UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington D.C. 20549

FORM 10-Q

(Mark One)

☒ **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: 001-37990

LEAP THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware State or other jurisdiction of incorporation or organization	**27-4412575** (I.R.S. Employer Identification No.)
47 Thorndike St, Suite B1-1, Cambridge, MA Address of Principal Executive Offices	**02141** Zip Code

(617) 714-0360
Registrant's Telephone Number, Including Area Code

N/A
Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report

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 per share	LPTX	Nasdaq Global Market

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

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

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

APPLICABLE ONLY TO ISSUERS INVOLVED IN BANKRUPTCY PROCEEDINGS DURING THE PRECEDING FIVE YEARS:

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Section 12, 13 or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court. Yes ☐ No ☐

APPLICABLE ONLY TO CORPORATE ISSUERS

As of November 12, 2019 there were 24,194,877 shares of the registrant's common stock, par value $0.001 per share, outstanding.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

This Quarterly Report on Form 10-Q (this "Quarterly Report") contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, which reflect our current views with respect to, among other things, our operations and financial performance. In some cases, you can identify forward-looking statements by terminology such as "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "will" or the negative of such terms or other comparable terminology. Forward-looking statements appear in a number of places throughout this Quarterly Report and include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, our ability and plan to develop and commercialize DKN-01 and TRX518; status, timing and results of preclinical studies and clinical trials; the potential benefits of DKN-01 and TRX518; the timing of our development programs and seeking regulatory approval of DKN-01 and TRX518; our ability to obtain and maintain regulatory approval; our estimates of expenses and future revenues and profitability; our estimates regarding our capital requirements and our needs for additional financing; our estimates of the size of the potential markets for DKN-01 and TRX518; our ability to attract collaborators with acceptable development, regulatory and commercial expertise; the benefits to be derived from any collaborations, license agreements, and other acquisition efforts, including those relating to the development and commercialization of DKN-01 and TRX518; sources of revenues and anticipated revenues, including contributions from any collaborations or license agreements for the development and commercialization of products; our ability to create an effective sales and marketing infrastructure if we elect to market and sell DKN-01 and TRX518 directly; the rate and degree of market acceptance of DKN-01 and TRX518; the timing and amount or reimbursement for DKN-01 and TRX518; the success of other competing therapies that may become available; the manufacturing capacity for DKN-01 and TRX518; our intellectual property position; our ability to maintain and protect our intellectual property rights; our results of operations, financial condition, liquidity, prospects, growth and strategies; the industry in which we operate; and the trends that may affect the industry or us.

By their nature, forward-looking statements involve risks and uncertainties because they relate to events, competitive dynamics and industry change, and depend on the economic circumstances that may or may not occur in the future or may occur on longer or shorter timelines than anticipated. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Quarterly Report, we caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this Quarterly Report. In addition, even if our results of operations, financial condition and liquidity, and events in the industry in which we operate are consistent with the forward-looking statements contained in this Quarterly Report, they may not be predictive of results or developments in future periods. You should carefully read this Quarterly Report and the documents that we have filed as exhibits to this Quarterly Report completely.

You should refer to Part II, Item 1A, Risk Factors in this Quarterly Report and Part I, Item IA, Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2018 as filed with the Securities and Exchange Commission on April 1, 2019 for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Quarterly Report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified timeframe, or at all. Any forward-looking statements that we make in this Quarterly Report speaks only as of the date of such statement, and, except to the extent required by applicable law, we undertake no obligation to update such statements to reflect events or circumstances after the date of this Quarterly Report or to reflect the occurrence of unanticipated events. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Quarterly Report. Comparisons of results for current and any prior periods are not intended to express any future trends or indications of future performance, unless expressed as such, and should only be viewed as historical data.

DKN-01 and TRX518 are investigational drugs undergoing clinical development and have not been approved by the U.S. Food and Drug Administration (the "FDA"), nor been submitted to the FDA for approval. DKN-01 and TRX518 have not been, and may never be, approved by any regulatory agency or marketed anywhere in the world. Statements contained in this Quarterly Report should not be deemed to be promotional.

