

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, 2019.

OR

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

For the transition period from ____ to ____

Commission File Number 001-13341

Titan Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

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

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

94080
(Zip Code)

(650) 244-4990

(Registrant's telephone number, including area code)

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. 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 11, 2019
Common Stock, par value \$0.001	55,549,885

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, 2019 (unaudited)	December 31, 2018 (Note 1)
Assets		
Current assets:		
Cash and cash equivalents	\$ 921	\$ 9,295
Restricted cash	—	361
Receivables	775	1,737
Inventory	1,309	1,262
Contract assets	—	99
Prepaid expenses and other current assets	941	547
Total current assets	<u>3,946</u>	<u>13,301</u>
Property and equipment, net	752	794
Operating lease right-of-use asset	456	—
Deferred offering costs	150	—
Total assets	<u>\$ 5,304</u>	<u>\$ 14,095</u>
Liabilities and Stockholders' (Deficit) Equity		
Current liabilities:		
Accounts payable	\$ 1,383	\$ 1,526
Accrued clinical trials expenses	434	620
Accrued sales allowances	750	—
Other accrued liabilities	653	466
Deferred revenue	—	313
Operating lease liability, current	262	—
Current portion of long-term debt	—	527
Total current liabilities	<u>3,482</u>	<u>3,452</u>
Operating lease liability, non-current	222	—
Long-term debt	3,872	3,787
Warrant liability	388	—
Derivative liability	—	25
Total liabilities	<u>7,964</u>	<u>7,264</u>
Stockholders' (deficit) equity:		
Common stock, \$0.001 par value per share: 125,000 shares authorized; 17,114 and 13,010 shares issued and outstanding at September 30, 2019 and December 31, 2018	17	13
Additional paid-in capital	342,419	339,397
Accumulated deficit	(345,096)	(332,579)
Total stockholders' (deficit) equity	<u>(2,660)</u>	<u>6,831</u>
Total liabilities and stockholders' (deficit) equity	<u>\$ 5,304</u>	<u>\$ 14,095</u>

See Notes to Condensed Financial Statements

TITAN PHARMACEUTICALS, INC.

CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except per share amount)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenues:				
License revenue	\$ —	\$ 1,406	\$ 313	\$ 5,063
Product revenue	190	244	811	318
Grant revenue	757	—	1,270	—
Total revenues	947	1,650	2,394	5,381
Operating expenses:				
Cost of goods sold	188	178	738	248
Research and development	1,619	1,910	5,370	5,623
Selling, general and administrative	3,023	1,514	9,336	4,508
Total operating expenses	4,830	3,602	15,444	10,379
Loss from operations	(3,883)	(1,952)	(13,050)	(4,998)
Other income (expense):				
Interest expense, net	(238)	(227)	(737)	(650)
Gain on debt extinguishment, net	291	—	226	—
Non-cash gain on changes in fair value	1,041	141	1,066	141
Other expense, net	(14)	(7)	(22)	(12)
Other income (expense), net	1,080	(93)	533	(521)
Net loss and comprehensive loss	(2,803)	(2,045)	(12,517)	(5,519)
Deemed dividend on trigger of down round provision	—	(285)	—	(285)
Net loss and comprehensive loss attributable to common stockholders	\$ (2,803)	\$ (2,330)	\$ (12,517)	\$ (5,804)
Basic net loss per share	\$ (0.18)	\$ (0.64)	\$ (0.89)	\$ (1.62)
Diluted net loss per share	\$ (0.18)	\$ (0.68)	\$ (0.89)	\$ (1.66)
Weighted-average shares for basic and diluted net loss per share	15,517	3,650	14,112	3,573

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, 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, net	1,480	2	571	—	573
Stock-based compensation	—	—	128	—	128
Balances at September 30, 2019	17,114	\$ 17	\$ 342,419	\$ (345,096)	\$ (2,660)

	Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Equity (Deficit)
	Shares	Amount	Shares	Amount			
Balances at December 31, 2017	—	\$ —	3,534	\$ 4	\$ 324,124	\$ (323,271)	\$ 857
Net loss	—	—	—	—	—	(2,605)	(2,605)
Issuance of warrants to purchase common stock, net	—	—	—	—	470	—	470
Stock-based compensation	—	—	—	—	432	—	432
Balances at March 31, 2018	—	—	3,534	4	325,026	(325,876)	(846)
Net loss	—	—	—	—	—	(869)	(869)
Stock-based compensation	—	—	—	—	402	—	402
Balances at June 30, 2018	—	—	3,534	4	325,428	(326,745)	(1,313)
Net loss	—	—	—	—	—	(2,045)	(2,045)
Issuance of common stock, net	—	—	850	1	1,127	—	1,128
Issuance of preferred stock, net	8	—	—	—	7,280	—	7,280
Issuance of common stock upon conversion of preferred stock, net	(8)	—	2,177	2	(2)	—	—
Issuance of warrants to purchase common stock, net	—	—	—	—	51	—	51
Deemed dividend resulting from down round provision	—	—	—	—	285	(285)	—
Stock-based compensation	—	—	—	—	388	—	388
Balances at September 30, 2018	—	—	6,561	\$ 7	\$ 334,557	\$ (329,075)	\$ 5,489

