2019.

In October 2020, we settled all of our outstanding debt obligations, to Horizon and Molteni. See Note 8 "Subsequent Events."

Molteni Convertible Loan

In connection with the amendment to the Molteni Purchase Agreement (see Note 4), in June 2019, the Molteni Convertible Loan, together with unpaid accrued interest, was converted in full into 448,287 shares of our common stock at \$1.50 per share upon the receipt of EMA approval of Sixmo. As a result, we recorded approximately \$0.1 million loss on debt extinguishment.

Paycheck Protection Program Loan

On April 20, 2020, we received an approximately \$0.7 million loan (“PPP Loan”) pursuant to the Paycheck Protection Program of the CARES Act. The PPP Loan matures in April 2022 with an annual interest rate of 1.0%. The PPP Loan originally had a six month deferral of payments period which was extended to sixteen months during the third quarter of 2020 and may be prepaid at any time without penalty. All other terms remained the same. Forgiveness of the loan, when requested, is not automatic and is only available for principal that is used for the limited purposes that expressly qualify for forgiveness under SBA requirements. The proceeds of the PPP Loan are to be used to retain workers and maintain payroll and make mortgage interest, lease and utility payments.

Approximately \$0.1 million of the PPP loan is included in current portion of long-term debt and approximately \$0.6 million is included in long-term debt on our condensed balance sheet at September 30, 2020.

Stockholders' Equity

**9 Months Ended
Sep. 30, 2020**

Stockholders' Equity Stockholders' Equity

6. Stockholders' Equity

Our common stock outstanding as of September 30, 2020 and December 31, 2019 was 116,763,180 shares and 57,378,794 shares, respectively.

January 2020 Offering

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 8,700,000 shares of our common stock with an exercise price of \$0.25 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. During the three months ended March 31, 2020, financing costs of \$211,000 allocated to the January 2020 warrant liability were expensed and included in other income (expense) 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 19,440,000 shares of our common stock at a price of \$0.14 per share. We received net cash proceeds of approximately \$2.4 million, after deduction of underwriting fees and other offering expenses.

Common Stock Warrants

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 31,244,386 shares of our common stock.

Warrant Liabilities

9 Months Ended
Sep. 30, 2020

Warrant Liabilities

Warrant Liabilities

7. Warrant Liabilities

On March 3, 2020, we amended certain outstanding warrants to purchase an aggregate of 11,552,314 shares of common stock, including the January 2020 Warrants and warrants we issued in connection with a financing in August 2019 (the "August 2019 Warrants"), to modify certain provisions that had required them to be previously classified as liabilities and to enable them to now be classified as equity under the relevant accounting standards. As a result, during the three months ended March 31, 2020, we reclassified the fair value of the warrants on the date of the amendment from warrant liabilities to additional paid-in capital in the condensed balance sheet and recognized a non-cash loss on changes in the fair value of warrants in the condensed statement of operations and comprehensive loss.

The following table provides a roll forward of the fair value of our warrant liabilities, the fair value of which was determined by Level 3 inputs for the nine months ended September 30, 2020 (in thousands):

| | | |
|--|----|---------|
| Fair value, December 31, 2019 | \$ | 320 |
| Issuance of the January 2020 Warrants | | 1,654 |
| Change in fair value ⁽¹⁾ | | 923 |
| Reclassification of warrants to additional paid-in capital | | (2,897) |
| Fair value, September 30, 2020 | \$ | — |

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

The warrant liability associated with the January 2020 Warrants was classified within Level 3 of the fair value hierarchy. The following table presents the weighted-average key assumptions used to calculate the fair value of the January 2020 Warrants:

| | As of | |
|---|---------------|-----------------|
| | March 3, 2020 | January 7, 2020 |
| Expected volatility | 124 % | 121 % |
| Risk-free interest rate | 0.8 % | 1.6 % |
| Dividend yield | — | — |
| Expected term (in years) | 4.9 | 5.0 |
| Weighted-average fair value per share warrant | \$ 0.26 | \$ 0.19 |

The warrant liability associated with the August 2019 Warrants was classified within Level 3 of the fair value hierarchy. The following table presents the weighted-average key assumptions used to calculate the fair value of the August 2019 Warrants:

| | As of | |
|---|---------------|-------------------|
| | March 3, 2020 | December 31, 2019 |
| Expected volatility | 124 % | 125 % |
| Risk-free interest rate | 0.8 % | 1.7 % |
| Dividend yield | — | — |
| Expected term (in years) | 4.5 | 4.6 |
| Weighted-average fair value per share warrant | \$ 0.21 | \$ 0.11 |

Subsequent Events

**9 Months Ended
Sep. 30, 2020**

[Subsequent Events](#)

[Subsequent Events](#)

8. Subsequent Events

In October 2020, we announced our decision to discontinue selling our Probuphine® (buprenorphine) implant and wind-down our commercialization activities and pursue a plan that will enable us to focus on our ProNeura-based product development efforts.