INTRODUCTORY COMMENT

References to Leap

Throughout this Quarterly Report on Form 10-Q, the “Company,” “Leap,” “Leap Therapeutics,” “we,” “us,” and “our,” except where the context requires otherwise, refer to Leap Therapeutics, Inc. and its consolidated subsidiaries, and “our board of directors” refers to the board of directors of Leap Therapeutics, Inc.

Part I — FINANCIAL INFORMATION

Item 1. Financial Statements

LEAP THERAPEUTICS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share amounts)

	September 30, 2019 (Unaudited)	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 10,058	$ 16,284
Research and development incentive receivable	752	836
Prepaid expenses and other current assets	210	202
Total current assets	11,020	17,322
Property and equipment, net	149	86
Right of use assets, net	1,214	—
Research and development incentive receivable, net of current portion	177	—
Deferred tax assets	120	124
Other assets	1,461	1,542
Total assets	$ 14,141	$ 19,074
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,889	$ 3,579
Accrued expenses	2,317	2,872
Restricted stock liability	159	—
Lease liability - current portion	566	—
Total current liabilities	7,931	6,451
Warrant liability	—	3,448
Lease liability, net of current portion	648	—
Total liabilities	8,579	9,899
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Common stock, $0.001 par value; 100,000,000 shares authorized; 24,194,877 and 14,703,159 shares issued and outstanding as of September 30, 2019 and December 31, 2018, respectively	24	15
Additional paid-in capital	192,383	162,393
Accumulated other comprehensive income	327	302
Accumulated deficit	(187,172)	(153,535)
Total stockholders' equity	5,562	9,175
Total liabilities and stockholders' equity	$ 14,141	$ 19,074

See notes to condensed consolidated financial statements.

LEAP THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except share and per share amounts)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Operating expenses:				
Research and development	$ 5,772	$ 6,457	$ 18,698	$ 14,922
General and administrative	2,151	2,142	6,481	6,858
Total operating expenses	7,923	8,599	25,179	21,780
Loss from operations	(7,923)	(8,599)	(25,179)	(21,780)
Interest income	80	128	281	327
Interest expense	(5)	(4)	(21)	(18)
Australian research and development incentives	(7)	299	129	1,188
Foreign currency loss	(80)	(249)	(114)	(615)
Change in fair value of warrant liability	—	1,793	—	(3,720)
Net loss	(7,935)	(6,632)	(24,904)	(24,618)
Dividend attributable to down round feature of warrants	—	—	(359)	—
Net loss attributable to common stockholders	$ (7,935)	$ (6,632)	$ (25,263)	$ (24,618)
Net loss per share				
Basic	$ (0.33)	$ (0.45)	$ (1.15)	$ (1.76)
Diluted	$ (0.33)	$ (0.55)	$ (1.15)	$ (1.76)
Weighted average common shares outstanding				
Basic	23,923,196	14,701,785	22,039,386	13,955,949
Diluted	23,923,196	15,211,716	22,039,386	13,955,949

See notes to condensed consolidated financial statements.

LEAP THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(In thousands)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Net loss	$ (7,935)	$ (6,632)	$ (24,904)	$ (24,618)
Other comprehensive income:				
Foreign currency translation adjustments	5	179	25	428
Comprehensive loss	$ (7,930)	$ (6,453)	$ (24,879)	$ (24,190)

See notes to condensed consolidated financial statements.