See Notes to Condensed Financial Statements

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

	Nine Months Ended September 30,	
	2019	2018
Cash flows from operating activities:		
Net loss	\$ (12,517)	\$ (5,519)
Adjustments to reconcile loss to net cash used in operating activities:		
Depreciation and amortization	186	337
Non-cash interest expense	467	331
Non-cash gain on inventory received from termination of license agreement	—	(1,293)
Non-cash gain on changes in fair value	(1,066)	(141)
Stock-based compensation	614	1,222
Other	(262)	—
Changes in operating assets and liabilities:		
Receivables	962	(617)
Prepaid expenses and other assets	(492)	(181)
Accounts payable and other liabilities	(111)	112
Accrued sales allowances	750	—
Deferred revenue	(313)	626
Net cash used in operating activities	<u>(11,782)</u>	<u>(5,123)</u>
Cash flows from investing activities:		
Purchases of property and equipment	(144)	(71)
Net cash used in operating activities	<u>(144)</u>	<u>(71)</u>
Cash flows from financing activities:		
Net proceeds from the exercises of common stock warrants	724	—
Net proceeds from equity offerings	2,467	8,459
Proceeds from long-term debt	—	640
Payments of long-term debt	—	(3,000)
Net cash provided by financing activities	<u>3,191</u>	<u>6,099</u>
Change in cash, cash equivalents and restricted cash	<u>(8,735)</u>	<u>905</u>
Cash, cash equivalents and restricted cash at beginning of period	9,656	7,883
Cash, cash equivalents and restricted cash at end of period	<u>\$ 921</u>	<u>\$ 8,788</u>
Supplemental disclosure of cash flow information:		
Interest paid	\$ 328	\$ 344
Non-cash conversion of convertible loan	\$ 650	\$ —
Warrants issued	\$ —	\$ 6,348
Derivatives issued	\$ —	\$ 158
Deemed dividend on trigger of down round provision	\$ —	\$ 285

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

	As of September 30,	
	2019	2018
Cash and cash equivalents	\$ 921	\$ 8,427
Restricted cash	—	361
Cash, cash equivalents and restricted cash shown in the statement of cash flows	<u>\$ 921</u>	<u>\$ 8,788</u>

See Notes to Condensed Financial Statements

TITAN PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS
(unaudited)

1. Organization and Summary of Significant Accounting Policies

The Company

We are a pharmaceutical company developing therapeutics utilizing our proprietary long-term drug delivery platform, ProNeura, for the treatment of select chronic diseases for which steady state delivery of a drug provides an efficacy and/or safety benefit. We have been transitioning to a commercial stage enterprise following the reacquisition of Probuphine® (buprenorphine) implant, or Probuphine, on May 25, 2018 from our former licensee. Probuphine 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. We operate in only one business segment, the development and commercialization of pharmaceutical products.

In January 2019, pursuant to prior stockholder authorization, our board of directors (the “Board”) effected a reverse split of the outstanding shares of our common stock at a ratio of one share for every six shares then outstanding (the “Reverse Split”). Pursuant to their respective terms, the number of shares underlying our outstanding options and warrants was reduced and their respective exercise prices increased by the Reverse Split ratio. The number of shares of common stock authorized and the par value of \$0.001 per share did not change as a result of the Reverse Split. All share and per share amounts contained in this Form 10-Q give retroactive effect to the Reverse Split.

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, 2019 are not necessarily indicative of the results that may be expected for the year ending December 31, 2019, or any future interim periods.

The balance sheet at December 31, 2018 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/A for the year ended December 31, 2018, 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.

In October 2019, we received gross proceeds of approximately \$9.1 million from the sale of 40,276,000 shares of our common stock and warrants to purchase 40,276,000 shares of our common stock in a public offering (see Note 7). As of September 30, 2019, we had cash and cash equivalents of approximately \$0.9 million, which, we believe, together with the proceeds from the public offering, is sufficient to fund our planned operations into the third quarter of 2020. We will require additional funds to finance our operations. We are exploring several financing alternatives; however, there can be no assurance that our efforts to obtain the funding required to continue our operations will be successful.

TITAN PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS - Continued
(unaudited)

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, 2019, 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, 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.

Revenue Recognition

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

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

We recognize revenue from product sales when control of the product transfers, generally upon shipment or delivery, to our customers, which include distributors. As customary in the pharmaceutical industry, our gross product revenue is subject to a variety of deductions in the forms of variable consideration, such as rebates, chargebacks, returns and discounts, in arriving at reported net product revenue. This variable consideration is 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. From time to time, we will adjust our estimates of this variable consideration when trends or significant events indicate that a change in estimate is appropriate to reflect the actual experience. Additionally, we will continue to assess the estimates of our variable consideration as we continue to accumulate additional historical data. Changes in the estimates of our variable consideration could materially affect our financial statements.

TITAN PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS - Continued
(unaudited)

Returns – Consistent with the provisions of ASC 606, we estimate 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 may impact future expected returns to the extent that we would not reverse any receivables, revenues, or contract assets already recognized under the agreement. During the nine months ended September 30, 2019, we entered into agreements with large national specialty pharmacies with a distribution channel different from that of our existing customers and, therefore, the related reserves have unique considerations. We will continue to evaluate the activities with these specialty pharmacies during upcoming quarters and will update the related reserves accordingly.

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

Discounts –The provision is 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 consolidated balance sheets within accrued sales allowances (in thousands):

	Product Returns Allowance	Discounts and Rebates Allowance	Total
Balance at December 31, 2018	\$ 33	\$ 48	\$ 81
Provision	681	189	870
Payments/credits	(50)	(151)	(201)
Balance at September 30, 2019	<u>\$ 664</u>	<u>\$ 86</u>	<u>\$ 750</u>

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

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

For arrangements that include sales-based royalties or earn-out payments, including milestone payments based on the level of sales, and the license or purchase agreement is deemed to be the predominant item to which the royalties or earn-out payments relate, we recognizes 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).

TITAN PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS - Continued
(unaudited)

Allocation of Consideration

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

Timing of Recognition

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

Research and Development Costs and Related Accrual

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

Leases

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

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

Lease expense is recognized over the expected term on a straight-line basis. Operating leases are recognized on our 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.