In October 2020, we entered into a Debt Settlement and Release Agreement (the “DSRA Agreement”) with Molteni and Horizon pursuant to which the parties agreed to settle the approximately \$5.2 million of outstanding indebtedness to Molteni and Horizon (\$4.0 million principal amount and approximately \$1.2 million in final payments) in exchange for the payment of \$1.6 million in cash, the transfer of certain Probuphine assets to Molteni, including manufacturing equipment, certain inventory and non-U.S. Probuphine intellectual property, and the termination of our rights to future payments under the Molteni Purchase Agreement.

In October 2020, we entered into an Asset Purchase Agreement (the “JT Agreement”) with JT Pharmaceuticals, Inc. (“JT Pharma”) to acquire JT Pharma’s kappa opioid agonist peptide, JT-09, for use in combination with our ProNeura® long-term, continuous drug delivery technology, for the treatment of chronic pruritus. Under the terms of the JT Agreement, JT Pharma received a \$15,000 closing payment and is entitled to receive future milestone payments, payable in cash or in stock, based on the achievement of regulatory milestones, and single-digit percentage earn-out payments on net sales of the product if successfully developed and approved for commercialization.

In October 2020, we completed the 2020 Public Offering pursuant to which we sold 80,000,000 units at a price of \$0.10 per unit, with each unit consisting of (i) one share of common stock and (ii) one warrant (the “October 2020 Warrants”) to purchase one share of common stock, resulting in gross proceeds of approximately \$8.0 million. The net proceeds of the 2020 Public Offering, after deduction of underwriting discounts and commissions and other offering expenses and the \$1.6 million payment pursuant to the DSRA Agreement, were approximately \$5.7 million. The October 2020 Warrants have an exercise price of \$0.10, will be exercisable commencing on the effective date of an increase in our authorized shares of common stock or a reverse split in an amount sufficient to permit the exercise in full of the October 2020 Warrants and will expire on the fifth anniversary of the initial exercise date.

**Organization and Summary
of Significant Accounting
Policies (Policies)**

9 Months Ended

Sep. 30, 2020

**Organization and Summary
of Significant Accounting
Policies**

The Company

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 provides the potential for an efficacy and/or safety benefit. Probuphine® (buprenorphine) implant is the first product based on our ProNeura technology approved in the U.S., Canada and the European Union, or EU, for the maintenance treatment of opioid use disorder, or OUD, in select patients. In October 2020, we made a determination to discontinue commercial activities associated with marketing Probuphine in the U.S. and we are now transitioning back to a development stage enterprise. We operate in only one business segment, the development of pharmaceutical products.

Basis of Presentation

Basis of Presentation

The accompanying unaudited condensed financial statements have been prepared in accordance with U.S. generally accepted accounting principles (“GAAP”) for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by 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, 2020 are not necessarily indicative of the results that may be expected for the year ending December 31, 2020, or any future interim periods.

The balance sheet at December 31, 2019 is derived from the audited financial statements at that date, but does not include all of 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, 2019, as filed with the Securities and Exchange Commission (“SEC”).

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

At September 30, 2020, we had cash and cash equivalents of approximately \$4.1 million, which we believe along with the approximately \$5.7 million of net proceeds from our October 2020 public offering (the “2020 Public Offering”) is sufficient to complete the wind down of the U.S. Probuphine commercialization activities and fund our planned operations into the third quarter of 2021. We will require additional funds to finance our operations beyond such period. 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.

Going concern assessment

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 financial statements are issued or available to be issued, which is referred to as the “look-forward period” as defined by Accounting Standard Update (“ASU”) No. 2014-15. As part of this assessment, based on conditions that are known and reasonably knowable to us, we will consider various scenarios, forecasts, projections, estimates and will make certain key assumptions, including the timing and nature of projected cash expenditures or programs, and its ability to delay or curtail expenditures or programs, if necessary, among other factors. Based on this assessment, as necessary or applicable, we make certain assumptions around implementing curtailments or delays in the nature and timing of programs and expenditures to the extent we deem probable those implementations can be achieved and we have the proper authority to execute them within the look-forward period in accordance with ASU No. 2014-15.

Based upon the above assessment, we concluded that, at the date of filing the financial statements in this Quarterly Report on Form 10-Q for the nine months ended September 30, 2020, 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 financial statements were issued.

Use of Estimates

Use of Estimates

The preparation of these unaudited condensed financial statements requires that we make estimates and judgments that affect the reported amounts of assets, liabilities, revenues, expenses and related disclosures. On an ongoing basis, we evaluate our estimates, including critical accounting policies or estimates related to warrants issued in equity financing, research and development expenses, income taxes, inventories, revenues, accrued sales allowances, contingencies and litigation and share-based compensation. We base our estimates on historical experience, information received from third parties and on various market specific and other relevant assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results could differ significantly from those estimates under different assumptions or conditions.

Inventories

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>As of</i> | |
|----------------------------|---------------------------|--------------------------|
| | <u>September 30, 2020</u> | <u>December 31, 2019</u> |
| Raw materials and supplies | 442 | 563 |
| Finished goods | 631 | 435 |
| | <u>\$ 1,073</u> | <u>\$ 998</u> |

Revenue Recognition

Revenue Recognition

We generate revenue principally from collaborative research and development arrangements, technology licenses and sales, government grants and, prior to the discontinuance of our commercial activities in October 2020, the sale of Probuphine in the U.S. Consideration received for revenue arrangements with multiple components is allocated among the separate performance obligations based upon their relative estimated standalone selling price.