LEAP THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
For the Three and Nine Months Ended September 30, 2018

(In thousands, except share amounts)

(Unaudited)

	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
Balances at June 30, 2018	14,700,681	15	$ 160,522	$ (19)	$ (148,383)	$ 12,135
Issuance of common stock upon exercise of stock options	2,478	—	14	—	—	14
Foreign currency translation adjustment	—	—	—	179	—	179
Stock-based compensation	—	—	932	—	—	932
Net loss	—	—	—	—	(6,632)	(6,632)
Balances at September 30, 2018	14,703,159	15	$ 161,468	$ 160	$ (155,015)	$ 6,628

	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
Balances at December 31, 2017	12,354,014	12	$ 141,770	$ (268)	$ (130,397)	$ 11,117
Issuance of common stock in connection with Public Offering, net of issuance costs of $1,304	2,146,667	3	14,793	—	—	14,796
Issuance of common stock upon exercise of warrants	200,000	—	2,347	—	—	2,347
Issuance of common stock upon exercise of stock options	2,478	—	14	—	—	14
Foreign currency translation adjustment	—	—	—	428	—	428
Stock-based compensation	—	—	2,544	—	—	2,544
Net loss	—	—	—	—	(24,618)	(24,618)
Balances at September 30, 2018	14,703,159	15	$ 161,468	$ 160	$ (155,015)	$ 6,628

See notes to condensed consolidated financial statements.

LEAP THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
For the Three and Nine Months Ended September 30, 2019

(In thousands, except share amounts)

(Unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances at June 30, 2019	22,949,064	23	$ 189,831	$ 322	$ (179,237)	$ 10,939
Issuance of common stock through ATM sales	344,384	—	617	—	—	617
To record ATM issuance costs in Additional Paid-in Capital	—	—	(4)	—	—	(4)
Issuance of common stock in connection with July 2019 Lincoln Park Capital Commitment Purchase Agreement	330,000	—	—	—	—	—
Issuance of common stock in connection with July 2019 Lincoln Park Capital Registered Offering Purchase Agreement, net of issuance costs of $10	571,429	1	989			990
Foreign currency translation adjustment	—	—	—	5	—	5
Stock-based compensation	—	—	950	—	—	950
Net loss	—	—	—	—	(7,935)	(7,935)
Balances at September 30, 2019	24,194,877	24	$ 192,383	$ 327	$ (187,172)	$ 5,562

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances at December 31, 2018	14,703,159	15	$ 162,393	$ 302	$ (153,535)	$ 9,175
Issuance of common stock in connection with February 2019 Public Offering, net of issuance costs of $1,102	7,557,142	7	12,115	—	—	12,122
Issuance of common stock through ATM sales	1,033,147	1	1,922	—	—	1,923
To record ATM issuance costs in Additional Paid-in Capital	—	—	(13)	—	—	(13)
Issuance of common stock in connection with July 2019 Lincoln Park Capital Commitment Purchase Agreement	330,000	—	—	—	—	—
Issuance of common stock in connection with July 2019 Lincoln Park Capital Registered Offering Purchase Agreement, net of issuance costs of $10	571,429	1	989	—	—	990
Reclassification of 2017 warrants from liability to equity	—	—	11,822	—	(8,374)	3,448
Record the value of the effect of the down round feature as a dividend	—	—	359	—	(359)	—
Foreign currency translation adjustment	—	—	—	25	—	25
Stock-based compensation	—	—	2,796	—	—	2,796
Net loss	—	—	—	—	(24,904)	(24,904)
Balances at September 30, 2019	24,194,877	24	$ 192,383	$ 327	$ (187,172)	$ 5,562

See notes to condensed consolidated financial statements.