TITAN PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS - Continued
(unaudited)

Recent Accounting Pronouncements

Accounting Standards Adopted

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*. Topic 842 requires most lessees to recognize right of use assets and lease liabilities, but recognize expenses in a manner similar with current accounting standards. Effective January 1, 2019, we adopted the provisions under Topic 842 using a modified retrospective transition approach without adjusting comparative periods. Additionally, as permitted by Topic 842, we elected to apply the following practical expedients: (i) not to reassess whether any expired or existing contracts are or contain leases or the classification of any expired or existing leases and (ii) not to apply the recognition requirements to short-term leases. As a result of this adoption, we recorded operating lease right-of-use asset and operating lease liability associated with our office lease in our condensed balance sheet as of March 31, 2019. We used a discount rate of 12%, which reflects our borrowing rate as of the adoption date, to measure the present value of future lease payments to determine the fair value of our operating lease right-of-use asset and liability. Our office lease expires in June 2021 and we did not include an estimated renewal in the calculation of our operating lease right-of-use asset and liability as we believe that it is less than probable we will renew our office lease. Our adoption of Topic 842 did not result in any cumulative adjustment to the balance of our accumulated deficit as of January 1, 2019. Lease expense for operating lease payments is recognized on a straight-line basis over the lease term, which is consistent with Topic 840.

The following table presents maturities of our operating lease (in thousands):

2019 (3 months)	\$	76
2020		308
2021		155
Total minimum lease payments (base rent)		539
Less: imputed interest		(55)
Total operating lease liabilities	\$	484

In June 2018, the FASB issued ASU 2018-07, *Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*, which aligns the accounting for share-based payment awards issued to nonemployees with the guidance applicable to grants to employees. Under the new standard, equity-classified share-based payment awards issued to nonemployees are measured on the grant date, instead of the current requirement to remeasure the awards through the performance completion date. We adopted ASU 2018-07 during the three months ended March 31, 2019 using the prospective approach. The adoption of ASU 2018-07 did not have any material impact to our condensed financial statements.

In August 2018, the SEC published Release No. 33-10532, *Disclosure Update and Simplification*, or DUSTR, which adopted amendments to certain disclosure requirements that have become redundant, duplicative, overlapping, outdated or superseded, in light of other SEC disclosure requirements, GAAP, or changes in the information environment. While most of the DUSTR amendments eliminate updated or duplicative disclosure requirements, the final rule amends the interim financial statement requirements to include a reconciliation of changes in stockholders' equity (deficit) in the notes or as a separate statement for each period for which a statement of comprehensive income (loss) is required to be filed. The new interim reconciliation of changes in stockholders' equity (deficit) for the three and nine months ended September 30, 2019 and 2018 is included herein.

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, 2020. We are currently assessing the impact of the adoption of Topic 326 on our financial statements and disclosures.

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. The ASU is effective for us in our interim period ending March 31, 2020, with early adoption permitted. We do not expect the adoption of this ASU to have any significant impact on our quarterly or annual disclosures.

TITAN PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS - Continued
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In August 2018, the FASB issued ASU No. 2018-15, *Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement that Is a Service Contract*. The ASU aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software (and hosting arrangements that include an internal-use software license). Adoption of the ASU is either retrospective or prospective. The ASU is effective for us in our interim period ending March 31, 2020, with early adoption permitted. We are currently evaluating the impact of the adoption of ASU No. 2018-15 on our condensed financial statements.

Subsequent Events

We have evaluated events that have occurred after September 30, 2019 and through the date that our condensed financial statements are issued. See Note 7, "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 warrant and derivative liabilities are 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 these liabilities.

At September 30, 2019 and December 31, 2018, the fair value of our investments in money market funds were approximately \$0.8 million and approximately \$8.9 million, respectively, which are included within our cash and cash equivalents in our condensed balance sheets.

2. Stock Plans

In January 2019, our stockholders approved an amendment to the Titan Pharmaceuticals, Inc. 2015 Omnibus Equity Incentive Plan to increase the number of shares authorized for awards thereunder from 583,334 to 1,666,667.

In January 2019, our stockholders approved a repricing of 122,115 fully-vested stock options with exercise prices in excess of \$21.00 held by employees and consultants other than the named executive officers or members of the Board. The effected options were repriced at \$1.55. As a result of the repricing of these stock options, we incurred a total of approximately \$136,000 of additional stock-based compensation expense during the nine months ended September 30, 2019, of which approximately \$77,000 was recorded within research and development and approximately \$59,000 within selling, general and administrative in our condensed statement of operations and comprehensive loss.

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,	
	2019	2018	2019	2018
Research and development	\$ —	\$ 136	\$ 91	\$ 455
Selling, general and administrative	128	252	523	767
Total stock-based compensation	<u>\$ 128</u>	<u>\$ 388</u>	<u>\$ 614</u>	<u>\$ 1,222</u>

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Weighted-average risk-free interest rate	—%	2.9%	2.2%	2.7%
Expected dividend payments	—	—	—	—
Expected holding period (years) ¹	—	6.4	5.4	6.4
Weighted-average volatility factor ²	—	0.91	0.94	0.89
Estimated forfeiture rates for options granted ³	—%	25%	21%	26%

(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.

TITAN PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS - Continued
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The following table summarizes option activity:

	Options (in thousands)	Weighted Average Exercise Price per share	Weighted Average Remaining Option Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at January 1, 2019	665	\$ 17.94	6.44	\$ 4.0
Granted	854	1.64		
Cancelled	(274)	21.32		
Outstanding at September 30, 2019	1,245	6.02	8.16	—
Exercisable at September 30, 2019	705	9.41	7.12	

As of September 30, 2019, there was approximately \$0.3 million of total unrecognized compensation expense related to non-vested stock options. This expense was expected to be recognized over a weighted-average period of approximately 1.7 years.