In determining the appropriate amount of revenue to be recognized as we fulfill our obligations under our agreements, we perform the following steps for our revenue recognition:

(i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations based on estimated selling prices; and (v) recognition of revenue when (or as) we satisfy each performance obligation.

Net Product Revenue

Until the discontinuance of our commercial activities in October 2020, we recognized revenue from product sales when control of the product transferred, 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, including 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 is typically at stated contractual rates. The actual outcome of this variable consideration may materially differ from our estimates.

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.

The following table provides a summary of activity with respect to our product returns, and discounts and rebates, which are included on our condensed balance sheets within accrued sales allowances (in thousands):

| | Accrued Sales Allowances | | | Allowance for Doubtful Accounts |
|-------------------------------|--------------------------------|---------------------------------------|--------|--|
| | Product Return Allowance | Discounts and Rebates Allowance | Total | |
| Balance at December 31, 2019 | \$ 721 | \$ 88 | \$ 809 | \$ 63 |
| Provision | 94 | 40 | 134 | 22 |
| Payments/credits | (722) | (102) | (824) | (76) |
| Balance at September 30, 2020 | \$ 93 | \$ 26 | \$ 119 | \$ 8 |

During the nine months ended September 30, 2020, we received customer returns of approximately \$0.7 million that had been reserved for previously.

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.

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 activity is considered variable until such costs are reimbursed at which point they are considered fixed. We allocate the total transaction price to each performance obligation based on the relative estimated standalone selling prices of the promised goods or services for each performance obligation.

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

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

Allocation of Consideration

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

Timing of Recognition

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

[Research and Development Costs and Related Accrual](#)

Research and Development 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 patent application and prosecution. We also record accruals for estimated ongoing non-clinical and clinical research 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 clinical research, 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

Leases

In February 2016, the Financial Accounting Standards Board (the “FASB”) issued ASU No. 2016-02, Leases (Topic 842), to enhance the transparency and comparability of financial reporting related to leasing arrangements.

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 sheet 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 sheet.

The following table presents obligation related to our operating lease:

| | | |
|--|----|------------|
| 2020 | \$ | 78 |
| 2021 | | 155 |
| Total minimum lease payments (base rent) | | 233 |
| Less: imputed interest | | (11) |
| Total operating lease liabilities | \$ | <u>222</u> |

Recent Accounting Pronouncements

Recent Accounting Pronouncements

Accounting Standards Adopted

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

Accounting Standards Not Yet Adopted

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

31, 2023. We are currently assessing the impact of the adoption of Topic 326 on our financial statements and disclosures.

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

Subsequent Events

Subsequent Events

We have evaluated events that have occurred after September 30, 2020 and through the date that our condensed financial statements are issued. See Note 8. "Subsequent Events."

Fair Value Measurements

Fair Value Measurements

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

At September 30, 2020 and December 31, 2019, the fair value of our investments in money market funds were approximately \$3.8 million and approximately \$4.9 million, respectively, which are included within our cash and cash equivalents in our condensed balance sheets.

**Organization and Summary
of Significant Accounting
Policies (Tables)**

**9 Months Ended
Sep. 30, 2020**

[Organization and Summary of
Significant Accounting Policies
Schedule of components of
inventories](#)

The components of inventories are as follows:

| | As of | |
|----------------------------|--------------------|-------------------|
| | September 30, 2020 | December 31, 2019 |
| Raw materials and supplies | 442 | 563 |
| Finished goods | 631 | 435 |
| | <u>\$ 1,073</u> | <u>\$ 998</u> |

[Summary of activity with respect
to our product returns, and
discounts and rebates](#)

The following table provides a summary of activity with respect to our product returns, and discounts and rebates, which are included on our condensed balance sheets within accrued sales allowances (in thousands):

| | Accrued Sales Allowances | | | Allowance for Doubtful Accounts |
|-------------------------------|--------------------------------|---------------------------------------|---------------|--|
| | Product Return Allowance | Discounts and Rebates Allowance | Total | |
| | Balance at December 31, 2019 | \$ 721 | \$ 88 | |
| Provision | 94 | 40 | 134 | 22 |
| Payments/credits | (722) | (102) | (824) | (76) |
| Balance at September 30, 2020 | <u>\$ 93</u> | <u>\$ 26</u> | <u>\$ 119</u> | <u>\$ 8</u> |

[Schedule of maturities of
operating lease](#)

The following table presents obligation related to our operating lease:

| | |
|--|---------------|
| 2020 | \$ 78 |
| 2021 | 155 |
| Total minimum lease payments (base rent) | 233 |
| Less: imputed interest | (11) |
| Total operating lease liabilities | <u>\$ 222</u> |

Stock Plans (Tables)

9 Months Ended Sep. 30, 2020

[Stock Plans](#)

[Schedule of the stock-based compensation expense](#)