LEAP THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Nine Months Ended September 30, 2019	Nine Months Ended September 30, 2018
Cash flows from operating activities:		
Net loss	$ (24,904)	$ (24,618)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	37	37
Non-cash lease expense	541	—
Stock-based compensation expense	2,796	2,544
Change in fair value of restricted stock liability	159	—
Change in fair value of warrant liability	—	3,720
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	280	(115)
Research and development incentive receivable	(128)	(480)
Accounts payable and accrued expenses	717	(71)
Lease liability	(506)	—
Net cash used in operating activities	(21,008)	(18,983)
Cash flows from investing activities:		
Purchases of property and equipment	(100)	—
Net cash used in investing activities	(100)	—
Cash flows from financing activities:		
Proceeds from the issuance of common stock, net of underwriter commissions and discounts	12,331	15,034
Proceeds from issuance of common stock from ATM sales	1,923	—
Proceeds from issuance of common stock in connection with July 2019 Lincoln Park Capital Registered Offering Purchase Agreement, net of issuance costs	999	—
Proceeds from exercise of common stock warrants	—	1,217
Proceeds from exercise of common stock options	—	14
Payment of deferred offering costs	(417)	(319)
Net cash provided by financing activities	14,836	15,946
Effect of exchange rate changes on cash and cash equivalents	46	549
Net decrease in cash and cash equivalents	(6,226)	(2,488)
Cash and cash equivalents at beginning of period	16,284	25,737
Cash and cash equivalents at end of period	$ 10,058	$ 23,249
Supplemental disclosure of non-cash financing activities:		
Reduction in fair value of warrant liability as a result of exercise of common stock warrants	$ —	$ 1,130
Reclassification of 2017 Warrants from liability to equity	$ 3,448	$ —
Dividend attributable to down round feature of warrants	$ 359	$ —
Offering costs included in accounts payable and accrued expenses	$ 20	$ 81
Right-of-use asset recorded upon adoption of ASU 2016-02	$ 1,755	$ —
Lease liability recorded upon adoption of ASU 2016-02	$ 1,720	$ —
Accrued rent reclassified upon adoption of ASU 2016-02	$ 35	$ —

See notes to condensed consolidated financial statements.

Leap Therapeutics, Inc.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(In thousands, except share and per share amounts)

(Unaudited)

1. Nature of Business, Basis of Presentation and Liquidity

Nature of Business

Leap Therapeutics, Inc. was incorporated in the state of Delaware on January 3, 2011 and changed its name to Leap Therapeutics, Inc. effective November 16, 2015 (the "Company"). During 2015, HealthCare Pharmaceuticals Pty Ltd. ("HCP Australia") was formed and is a wholly owned subsidiary of the Company.

The Company is a biopharmaceutical company acquiring and developing novel therapeutics at the leading edge of cancer biology. The Company's approach is designed to target compelling tumor-promoting and immuno-oncology pathways to generate durable clinical benefit and enhanced outcomes for patients. The Company's programs are monoclonal antibodies that target key cellular pathways that enable cancer to grow and spread and specific mechanisms that activate the body's immune system to identify and attack cancer.

Basis of Presentation

The accompanying condensed consolidated financial statements as of September 30, 2019 and for the three and nine months ended September 30, 2019 and 2018 have been prepared by the Company, pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC") for interim financial statements. Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") have been condensed or omitted pursuant to such rules and regulations. However, the Company believes that the disclosures are adequate to make the information presented not misleading. These condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and the notes thereto for the year ended December 31, 2018 included in the Company's Annual Report on Form 10-K filed with the SEC on April 1, 2019.

The condensed consolidated financial statements have been prepared on the same basis as the audited consolidated financial statements. In the opinion of management, the accompanying condensed consolidated financial statements contain all adjustments which are necessary for the fair presentation of the Company's financial position as of September 30, 2019, statements of operations and statements of comprehensive loss for the three and nine months ended September 30, 2019 and 2018 and statements of cash flows for the nine months ended September 30, 2019 and 2018. Such adjustments are of a normal and recurring nature. The results of operations for the three and nine months ended September 30, 2019 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2019.

Liquidity

Since inception, the Company has been engaged in organizational activities, including raising capital, and research and development activities. The Company does not yet have a product that has been approved by the Food and Drug Administration (the "FDA"), has not generated any revenues and has not yet achieved profitable operations, nor has it ever generated positive cash flows from operations. There is no assurance that profitable operations, if achieved, could be sustained on a continuing basis. Further, the Company's future operations are dependent on the success of the Company's efforts to raise additional capital, its research and commercialization efforts, regulatory approval, and, ultimately, the market acceptance of the Company's products.