3. Net Loss Per Share

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

The following table sets forth the reconciliation of the numerator and denominator used in the computation of basic and diluted net loss per common share:

(in thousands, except per share amounts)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Numerator:				
Net loss attributable to common stockholders for basic earnings per share	\$ (2,803)	\$ (2,330)	\$ (12,517)	\$ (5,804)
Less change in fair value of derivatives	—	(141)	—	(141)
Net loss used for diluted earnings per share	\$ (2,803)	\$ (2,471)	\$ (12,517)	\$ (5,945)
Denominator:				
Basic weighted-average common shares outstanding	15,517	3,650	14,112	3,573
Diluted weighted-average common shares outstanding	15,517	3,650	14,112	3,573
Net loss per common share:				
Basic	\$ (0.18)	\$ (0.64)	\$ (0.89)	\$ (1.62)
Diluted	\$ (0.18)	\$ (0.68)	\$ (0.89)	\$ (1.66)

The table below presents common shares underlying stock options, warrants and convertible loans (see Note 5) that are excluded from the calculation of the weighted average number of common shares outstanding used for the calculation of diluted net loss per common share. These are excluded from the calculation due to their anti-dilutive effect (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Weighted-average anti-dilutive common shares resulting from options	1,282	3,531	1,027	3,396
Weighted-average anti-dilutive common shares resulting from warrants	5,961	1,461	1,222	1,618
Anti-dilutive common shares resulting from convertible loans	330	—	332	—
	7,573	4,992	2,581	5,014

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 in the EU, as well as certain countries of the Commonwealth of Independent States, the Middle East and North Africa (the “Molteni Territory”).

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

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

TITAN PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS - Continued
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We used the expected cost-plus approach to estimate the standalone selling price of approximately \$1.4 million related to our efforts towards an approval by the EMA and other regulatory bodies (“Titan Services”). This includes employee related expenses as well as other manufacturing, regulatory and clinical costs, which are incurred as part of our efforts. As of March 31, 2019, we fully recognized the revenue associated with the Titan Services under the Molteni Purchase Agreement as we completed the Titan Services.

The following table presents changes in contract assets and liabilities during the nine months ended September 30, 2019 (in thousands):

	Beginning Balance	Deductions	Ending Balance
Contract assets	\$ 99	\$ (99)	\$ —
Contract liability:			
Deferred revenue	\$ 313	\$ (313)	\$ —

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. We concluded that the approximately \$1.1 million immediate payment by Molteni reflected a milestone payment with no additional obligations to us and, therefore, was recognized as revenue during the year ended December 31, 2018.

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 from the original range of low-teens to mid-twenties to low-teens to mid-teens. We also agreed to delay payments of any earn-outs 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 by the end of this year). The milestone payments under the Purchase Agreement remain unchanged.

5. Debt Agreements

Horizon and Molteni Loan

In July 2017, we entered into a venture loan and security agreement that was subsequently amended in February 2018, (“Horizon Loan Agreement”) with Horizon Technology Finance Corporation (“Horizon”). In connection with the Horizon Loan Agreement, we issued Horizon warrants that are currently exercisable to purchase an aggregate of 366,668 shares of our common stock at an exercise price per share of \$1.50.

In March 2018, we entered into an Amended and Restated Venture Loan and Security Agreement (the “Restated Loan Agreement”) with Horizon and Molteni pursuant to which Horizon assigned approximately \$2.4 million of the \$4.0 million outstanding principal balance of the loan to Molteni and Molteni was appointed as the collateral agent and assumed majority and administrative control of the loan. Under the Restated 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 if we complete an equity financing resulting in gross proceeds of at least \$10.0 million at a price per share of common stock in excess of \$7.20 and repay the \$1.6 million balance of Horizon’s loan amount. In connection with the Restated 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 consideration of Molteni’s entry into the Restated Loan Agreement and the Purchase Agreement, on March 21, 2018, we entered into a rights agreement (the “Rights Agreement”) with Molteni pursuant to which we agreed to (i) issue Molteni seven-year warrants to purchase 90,000 shares of our common stock at an exercise price of \$7.20 per share (the “Molteni Warrants”), (ii) provide Molteni customary demand and piggy-back registration rights with respect to the shares of common stock issuable upon conversion of its loan and exercise of the Molteni Warrants, (iii) designate one member of our board of directors following conversion of the loan in full and (iv) provide board observer rights to Molteni if it has not designated a board nominee as well as certain information rights.

TITAN PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS - Continued
(unaudited)

In September 2019, we entered into an amendment to the Restated 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 Restated 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.

As of September 30, 2019, the loan from Molteni under the amendment to the Restated Loan Agreement was convertible into 3,422,777 shares of our common stock.

In accordance with ASC 470, "Debt," 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.

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.

6. Stockholders' Equity

At-the-Market Offering (the "ATM")

In April 2019, we implemented the ATM for the sale of up to \$8.6 million of our common stock. During the three months ended June 30, 2019, we issued a total of 329,656 shares of our common stock at a weighted-average price of \$1.60 per share for total net proceeds of approximately \$0.5 million under the ATM. In August 2019, we reduced the dollar amount that can be sold under ATM to \$4.0 million.

August 2019 Offering

In August 2019, we completed an offering (the "August 2019 Offering") with a single accredited institutional investor (the "Purchaser") pursuant to which we issued 1,480,000 shares of our common stock and pre-funded warrants to purchase 1,372,314 shares of our common stock with an exercise price of \$0.01 per share (the "Pre-funded Warrants") in a registered direct offering and warrants to purchase 2,852,314 shares of our common stock with an exercise price of \$1.07 per share (the "Placement Warrants") in a concurrent private placement. The Pre-Funded Warrants, which were exercised for common stock in September 2019, were issued in lieu of common stock in order to ensure the Purchaser did not exceed certain beneficial ownership limitations. The Placement Warrants will become exercisable in February 2020 and will expire in February 2025. The Placement Warrants agreement contains a provision where the warrant holder has the option to receive cash, equal to the Black Scholes fair value of the remaining unexercised portion of the warrant, as cash settlement in the event that there is a fundamental transaction (contractually defined to include various merger, acquisition or stock transfer activities). As a result of this provision, in accordance with ASC 480, "Distinguishing Liabilities from Equity," the Placement Warrants are required to be classified as liabilities. The fair value of the Placement Warrants is determined using the Black-Scholes Option Pricing model to calculate the call option and Binomial Option Pricing model to calculate the put option with changes in the fair value recorded in the condensed statements of operations and comprehensive loss.

During the three months ended September 30, 2019, approximately \$1.4 million and approximately \$0.6 million, respectively, were allocated to warrant liability and additional paid-in capital.