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

| | Three Months Ended | | Nine Months Ended | |
|-------------------------------------|--------------------|---------------|-------------------|---------------|
| | September 30, | | September 30, | |
| | 2020 | 2019 | 2020 | 2019 |
| Research and development | \$ — | \$ — | \$ — | \$ 91 |
| Selling, general and administrative | 9 | 128 | 4 | 523 |
| Total stock-based compensation | <u>\$ 9</u> | <u>\$ 128</u> | <u>\$ 4</u> | <u>\$ 614</u> |

[Schedule of assumptions to estimate the fair value of options](#)

| | Three Months Ended | | Nine Months Ended | |
|---|--------------------|------|-------------------|-------|
| | September 30, | | September 30, | |
| | 2020 | 2019 | 2020 | 2019 |
| Weighted-average risk-free interest rate | 0.3 % | — | 0.4 % | 2.2 % |
| Expected dividend payments | — | — | — | — |
| Expected holding period (years) ¹ | 5.7 | — | 5.8 | 5.4 |
| Weighted-average volatility factor ² | 1.07 | — | 1.04 | 0.94 |
| Estimated forfeiture rates for options granted ³ | 24 % | — | 27 % | 21 % |

- (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.

[Schedule of option activity](#)

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) |
|-----------------------------------|------------------------|---|---|--|
| | | | | |
| <i>(in thousands)</i> | | | | |
| Outstanding December 31, 2019 | 1,192 | \$ 6.23 | 7.9 | \$ — |
| Granted | 60 | 0.27 | | |
| Forfeited or expired | (334) | 1.88 | | |
| Outstanding at September 30, 2020 | <u>918</u> | 7.42 | 6.8 | — |
| Exercisable at September 30, 2020 | <u>827</u> | 8.16 | 6.6 | — |

Net Loss Per Share (Tables)

**9 Months Ended
Sep. 30, 2020**

Net Loss Per Share

Schedule of antidilutive securities excluded from computation of 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, | |
|---|---|--------------|--|--------------|
| | 2020 | 2019 | 2020 | 2019 |
| Weighted-average anti-dilutive common shares resulting from options | 913 | 1,282 | 934 | 1,027 |
| Weighted-average anti-dilutive common shares resulting from warrants | 8,342 | 5,961 | 8,342 | 1,222 |
| Weighted-average anti-dilutive common shares resulting from convertible loans | 3,243 | 330 | 3,243 | 332 |
| | <u>12,498</u> | <u>7,573</u> | <u>12,519</u> | <u>2,581</u> |

Warrant Liabilities (Tables)

9 Months Ended Sep. 30, 2020

Warrant Liabilities

Schedule of fair value of warrant liabilities by Level 3 inputs

The following table provides a roll forward of the fair value of our warrant liabilities, the fair value of which was determined by Level 3 inputs for the nine months ended September 30, 2020 (in thousands):

| | | |
|--|----|---------|
| Fair value, December 31, 2019 | \$ | 320 |
| Issuance of the January 2020 Warrants | | 1,654 |
| Change in fair value ⁽¹⁾ | | 923 |
| Reclassification of warrants to additional paid-in capital | | (2,897) |
| Fair value, September 30, 2020 | \$ | — |

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

Schedule of weighted-average key assumptions used to calculate the fair value of the warrants

The warrant liability associated with the January 2020 Warrants was classified within Level 3 of the fair value hierarchy. The following table presents the weighted-average key assumptions used to calculate the fair value of the January 2020 Warrants:

| | As of | |
|---|---------------|-----------------|
| | March 3, 2020 | January 7, 2020 |
| Expected volatility | 124 % | 121 % |
| Risk-free interest rate | 0.8 % | 1.6 % |
| Dividend yield | — | — |
| Expected term (in years) | 4.9 | 5.0 |
| Weighted-average fair value per share warrant | \$ 0.26 | \$ 0.19 |

The warrant liability associated with the August 2019 Warrants was classified within Level 3 of the fair value hierarchy. The following table presents the weighted-average key assumptions used to calculate the fair value of the August 2019 Warrants:

| | As of | |
|---|---------------|-------------------|
| | March 3, 2020 | December 31, 2019 |
| Expected volatility | 124 % | 125 % |
| Risk-free interest rate | 0.8 % | 1.7 % |
| Dividend yield | — | — |
| Expected term (in years) | 4.5 | 4.6 |
| Weighted-average fair value per share warrant | \$ 0.21 | \$ 0.11 |

**Organization and Summary
of Significant Accounting
Policies - Components of
Inventories (Details) - USD
(\$)**

Sep. 30, 2020 Dec. 31, 2019

\$ in Thousands

Organization and Summary of Significant Accounting Policies

| | | |
|-----------------------------------|----------|--------|
| <u>Raw materials and supplies</u> | \$ 442 | \$ 563 |
| <u>Finished goods</u> | 631 | 435 |
| <u>Total inventories</u> | \$ 1,073 | \$ 998 |

Organization and Summary of Significant Accounting Policies - Summary of Activity Product Returns and Discounts and Rebates (Details)

9 Months Ended

Sep. 30, 2020

USD (\$)