In accordance with Accounting Standards Codification ("ASC") 205-40, Going Concern, the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the condensed consolidated financial statements are issued. As of September 30, 2019, the Company had cash and cash equivalents of $10,058 and expects to receive $752 of research and development tax incentive payments in 2019 from the Commonwealth of Australia as a result of the 2018 research and development activities of the Company's Australian subsidiary, HCP Australia. Additionally, the Company had an accumulated deficit of $187,172 at September 30, 2019, and during the nine months ended September 30, 2019, the Company incurred a net loss of $24,904. The Company expects to continue to generate operating losses in the foreseeable future. Due to the Company's need for additional capital and the uncertainties surrounding the Company's ability to raise such funding, substantial doubt exists as to the Company's ability to continue as a going concern for a period through one year after the financial statements have been issued.

On July 10, 2019, the Company entered into a purchase agreement (the "Commitment Purchase Agreement") and a Registration Rights Agreement (the "Registration Rights Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park"), pursuant to which the Company has the right to sell to Lincoln Park up to $20,000 in shares of its common stock, $0.001 par value per share ("Common Stock"), subject to certain limitations and conditions set forth in the Commitment Purchase Agreement. On July 11, 2019, the Company entered into a purchase agreement (the "Registered Offering Purchase Agreement" and together with the Commitment Purchase Agreement, the "Purchase Agreements"), under which the Company sold to Lincoln Park 571,429 shares of its Common Stock, at a price of $1.75 per share for an aggregate purchase price of $1,000, pursuant to the Company's shelf registration statement on Form S-3 filed with the SEC, including the prospectus supplement thereto dated July 11, 2019.

The Company has suspended enrollment of a TRX518 clinical trial until additional funding is available. In addition, the Company will seek additional funding through public or private equity financings or government programs and will seek funding or development program cost-sharing through collaboration agreements or licenses with larger pharmaceutical or biotechnology companies. If the Company does not obtain additional funding or development program cost-sharing, the Company would be forced to delay, reduce or eliminate certain clinical trials or research and development programs, reduce or eliminate discretionary operating expenses, and delay company and pipeline expansion, which would adversely affect its business prospects. The inability to obtain funding, as and when needed, would have a negative impact on the Company's financial condition and ability to pursue its business strategies.

2. Summary of Significant Accounting Policies

Principles of Consolidation

The accompanying condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All intercompany accounts and transactions are eliminated upon consolidation.

Use of Estimates

The presentation of condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Research and development incentive income and receivable

The Company recognizes other income from Australian research and development incentives when there is reasonable assurance that the income will be received, the relevant expenditure has been incurred, and the consideration can be reliably measured. The research and development incentive is one of the key elements of the Australian Government's support for Australia's innovation system and is supported by legislative law primarily in the form of the Australian Income Tax Assessment Act 1997, as long as eligibility criteria are met.

Management has assessed the Company's research and development activities and expenditures to determine which activities and expenditures are likely to be eligible under the research and development incentive regime described above. At each period end, management estimates the refundable tax offset available to the Company based on available information at the time. This estimate is also reviewed by external tax advisors on an annual basis.

Under the program, a percentage of eligible research and development expenses incurred by the Company through its subsidiary in Australia are reimbursed. The percentage was 43.5% for the year ended December 31, 2018 and for the three and nine months ended September 30, 2019.

The research and development incentive receivable represents an amount due in connection with the above program. The Company has recorded a research and development incentive receivable of $929 and $836 as of September 30, 2019 and December 31, 2018, respectively, in the condensed consolidated balance sheets and other income from Australian research and development incentives of $299 for the three months ended September 30, 2018. During the three months ended September 30, 2019, the Australian research and development incentives recognized were offset by an adjustment to the prior year estimated Australian research and development incentives, resulting in a net expense for the period. During the nine months ended September 30, 2019 and 2018, the Company recorded $129 and $1,188, respectively, of other income from Australian research and development incentives.