TITAN PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS - Continued
(unaudited)

The warrant liability associated with the Placement Warrants is classified within level 3 of the fair value hierarchy. The below table represents the weighted-average key assumptions used to calculate the fair value of the Placement Warrants:

	As of	
	August 7, 2019	September 30, 2019
Volatility	87%	97%
Risk-free Interest Rate	1.5%	1.6%
Dividend Rate	—	—
Expected Term (in years)	4.9	4.8
Weighted-Average Fair Value per share warrant	\$ 0.50	\$ 0.14

The below table presents the roll-forward of the warrant liability associated with the Placement Warrants (in thousands):

Beginning balance as of January 1, 2019	\$	—
Warrant liability		1,429
Non-cash gain on changes in fair value ¹		(1,041)
Ending balance as of September 30, 2019	\$	<u>388</u>

(1) Recorded within other income in the condensed statements of operations and comprehensive loss for the three and nine months ended September 30, 2019.

7. Subsequent Events

In October 2019, we completed an underwritten public offering (the “Public Offering”) pursuant to which we issued 40,276,000 units at an offering price of \$0.225 per unit, consisting of 35,886,000 shares of our common stock and pre-funded warrants to purchase 4,390,000 shares of our common stock with an exercise price of \$0.01 per share (the “Pre-funded Warrants”), and Class B Warrants to purchase 40,276,000 shares of our common stock at \$0.225 per share (the “Class B Warrants”). The Pre-Funded Warrants, which were exercised for common stock in October 2019, were issued in lieu of common stock in order to ensure the Purchaser did not exceed certain beneficial ownership limitations. The Class B Warrants are immediately exercisable and will expire in October 2024. The Class B Warrant agency agreement contains a provision where the warrant holder has the option to receive cash equal to the Black Scholes fair value of the remaining unexercised portion of the warrant in the event that there is a fundamental transaction (contractually defined to include various merger, acquisition or stock transfer activities). Through the date of filing this Quarterly Report on Form 10-Q, we received net cash proceeds of approximately \$8.1 million, after deduction of underwriting fees and other offering expenses.

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

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 an efficacy and/or safety benefit. We have been transitioning to a commercial stage enterprise following the reacquisition of Probuphine® (buprenorphine) implant, or Probuphine, on May 25, 2018 from our former licensee. Probuphine is the first product based on our ProNeura technology approved in the U.S., Canada and the EU for the maintenance treatment of opioid use disorder, or OUD, in eligible patients. Since the reacquisition, we have been implementing a strategic plan aimed at building the foundation to support an effective U.S. product relaunch targeted at select OUD market segments best suited for Probuphine, including the establishment of a small experienced commercial team and the engagement of new strategic partners in the product order and distribution process.

ProNeura consists of a small, solid rod made from a mixture of ethylene-vinyl acetate, or EVA, and a drug substance. The resulting product is a solid matrix that is placed subdermally, normally in the inside part of the upper arm in a short physician office based outpatient procedure, and is removed in a similar manner at the end of the treatment period. The drug substance is released continuously through the process of diffusion-controlled dissolution, resulting in a steady rate of release generally similar to intravenous administration thereby avoiding the fluctuating peak and trough levels of oral dosing that often pose problems in many disease settings. We believe that our ProNeura long term drug delivery platform has the potential to be used in the treatment of other chronic conditions where maintaining stable, around the clock blood levels of a medication may benefit the patient and improve medical outcomes. While our primary focus is on the commercialization of Probuphine, we are also engaged in early stage research and development efforts on a product pipeline based on this platform technology.

We operate in only one business segment, the development and commercialization 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, 2019 and 2018

Revenues

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2019	2018	Change	2019	2018	Change
	(in thousands)					
Revenues:						
License revenue	\$ —	\$ 1,406	\$ (1,406)	\$ 313	\$ 5,063	\$ (4,750)
Product revenue	190	244	(54)	811	318	493
Grant revenue	757	—	757	1,270	—	1,270
Total revenues	<u>\$ 947</u>	<u>\$ 1,650</u>	<u>\$ (703)</u>	<u>\$ 2,394</u>	<u>\$ 5,381</u>	<u>\$ (2,987)</u>

The decrease in total revenues for the three and nine months ended September 30, 2019 was primarily due to one-time payments in 2018 from license agreements associated with Probuphine, partially offset by grant revenue and higher product revenue during 2019. License revenues recognized for the three and nine months ended September 30, 2018 were related to the sale of our European intellectual property rights to Molteni, the return of Probuphine commercialization rights in May 2018 and earned royalties while license revenue recognized for the nine months ended September 30, 2019 was related to 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,		
	2019	2018	Change	2019	2018	Change
	(in thousands)					
Operating expenses:						
Cost of goods sold	\$ 188	\$ 178	\$ 10	\$ 738	\$ 248	\$ 490
Research and development	1,619	1,910	(291)	5,370	5,623	(253)
Selling, general and administrative	3,023	1,514	1,509	9,336	4,508	4,828
Total operating expenses	<u>\$ 4,830</u>	<u>\$ 3,602</u>	<u>\$ 1,228</u>	<u>\$ 15,444</u>	<u>\$ 10,379</u>	<u>\$ 5,065</u>

Cost of goods sold reflects product costs and distribution expenses associated with sales of Probuphine product by us after reacquiring the commercialization rights in May 2018.

The decrease in our research and development expenses for the three months ended September 30, 2019 was primarily due to approximately \$0.6 million of lower research and development expenses related to Probuphine and approximately \$0.2 million of lower expenses related to employee compensation, partially offset by approximately \$0.5 million of higher research and development expenses related to the nalmafene product development program, which were partially reimbursed under an NIH (National Institute of Health)/NIDA (National Institute of Drug Abuse) grant. The decrease in our research and development expenses for the nine months ended September 30, 2019 was primarily due to approximately \$1.0 million of lower external research and development expenses related to the ropinirole implant program and other programs and approximately \$0.9 million of lower other research and development expenses mainly related to the reduction of our workforce, partially offset by \$1.1 million of higher research and development expenses related to the nalmafene product development program, which were partially reimbursed under an NIH/NIDA grant, and approximately \$0.4 million of higher research and development expenses related to Probuphine, which includes the preparation for initiation of a phase 4 clinical trial. Other research and development expenses include internal operating costs such as clinical research and development personnel-related expenses, clinical trials related travel expenses, and the allocation of facility and corporate costs. As a result of the risks and uncertainties inherently associated with pharmaceutical research and development and activities described elsewhere in this report, we are unable to estimate the specific timing and future costs of our research and development programs or the timing of material cash inflows, if any, from our product candidates.