\$ in Thousands

| | |
|--|--------|
| <u>Balance at December 31, 2019</u> | \$ 809 |
| <u>Provision</u> | 134 |
| <u>Payments/credits</u> | (824) |
| <u>Balance at June 30, 2020</u> | 119 |
| <u>Product Returns Allowance</u> | |
| <u>Balance at December 31, 2019</u> | 721 |
| <u>Provision</u> | 94 |
| <u>Payments/credits</u> | (722) |
| <u>Balance at June 30, 2020</u> | 93 |
| <u>Discounts and Rebates Allowance</u> | |
| <u>Balance at December 31, 2019</u> | 88 |
| <u>Provision</u> | 40 |
| <u>Payments/credits</u> | (102) |
| <u>Balance at June 30, 2020</u> | 26 |
| <u>Allowance for Doubtful Accounts</u> | |
| <u>Balance at December 31, 2019</u> | 63 |
| <u>Provision</u> | 22 |
| <u>Payments/credits</u> | (76) |
| <u>Balance at June 30, 2020</u> | \$ 8 |

**Organization and Summary
of Significant Accounting
Policies - Summary of
Maturities of Operating
Lease (Details)
\$ in Thousands**

**Sep. 30, 2020
USD (\$)**

Organization and Summary of Significant Accounting Policies

| | |
|---|--------|
| <u>2020</u> | \$ 78 |
| <u>2021</u> | 155 |
| <u>Total minimum lease payments (base rent)</u> | 233 |
| <u>Less: imputed interest</u> | (11) |
| <u>Total operating lease liabilities</u> | \$ 222 |

| | | | |
|--|---|--|------------------------------|
| Organization and Summary of Significant Accounting Policies - Additional Information (Details) - USD (\$) \$ in Thousands | 1 Months Ended Oct. 31, 2020 | 9 Months Ended Sep. 30, 2020 | Dec. 31, 2019 |
|--|---|--|------------------------------|

[Schedule of Organization
and Summary of Significant
Accounting Policies](#)

[Substantial Doubt about Going
Concern, Management's
Evaluation](#)

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 financial statements are issued or available to be issued, which is referred to as the "look-forward period" as defined by Accounting Standard Update ("ASU") No. 2014-15. As part of this assessment, based on conditions that are known and reasonably knowable to us, we will consider various scenarios, forecasts, projections, estimates and will make certain key assumptions, including the timing and nature of projected cash expenditures or programs, and its ability to delay or curtail expenditures or programs, if necessary, among other factors. Based on this assessment, as necessary or applicable, we make certain assumptions around implementing curtailments or delays in the nature and timing of programs and expenditures to the extent we deem probable those implementations can be achieved and we have the proper authority to execute them within the look-forward period in accordance with ASU No. 2014-15. Based upon the above assessment, we concluded that, at the date of filing the financial statements in this Quarterly Report on Form 10-Q for the nine months ended September 30, 2020, 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 financial statements were issued.

| | | |
|--|----------|----------|
| <u>Cash and cash equivalents</u> | \$ 4,073 | \$ 5,223 |
| <u>Proceeds from customer returns</u> | 700 | |
| <u>Fair Value, Recurring Money Market Funds</u> | | |
| <u>Schedule of Organization and Summary of Significant Accounting Policies</u> | | |
| <u>Cash and cash equivalents</u> | 3,800 | \$ 4,900 |
| <u>October 2020 Offering</u> | | |

**Schedule of Organization
and Summary of Significant
Accounting Policies**

Cash and cash equivalents \$ 4,100

October 2020 Offering |

Subsequent Events

**Schedule of Organization
and Summary of Significant
Accounting Policies**

Net proceeds \$ 5,700

| Stock Plans - Stock-based compensation expense (Details) - USD (\$) \$ in Thousands | 3 Months Ended | | 9 Months Ended | |
|--|--------------------------|--------------------------|--------------------------|--------------------------|
| | Sep. 30, 2020 | Sep. 30, 2019 | Sep. 30, 2020 | Sep. 30, 2019 |
| <u>Share-based Compensation Arrangement by Share-based Payment Award, Compensation Cost</u> | | | | |
| <u>Total stock-based compensation expense</u> | \$ 9 | \$ 128 | \$ 4 | \$ 614 |
| <u>Research and development</u> | | | | |
| <u>Share-based Compensation Arrangement by Share-based Payment Award, Compensation Cost</u> | | | | |
| <u>Total stock-based compensation expense</u> | 0 | 0 | 0 | 91 |
| <u>Selling, general and administrative</u> | | | | |
| <u>Share-based Compensation Arrangement by Share-based Payment Award, Compensation Cost</u> | | | | |
| <u>Total stock-based compensation expense</u> | \$ 9 | \$ 128 | \$ 4 | \$ 523 |