The following table shows the change in the research and development incentive receivable from December 31, 2017 to September 30, 2019 (in thousands):

Balance at December 31, 2017	$	1,744
Australian research and development incentive income		756
Cash received for 2016 eligible overseas research and development expenses		(740)
Cash received for 2017 eligible expenses		(793)
Foreign currency translation		(131)
Balance at December 31, 2018		836
Australian research and development incentive income		182
Adjustment to prior year estimated incentives		(53)
Foreign currency translation		(36)
Balance at September 30, 2019	$	929

Foreign Currency Translation

The financial statements of the Company's Australian subsidiary are measured using the local currency as the functional currency. Assets and liabilities of this subsidiary are translated into U.S. dollars at an exchange rate as of the consolidated balance sheet date. Equity is translated at historical exchange rates. Revenues and expenses are translated into U.S. dollars at average rates of exchange in effect during the year. The resulting cumulative translation adjustments have been recorded as a separate component of stockholders' equity. Realized foreign currency transaction gains and losses are included in the results of operations.

Other Assets

Other assets as of September 30, 2019 and December 31, 2018 included $1,074 and $1,380, respectively, of deposits made by the Company with certain service providers that are to be applied to future payments due under the service agreements or returned to the Company if not utilized. In addition, as of September 30, 2019 and December 31, 2018 other assets included $387 and $162 of deferred issuance costs, respectively.

Warrants

On January 1, 2019, the Company adopted ASU No. 2017-11, *Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480), and Derivatives and Hedging (Topic 815)* ("ASU 2017-11"), which changes the classification analysis of certain equity-linked financial instruments (or embedded features) with down round features. The amendments require entities that present earnings per share ("EPS") in accordance with Topic 260 to recognize the effect of the down round feature when triggered with the effect treated as a dividend and as a reduction of income available to common shareholders in basic EPS.

The Company concluded that the common stock warrants (the "2017 Warrants") issued in connection with the private placement of common stock completed in November 2017 (the "Private Placement"), qualify for equity classification. The adoption guidance of ASU 2017-11 provides for a modified retrospective adoption. The Company applied the guidance retrospectively to the 2017 Warrants by means of a cumulative-effect adjustment to its statement of financial position as of the beginning of the interim and annual period beginning January 1, 2019. The Company performed a final remeasurement of the warrant liability as of January 1, 2019 and reclassified $3,448 to equity.

The Company will recognize on a prospective basis the value of the effect of the down round feature in the 2017 Warrants when it is triggered (i.e., when the exercise price is adjusted downward). This value is measured as the difference between (1) the financial instrument's fair value (without the down round feature) using the pre-trigger exercise price and (2) the financial instrument's fair value (with the down round feature) using the reduced exercise price. The value of the effect of the down round feature will be treated as a dividend and a reduction to income available to common shareholders in the basic EPS calculation. In connection with the public offering, completed in February 2019 (the "2019 Public Offering"), when the 2017 Warrants were repriced from $6.085 to $1.75 as a result of a down round, the Company recorded a dividend of $359 during the nine months ended September 30, 2019.

Fair Value of Financial Instruments

Certain assets and liabilities are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

During the periods presented, the Company has not changed the manner in which it values assets and liabilities that are measured at fair value using Level 3 inputs. There were no transfers within the hierarchy during the three and nine months ended September 30, 2019 and the year ended December 31, 2018.

A summary of the assets and liabilities carried at fair value in accordance with the hierarchy defined above is as follows (in thousands):

	Total	Level 1	Level 2	Level 3
September 30, 2019				
Assets:				
Cash & cash equivalents	$ 10,058	$ 10,058	$ —	$ —
Total assets	$ 10,058	$ 10,058	$ —	$ —
December 31, 2018				
Assets:				
Cash & cash equivalents	$ 16,284	$ 16,284	$ —	$ —
Total assets	$ 16,284	$ 16,284	$ —	$ —
Liabilities:				
Warrant liability	$ 3,448	$ —	$ —	$ 3,448
Total liabilities	$ 3,448	$ —	$ —	$ 3,448

Cash equivalents of $10,058 and $16,284 as of September 30, 2019 and December 31, 2018, respectively, consisted of overnight investments and money market funds and are classified within Level 1 of the fair value hierarchy because they are valued using quoted market prices in active markets.