The substantial increase in selling, general and administrative expenses for the three and nine months ended September 30, 2019 was primarily due to expenses associated with the commencement of activities associated with our commercialization of Probuphine, which resulted in increases in employee related expenses, consulting and professional fees, other outside services, travel costs and facilities related expenses. The increase in selling, general and administrative expenses for the three months ended September 30, 2019 was primarily attributable to increases in employee-related expenses of approximately \$0.5 million, expenses related to consulting, professional and outside services of approximately \$0.8 million and expenses related to facilities and travel of approximately \$0.2 million. The increase in selling, general and administrative expenses for the nine months ended September 30, 2019 was primarily attributable to increases in expenses related to consulting, professional and outside services of approximately \$2.1 million, employee-related expenses of approximately \$1.8 million and expenses related to facilities and travel of approximately \$0.9 million.

Other Expense, Net

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2019	2018	Change	2019	2018	Change
	(in thousands)					
Other income (expense):						
Interest expense, net	\$ (238)	\$ (227)	\$ (11)	\$ (737)	\$ (650)	\$ (87)
Gain on debt extinguishment, net	291	—	291	226	—	226
Non-cash gain on changes in fair value	1,041	141	900	1,066	141	925
Other expense, net	(14)	(7)	(7)	(22)	(12)	(10)
Other income (expense), net	<u>1,080</u>	<u>(93)</u>	<u>1,173</u>	<u>533</u>	<u>(521)</u>	<u>1,054</u>

Other income, net for the three and nine months ended September 30, 2019 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, partially offset by interest expense. Other expense for the three and nine months ended September 30, 2018 was primarily attributable to interest expense on our loans, partially offset by a non-cash gain on changes in the fair value of our derivative liability. During the nine months ended September 30, 2019, the increase in interest expense compared to the same period in 2018 was primarily due to higher outstanding loan balances.

Net Loss and Net Loss per Share

Our net loss for the three months ended September 30, 2019 was approximately \$2.8 million, or approximately \$0.18 per share, compared to our net loss of approximately \$2.3 million, or approximately \$0.64 per share, for the comparable period in 2018. Our net loss for the nine months ended September 30, 2019 was approximately \$12.5 million, or approximately \$0.89 per share, compared to our net loss of approximately \$5.8 million, or approximately \$1.62 per share, for the comparable period in 2018. Our net loss for the three and nine months ended September 30, 2018 includes a deemed dividend of approximately \$0.3 million.

Liquidity and Capital Resources

We have funded our operations since inception primarily through the sale of 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, 2019, we had working capital of approximately \$0.5 million compared to working capital of approximately \$9.8 million at December 31, 2018.

In April 2019, we implemented the ATM for the sale of up to \$8.6 million of our common stock. During the three months ended June 30, 2019, we received total net proceeds of approximately \$0.5 million from the sale of 329,656 shares of our common stock at a weighted-average price of \$1.60 per share under the ATM. In August 2019, we reduced the dollar amount that can be sold under the ATM to \$4.0 million.

In June 2019, we issued 448,287 shares of our common stock upon the conversion of the Molteni Convertible Loan upon the receipt of the European Medicines Agency approval of Sixmo. See Note 5 of the Notes to Condensed Financial Statements in Item 1.

In August 2019, we completed the August 2019 Offering pursuant to which we issued the Purchaser 1,480,000 shares of our common stock and Pre-Funded Warrants to purchase 1,372,314 shares of our common stock with an exercise price of \$0.01 per share in a registered direct offering and Placement Warrants to purchase 2,852,314 shares of our common stock with an exercise price of \$1.07 per share in a concurrent private placement. We received net cash proceeds totaling approximately \$1.8 million, after deduction of underwriting fees and other offering expenses.

In October 2019, we completed the Public Offering pursuant to which we issued 40,276,000 units at an offering price of \$0.225 per unit, consisting of 35,886,000 shares of our common stock and Pre-Funded Warrants to purchase 4,390,000 shares of our common stock with an exercise price of \$0.01 per share and Class B Warrants to purchase 40,276,000 shares of our common stock at \$0.225 per share. We received net cash proceeds totaling approximately \$8.1 million, after deduction of underwriting fees and other offering expenses.

As of September 30, 2019, we had cash and cash equivalents of approximately \$0.9 million, which we believe, together with the proceeds of the Public Offering, is sufficient to fund our planned operations into the third quarter of 2020. 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. We have also been seeking to implement appropriate cost-cutting measures to preserve cash. In furtherance of these efforts, our Chief Executive Officer and our Executive Chairman have agreed to a 50% reduction in their base salaries effective January 1, 2020 through June 30, 2020 and the non-employee members of our Board have agreed to a 25% reduction in their annual retainer for 2020.

Sources and Uses of Cash

	Nine Months Ended September 30,	
	2019	2018
	(in thousands)	
Net cash used in operating activities	(11,782)	(5,123)
Net cash used in investing activities	(144)	(71)
Net cash provided by financing activities	3,191	6,099
Change in cash, cash equivalents and restricted cash	(8,735)	905

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 \$1.0 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. Net cash used in operating activities for the nine months ended September 30, 2018 consisted primarily of the net loss for the period of approximately \$5.5 million, approximately \$1.3 million of non-cash gain on inventory and approximately \$0.1 million of other non-cash charges. This was partially offset by non-cash charges of approximately \$1.2 million related to stock-based compensation, approximately \$0.3 million related to depreciation and amortization and approximately \$0.3 million related to non-cash interest expense. Uses of cash in operating activities were primarily to fund commercialization, product development programs and administrative expenses.