| Stock Plans - Fair value of stock options (Details) - USD (\$) | 3 Months Ended | | 9 Months Ended | |
|--|-----------------------------|------------------|-----------------------------|-----------------------------|
| | Sep. 30, 2020 | Sep. 30, 2019 | Sep. 30, 2020 | Sep. 30, 2019 |
| Stock Plans | | | | |
| <u>Weighted-average risk-free interest rate</u> | 0.30% | 0.00% | 0.40% | 2.20% |
| <u>Expected dividend payments</u> | \$ 0 | \$ 0 | \$ 0 | \$ 0 |
| <u>Expected holding period (years)</u> | 5 years 8 months 12 days | 0 years | 5 years 9 months 18 days | 5 years 4 months 24 days |
| <u>Weighted-average volatility factor</u> | 1.07% | 0.00% | 1.04% | 0.94% |
| <u>Estimated forfeiture rates for options granted</u> | 24.00% | 0.00% | 27.00% | 21.00% |

| Stock Plans - Option activity (Details) - USD (\$) \$ / shares in Units, \$ in Thousands | 3 Months Ended Sep. 30, 2020 | 9 Months Ended Sep. 30, 2020 | 12 Months Ended Dec. 31, 2019 |
|---|---|---|--|
| <u>Stock Plans</u> | | | |
| <u>Number of options outstanding at Beginning of year</u> | | 1,192,000 | |
| <u>Shares, Granted</u> | 10,000 | 60,000 | |
| <u>Shares, Forfeited or expired</u> | | (334,000) | |
| <u>Number of Options and Awards outstanding at end of year</u> | 918,000 | 918,000 | 1,192,000 |
| <u>Shares, Exercisable at end of year</u> | 827,000 | 827,000 | |
| <u>Weighted Average Exercise Price, Outstanding at Beginning of year</u> | | \$ 6.23 | |
| <u>Weighted Average Exercise Price, Granted</u> | | 0.27 | |
| <u>Weighted Average Exercise Price, Forfeited or expired</u> | | 1.88 | |
| <u>Weighted Average Exercise Price, Outstanding at End of year</u> | \$ 7.42 | 7.42 | \$ 6.23 |
| <u>Weighted Average Exercise Price, Exercisable at end of year</u> | \$ 8.16 | \$ 8.16 | |
| <u>Weighted Average Remaining Contractual Term, Outstanding (Years)</u> | | 6 years 9 months 18 days | 7 years 10 months 24 days |
| <u>Weighted Average Remaining Contractual Term, Exercisable at end of year</u> | | 6 years 7 months 6 days | |
| <u>Aggregate Intrinsic Value, Outstanding at Beginning of year</u> | | \$ 0 | |
| <u>Aggregate Intrinsic Value, Outstanding at End of year</u> | \$ 0 | 0 | \$ 0 |
| <u>Aggregate Intrinsic Value, Exercisable at September 30, 2020</u> | \$ 0 | \$ 0 | |

**Stock Plans - Additional
Information (Details)**

| | 3 Months Ended Sep. 30, 2020 USD (\$) shares | 9 Months Ended Sep. 30, 2020 USD (\$) shares |
|---|---|---|
| <u>Share-based Compensation Arrangement by Share-based Payment Award</u> | | |
| <u>Shares, Granted shares</u> | 10,000 | 60,000 |
| <u>Weighted-average period for recognizing non-vested stock option</u> | | 1 year 9 months 18 days |
| <u>Employee Stock Option</u> | | |
| <u>Share-based Compensation Arrangement by Share-based Payment Award</u> | | |
| <u>Employee Service Share-based Compensation, Nonvested Awards, Compensation Cost Not yet Recognized \$</u> | \$ 30,000 | \$ 30,000 |

| Net Loss Per Share (Details) - shares shares in Thousands | 3 Months Ended | | 9 Months Ended | |
|---|------------------|------------------|------------------|------------------|
| | Sep. 30, 2020 | Sep. 30, 2019 | Sep. 30, 2020 | Sep. 30, 2019 |
| <u>Amount of weighted-average anti-dilutive common shares</u> | 12,498 | 7,573 | 12,519 | 2,581 |
| <u>Employee Stock Option</u> | | | | |
| <u>Amount of weighted-average anti-dilutive common shares</u> | 913 | 1,282 | 934 | 1,027 |
| <u>Warrant</u> | | | | |
| <u>Amount of weighted-average anti-dilutive common shares</u> | 8,342 | 5,961 | 8,342 | 1,222 |
| <u>Convertible loans</u> | | | | |
| <u>Amount of weighted-average anti-dilutive common shares</u> | 3,243 | 330 | 3,243 | 332 |

| Molteni Purchase Agreement (Details) \$ in Millions | 1 Months Ended | | 3 | 9 | | |
|--|------------------|---------------------|---------------------|---------------------|------------------|---------------------|
| | Mar. 21, 2018 | Mar. 21, 2018 | Aug. 31, 2018 | Aug. 31, 2018 | Mar. 31, 2019 | Aug. 31, 2018 |
| | EUR (€) | USD (\$) | EUR (€) | USD (\$) | USD (\$) | USD (\$) |
| <u>Purchase Agreement</u> | | | | | | |
| <u>Proceeds from Sale of Productive Assets</u> | € 2,000,000 | \$ 2.4 | | | | |
| <u>Estimated Selling Price</u> | | | | | \$ 1.4 | |
| <u>Amount Received Under Amendment To Purchase Agreement</u> | | | € 950,000 | | | \$ 1.1 |
| <u>Convertible Debt</u> | | | 550,000 | | | \$ 0.6 |
| <u>Revenue recognized</u> | | | € 2,000,000 | \$ 2.3 | \$ 0.3 | |
| <u>Intellectual Property [Member] Purchase Agreement</u> | | | | | | |
| <u>Finite-Lived Intangible Assets, Translation and Purchase Accounting Adjustments</u> | | | | | \$ 1.0 | |

| Debt Agreements (Details) - USD (\$) \$ / shares in Units, \$ in Thousands | 1 Months Ended | | 3 Months Ended | | 9 Months Ended | | 12 Months Ended | | |
|--|---------------------|------------------|---------------------|------------------|---------------------|--|---------------------|---------------------|---------------------|
| | Apr. 30, 2020 | Sep. 30, 2019 | Jun. 30, 2019 | Sep. 30, 2020 | Sep. 30, 2019 | Sep. 30, 2020 | Sep. 30, 2019 | Dec. 31, 2019 | Mar. 31, 2018 |
| Loan proceeds | | | | | | \$ 654 | \$ 0 | | |
| Class of Warrant or Right, Number of Securities Called by Warrants or Rights | | | | 31,244,386 | | 31,244,386 | | | |
| Gain on debt extinguishment | | | | \$ 0 | \$ 291 | \$ 0 | \$ 226 | | |
| Current portion of long-term debt | | | | 2,082 | | 2,082 | | \$ 0 | |
| Long-term debt | | | | 3,038 | | \$ 3,038 | | 4,019 | |
| Molteni Loan | | | | | | | | | |
| Conversion Price, (in dollars per share) | \$ 0.225 | | | | \$ 0.225 | | \$ 0.225 | | |
| Gain on debt extinguishment | | | | | \$ 300 | | | | |
| Increase in repayment of long term debt | \$ 300 | | | | | | | | |
| Long-term Debt | | | | | | | | | \$ 4,000 |
| Debt Conversion, Converted Instrument, Shares Issued | 3,422,777 | | | | | | | | |
| Horizon Loan | | | | | | | | | |
| Class of Warrant or Right, Exercise Price of Warrants or Rights | | | | | | | | | \$ 7.20 |
| Class of Warrant or Right, Number of Securities Called by Warrants or Rights | | | | | | | | | 6,667 |
| Conversion Price, (in dollars per share) | | | | | | | | | \$ 7.20 |
| Long-term Debt | | | | | | | | | \$ 2,400 |
| Horizon and Molteni Loans | | | | | | | | | |
| Debt Instrument, Term | | | | | | 46 months | | | |
| Debt Instrument, Description of Variable Rate Basis | | | | | | one-month LIBOR (floor of 1.10%) plus 8.40% | | | |
| Debt Instrument Final Payment On Each Loan Tranche Percentage | | | | | | 5.00% | | | |

| | | | |
|---|-----------|--------|--------|
| <u>Amortization of Debt Discount (Premium)</u> | | \$ 300 | \$ 300 |
| <u>Molteni Purchase Agreement</u> | | | |
| <u>Conversion Price, (in dollars per share)</u> | \$ 1.50 | | |
| <u>Gain on debt extinguishment</u> | \$ 100 | | |
| <u>Debt Conversion, Converted Instrument, Shares Issued</u> | 448,287 | | |
| <u>PPP loans</u> | | | |
| <u>Loan proceeds</u> | \$ 700 | | |
| <u>Loan annual interest rate</u> | 1.00% | | |
| <u>Debt Instrument, Term</u> | 6 months | | |
| <u>Current portion of long-term debt</u> | 100 | 100 | |
| <u>Long-term debt</u> | \$ 600 | \$ 600 | |
| <u>Maximum PPP loans</u> | | | |
| <u>Debt Instrument, Term</u> | 16 months | | |

| Stockholders' Equity (Details) - USD (\$) \$ / shares in Units, \$ in Thousands | 1 Months Ended | | 3 Months Ended | 9 Months Ended | | |
|--|------------------|------------------|-------------------|------------------|---------------------|------------------|
| | Sep. 30, 2020 | Jan. 31, 2020 | Sep. 30, 2020 | Sep. 30, 2020 | Sep. 30, 2019 | Dec. 31, 2019 |
| Equity Offering | | | | | | |
| <u>Common Stock shares, Outstanding</u> | 116,763,180 | | 116,763,180 | 116,763,180 | | 57,378,794 |
| <u>Class of Warrant or Right, Number of Securities Called by Warrants or Rights</u> | 31,244,386 | | 31,244,386 | 31,244,386 | | |
| <u>Net proceeds from the exercises of common stock warrants</u> | | | | \$ 7,030 | \$ 724 | |
| <u>Finance costs attributable to issuance of warrants</u> | | | | \$ 211 | \$ 0 | |
| <u>January 2020 Offering</u> | | | | | | |
| Equity Offering | | | | | | |
| <u>Class of Warrant or Right, Number of Securities Called by Warrants or Rights</u> | | 8,700,000 | | | | |
| <u>Class of Warrant or Right, Exercise Price of Warrants or Rights</u> | | \$ 0.25 | | | | |
| <u>Issuance of common stock, net (in shares)</u> | | 8,700,000 | | | | |
| <u>Proceeds from sale of common stock</u> | | \$ 1,900 | | | | |
| <u>Finance costs attributable to issuance of warrants</u> | | | \$ 211 | | | |
| <u>September 2020 Offering</u> | | | | | | |
| Equity Offering | | | | | | |
| <u>Issuance of common stock, net (in shares)</u> | 19,440,000 | | | | | |
| <u>Share issue price (in dollars per share)</u> | \$ 0.14 | | \$ 0.14 | \$ 0.14 | | |
| <u>Proceeds from sale of common stock</u> | \$ 2,400 | | | | | |