Cash used in investing activities was primarily related to purchases of equipment for both the nine months ended September 30, 2019 and 2018.

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. Net cash provided by financing activities for the nine months ended September 30, 2018 was primarily due to approximately \$8.5 million of net proceeds from equity offering and approximately \$0.6 million of loan proceeds from Molteni, partially offset by approximately \$3.0 million repayment of long-term debt.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our market risk disclosures set forth in our Annual Report on Form 10-K/A for the year ended December 31, 2018 have not materially changed.

Item 4. Controls and Procedures

Disclosure Controls and Procedures

Our President and Chief Executive Officer, being our principal executive and financial officer, has evaluated the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act as of September 30, 2019, 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, 2019 that materially affected, or were reasonably likely to materially affect, our internal controls over financial reporting.

PART II

Item 1A. Risk Factors

In addition to the other information set forth in this report, you should carefully consider the factors discussed in Part I, “Item 1A. Risk Factors” in our Annual Report on Form 10-K/A for the year ended December 31, 2018 and in our Registration Statement on Form S-1 (File No. 333-233722, which could materially affect our business, financial condition or future results. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results.

Item 6. Exhibits

Exhibit No.

1.1	Underwriting Agreement between Titan Pharmaceuticals, Inc. and Maxim Group LLC(30)
3.1.1	Amended and Restated Certificate of Incorporation of the Registrant, as amended(5)
3.1.2	Certificate of Amendment to the Restated Certificate of Incorporation dated September 24, 2015(12)
3.1.3	Certificate of Amendment to the Restated Certificate of Incorporation dated January 23, 2019(23)
3.2	By-laws of the Registrant(1)
3.3	Certificate of Designation of Series A Convertible Preferred Stock(22)
4.1	Form of 2014 Class A Warrant(11)
4.3	Form of 2014 Underwriter Warrant(11)
4.4	Form of Lender Warrant(15)
4.5	Form of Rights Agreement Warrant(17)
4.6	2018 Warrant Agency Agreement between Titan Pharmaceuticals, Inc. and Continental Stock Transfer & Trust Company and Form of Offering Warrant(22)
4.7	2018 Representative’s Purchase Warrant(22)
4.8	Form of August 2019 Offering Pre-Funded Warrant(27)
4.9	Form of August 2019 Placement Warrant(27)
4.10	Form of October 2019 Offering Pre-Funded Warrant(28)
4.11	2019 Class B Warrant Agency Agreement between Titan Pharmaceuticals, Inc. and Continental Stock Transfer & Trust Company and Form of Class B Warrant(30)
10.1	2001 Non-Qualified Employee Stock Option Plan(2)
10.2	2002 Stock Option Plan(3)
10.3	Lease for the Registrant’s facilities, amended as of October 1, 2004(4)
10.4	Amendments to lease for Registrant’s facilities dated May 21, 2007 and March 12, 2009(5)
10.5	Amendment to lease for Registrant’s facilities dated June 15, 2010(6)
10.6±	License Agreement by and between Titan Pharmaceuticals, Inc. and Braeburn Pharmaceuticals Sprl, dated December 14, 2012(7)
10.7	Amendment dated May 28, 2013 to License Agreement by and between Titan Pharmaceuticals, Inc. and Braeburn Pharmaceuticals Sprl(8)
10.8	Second Amendment dated July 2, 2013 to License Agreement by and between Titan Pharmaceuticals, Inc. and Braeburn Pharmaceuticals Sprl(9)
10.9	Third Amendment dated November 12, 2013 to License Agreement by and between Titan Pharmaceuticals, Inc. and Braeburn Pharmaceuticals Sprl(13)
10.10	Titan Pharmaceuticals, Inc. 2014 Incentive Plan(12)
10.11	Titan Pharmaceuticals, Inc. Third Amended and Restated 2015 Omnibus Equity Incentive Plan(23)
10.12	Employment Agreement between Titan Pharmaceuticals, Inc. and Titan Pharmaceuticals, Inc. and Sunil Bhonsle(14)
10.13	Employment Agreement between Titan Pharmaceuticals, Inc. and Titan Pharmaceuticals, Inc. and Marc Rubin(14)
10.14	Venture Loan and Security Agreement, dated July 27, 2017, by and between Titan Pharmaceuticals, Inc. and Horizon Technology Finance Corporation(15)