| Warrant Liabilities - Fair value of warrant liabilities by Level 3 inputs (Details) - USD (\$) \$ in Thousands | 3 Months Ended | | 9 Months Ended | | Mar. 03, 2020 |
|--|------------------|---------------------|------------------|---------------------|------------------|
| | Sep. 30, 2020 | Sep. 30, 2019 | Sep. 30, 2020 | Sep. 30, 2019 | |
| <u>Fair Value, Liabilities Measured on Recurring Basis, Unobservable Input Reconciliation [Line Items]</u> | | | | | |
| <u>Warrants to purchase shares of common stock</u> | 31,244,386 | | 31,244,386 | | |
| <u>Fair value of warrant liabilities by Level 3 inputs</u> | | | | | |
| <u>Beginning balance</u> | | | \$ 320 | | |
| <u>Issuance of the January 2020 Warrants</u> | | | 1,654 | | |
| <u>Change in fair value</u> | \$ 0 | \$ (1,041) | 923 | \$ (1,066) | |
| <u>Reclassification of warrants to additional paid-in capital</u> | | | (2,897) | | |
| <u>Ending balance</u> | \$ 0 | | \$ 0 | | |
| <u>Warrant</u> | | | | | |
| <u>Fair Value, Liabilities Measured on Recurring Basis, Unobservable Input Reconciliation [Line Items]</u> | | | | | |
| <u>Warrants to purchase shares of common stock</u> | | | | | 11,552,314 |

| Warrant Liabilities - Weighted-average key assumptions (Details) | Mar. 03, 2020 | Jan. 07, 2020 | Dec. 31, 2019 |
|--|--------------------------|--------------------------|--------------------------|
| January 2020 Private Placement Warrant Expected volatility | | | |
| Class of Warrant or Right [Line Items] | | | |
| Warrants and rights outstanding | 124 | 121 | |
| January 2020 Private Placement Warrant Risk-free interest rate | | | |
| Class of Warrant or Right [Line Items] | | | |
| Warrants and rights outstanding | 0.8 | 1.6 | |
| January 2020 Private Placement Warrant Dividend yield | | | |
| Class of Warrant or Right [Line Items] | | | |
| Warrants and rights outstanding | 0.0 | 0.0 | |
| January 2020 Private Placement Warrant Expected term (in years) | | | |
| Class of Warrant or Right [Line Items] | | | |
| Warrants and rights outstanding | 4.9 | 5.0 | |
| January 2020 Private Placement Warrant Weighted-average fair value per share warrant | | | |
| Class of Warrant or Right [Line Items] | | | |
| Warrants and rights outstanding | 0.26 | 0.19 | |
| August 2019 Placement Warrants Expected volatility | | | |
| Class of Warrant or Right [Line Items] | | | |
| Warrants and rights outstanding | 124 | | 125 |
| August 2019 Placement Warrants Risk-free interest rate | | | |
| Class of Warrant or Right [Line Items] | | | |
| Warrants and rights outstanding | 0.8 | | 1.7 |
| August 2019 Placement Warrants Dividend yield | | | |
| Class of Warrant or Right [Line Items] | | | |
| Warrants and rights outstanding | 0.0 | | 0.0 |
| August 2019 Placement Warrants Expected term (in years) | | | |
| Class of Warrant or Right [Line Items] | | | |
| Warrants and rights outstanding | 4.5 | | 4.6 |
| August 2019 Placement Warrants Weighted-average fair value per share warrant | | | |
| Class of Warrant or Right [Line Items] | | | |
| Warrants and rights outstanding | 0.21 | | 0.11 |

1 Months Ended
Oct. 31, 2020
USD (\$)
\$ / shares
shares

Subsequent Events (Details)
- Subsequent Events

Subsequent Event

Amount of closing payments made for JT Agreement \$ 15,000

Horizon and Molteni Loans

Subsequent Event

Outstanding amount 5,200,000

Principal amount 4,000,000

Final payments 1,200,000

Cash payment for settlement of debt \$ 1,600,000

October 2020 Offering

Subsequent Event

Number of units issued | shares 80,000,000

Issue price of units (in dollars per share) | \$ / shares \$ 0.10

Number of shares that each unit entitles | shares 1

Number of warrant that each unit entitles | shares 1

Number of shares that each warrant entitles | shares 1

Proceeds from sale of common stock \$ 8,000,000

Underwriting discounts and commissions 1,600,000

Net proceeds \$ 5,700,000

Exercise price of warrants (in dollars per share) | \$ / shares \$ 0.10