<u>10.15</u>	<u>Amendment of Venture Loan and Security Agreement, dated February 2, 2018, by and between Titan Pharmaceuticals, Inc. and Horizon Technology Finance Corporation(16)</u>
<u>10.16</u>	<u>Amended and Restated Venture Loan and Security Agreement, dated March 21, 2018, by and between Titan Pharmaceuticals, Inc., Horizon Technology Finance Corporation and L. Molteni & C. Dei Frattelli Alitti Società Di Esercizio S.P.A.(17)</u>
<u>10.17±</u>	<u>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.(17)</u>
<u>10.18</u>	<u>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.(17)</u>
<u>10.19±</u>	<u>Termination and Transition Services Agreement dated May 25, 2018 by and between Titan Pharmaceuticals, Inc. and Braeburn Pharmaceuticals, Inc.(18)</u>
<u>10.20±</u>	<u>Amendment dated August 3, 2018 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(19)</u>
<u>10.21±</u>	<u>Distribution and Sublicense Agreement dated February 1, 2016 as amended by agreement dated August 2, 2018 between Titan Pharmaceuticals, Inc. and Knight Therapeutics Inc.(20)</u>
<u>10.22</u>	<u>Amendment to lease for Registrant's facility dated March 21, 2016(20)</u>
<u>10.23</u>	<u>Amendment to Employment Agreement with Sunil Bhonsle dated August 9, 2018(20)</u>
<u>10.24</u>	<u>Amendment to Employment Agreement with Marc Rubin dated August 9, 2018(20)</u>
<u>10.25</u>	<u>Unsecured Convertible Loan Agreement dated September 18, 2018(21)</u>
<u>10.26</u>	<u>Employment Agreement with Katherine Beebe DeVarney dated November 1, 2018(24)</u>
<u>10.27</u>	<u>Employment Agreement with Dane Hallberg dated September 26, 2018(24)</u>
<u>10.28</u>	<u>Employment Agreement with Sunil Bhonsle dated April 1, 2019(25)</u>
<u>10.29</u>	<u>Employment Agreement with Marc Rubin dated April 1, 2019(25)</u>
<u>10.30</u>	<u>Sales Agreement dated April 25, 2019 between Titan Pharmaceuticals, Inc. and A.G.P./Alliance Global Partners(26)</u>
<u>10.31</u>	<u>Form of August 2019 Securities Purchase Agreement(27)</u>
<u>10.32</u>	<u>Placement Agency Agreement dated August 7, 2019 between Titan Pharmaceuticals, Inc. and Maxim Group LLC(27)</u>
<u>10.33</u>	<u>Amendment dated September 10, 2019 to Amended and Restated Venture Loan and Security Agreement, dated March 21, 2018, by and between Titan Pharmaceuticals, Inc., Horizon Technology Finance Corporation and L. Molteni & C. Dei Frattelli Alitti Società Di Esercizio S.P.A. (28)</u>
<u>10.34±</u>	<u>Amendment No. 2 dated September 10, 2019 to Asset Purchase, Supply and Support Agreement by and between Titan Pharmaceuticals, Inc. and L. Molteni & C. Dei Frattelli Alitti Società Di Esercizio S.P.A(28)</u>
<u>14.1</u>	<u>Code of Business Conduct and Ethics(10)</u>
<u>31.1</u>	<u>Certification of the Principal Executive and Financial Officer pursuant to Rule 13(a)-14(a) of the Securities Exchange Act of 1934</u>
<u>32.1</u>	<u>Certification of the Principal Executive and Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</u>

101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

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

- (1) Incorporated by reference from the Registrant's Registration Statement on Form S-3 (File No. 333-21126).
- (2) Incorporated by reference from the Registrant's Annual Report on Form 10-K for the year ended December 31, 2001.
- (3) Incorporated by reference from the Registrant's Annual Report on Form 10-K for the year ended December 31, 2002.
- (4) Incorporated by reference from the Registrant's Annual Report on Form 10-K for the year ended December 31, 2005.
- (5) Incorporated by reference from the Registrant's Registration Statement on Form 10 filed on January 14, 2010.
- (6) Incorporated by reference from the Registrant's Quarterly Report on Form 10-Q for the period ended June 30, 2010.
- (7) Incorporated by reference from the Registrant's Current Report on Form 8-K/A filed on February 28, 2013.
- (8) Incorporated by reference from the Registrant's Current Report on Form 8-K filed on May 29, 2013.
- (9) Incorporated by reference from the Registrant's Current Report on Form 8-K filed on July 5, 2013.

- (10) Incorporated by reference from the Registrant's Annual Report on Form 10-K for the year ended December 31, 2013.
- (11) Incorporated by reference from the Registrant's Registration Statement on Form S-1/A dated September 30, 2014.
- (12) Incorporated by reference from the Registrant's Current Report on Form 8-K filed on September 28, 2015.
- (13) Incorporated by reference from the Registrant's Current Report on Form 8-K filed on November 13, 2013.
- (14) Incorporated by reference from the Registrant's Current Report on Form 8-K filed on September 30, 2016.
- (15) Incorporated by reference from the Registrant's Current Report on Form 8-K filed on July 27, 2017.
- (16) Incorporated by reference from the Registrant's Current Report on Form 8-K filed on February 7, 2018.
- (17) Incorporated by reference from the Registrant's Current Report on Form 8-K filed on March 26, 2018.
- (18) Incorporated by reference from the Registrant's Current Report on Form 8-K filed on May 30, 2018.
- (19) Incorporated by reference from the Registrant's Current Report on Form 8-K filed on August 3, 2018.
- (20) Incorporated by reference from the Registrant's Quarterly Report on Form 10-Q for the period ended June 30, 2018.
- (21) Incorporated by reference from the Registrant's Current Report on Form 8-K dated September 20, 2018.
- (22) Incorporated by reference from the Registrant's Current Report on Form 8-K dated September 25, 2018.
- (23) Incorporated by reference from the Registrant's Current Report on Form 8-K dated January 25, 2019.
- (24) Incorporated by reference from the Registrant's Annual Report on Form 10-K for the year ended December 31, 2018.
- (25) Incorporated by reference from the Registrant's Current Report on Form 8-K dated April 3, 2019.
- (26) Incorporated by reference from the Registrant's Current Report on Form 8-K dated April 25, 2019.
- (27) Incorporated by reference from the Registrant's Current Report on Form 8-K dated August 7, 2019.
- (28) Incorporated by reference from the Registrant's Registration Statement on Form S-1 dated September 12, 2019.
- (29) Incorporated by reference from the Registrant's Registration Statement on Form S-1/A dated October 8, 2019.
- (30) Incorporated by reference from the Registrant's Current Report on Form 8-K dated October 18, 2019.

SIGNATURES

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

TITAN PHARMACEUTICALS, INC.

Dated: November 14, 2019

By: _____ /s/ Sunil Bhonsle
Name: **Sunil Bhonsle**
Title: **President and Chief Executive Officer**
(Principal Executive and Principal Financial Officer)

CERTIFICATION

I, Sunil Bhonsle, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Titan Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the registrant is made known to me by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under my supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14, 2019

/s/ Sunil Bhonsle

Name: Sunil Bhonsle
Title: President and Chief Executive Officer
(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, 2019, 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 14, 2019

/s/ Sunil Bhonsle

Name: Sunil Bhonsle
Title: President and Chief Executive Officer
(Principal Executive Officer and Principal Financial Officer)