The carrying value of the research and development incentive receivable, accounts payable and accrued liabilities approximate their fair value due to the short-term nature of these assets and liabilities.

A roll-forward of the recurring fair value measurements of the warrant liability categorized with Level 3 inputs is as follows (in thousands):

	Warrant Liability
Balance—December 31, 2017	$ 11,862
Change in fair value	4,851
Balance—March 31, 2018	16,713
Exercise of warrants	(1,130)
Change in Fair value	662
Balance—June 30, 2018	16,245
Change in Fair value	(1,793)
Balance—September 30, 2018	14,452
Change in Fair value	(11,004)
Balance—December 31, 2018	3,448
Final remeasurement and reclassification of 2017 Warrants to equity in connection with the adoption of ASU 2017-11	(3,448)
Balance—January 1, 2019	$ —

The warrant liability in the table above is composed of the fair value of the 2017 Warrants that the Company issued in connection with the Private Placement. The fair value of the warrant liability was determined based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. The Company utilized a Monte Carlo simulation, which is a statistical method used to generate a defined number of share price paths to developa reasonable estimate of the range of the future expected share prices, to value the warrant liability. The Monte Carlo simulation incorporated assumptions and estimates to value the warrant liability. Estimates and assumptions impacting the fair value measurement included the estimated probability of adjusting the exercise price of the warrants, the number of shares for which the warrants will be exercisable, the remaining contractual term of the warrants, the risk-free interest rate, the expected dividend yield, and the expected volatility of the price of the underlying common shares.

The Company historically had been a private company and lacks company-specific historical and implied volatility information of its shares. Therefore, it estimated its expected share volatility based on the historical volatility of publicly traded peer companies for a term equal to the remaining contractual term of the warrants. The risk-free interest rate was determined by reference to the U.S. Treasury yield curve for time periods approximately equal to the remaining contractual term of the warrants. The Company estimated a 0% expected dividend yield based on the fact that the Company has never paid or declared dividends and does not intend to do so in the foreseeable future.

Leases

In February 2016, the FASB issued ASU 2016-02,*Leases,* or ASU 2016-02, to enhance the transparency and comparability of financial reporting related to leasing arrangements. The Company adopted ASU 2016-02 on January 1, 2019, or the effective date, and used the effective date as its date of initial application.

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present. Most leases with a term greater than one year are recognized on the balance sheet as right-of-use assets, lease liabilities and, if applicable, long-term lease liabilities. The Company has elected not to recognize on the balance sheet leases with terms of one year or less. Operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the expected remaining lease term. The Company has determined that the rate implicit in the lease is not determinable and the Company does not have borrowings with similar terms and collateral. Therefore, the Company considered a variety of factors, including observable debt yields from comparable companies and the volatility in the debt market for securities with similar terms, in determining that 8% was reasonable to use as the incremental borrowing rate for purposes of the calculation of lease liabilities.

In accordance with the guidance in ASU 2016-02, components of a lease should be split into three categories: lease components (e.g. land, building, etc.), non-lease components (e.g. common area maintenance, maintenance, consumables, etc.), and non-components (e.g. property taxes, insurance, etc.). Then the fixed and in-substance fixed contract consideration (including any related to non-components) must be allocated based on fair values to the lease components and non-lease components.

Although separation of lease and non-lease components is required, certain practical expedients are available. Entities may elect the practical expedient to not separate lease and non-lease components. Rather, they would account for each lease component and the related non-lease component together as a single component. The Company has elected to account for the lease and non-lease components of each of its operating leases as a single lease component and allocate all of the contract consideration to the lease component only. The lease component results in an operating right-of-use asset being recorded on the consolidated balance sheets and amortized such that lease expense is recorded on a straight line basis over the term of the lease.

Net Loss per Share

Basic net loss per share is computed using the weighted average number of common shares outstanding during the period. Diluted net loss per share is computed using the weighted average number of common shares outstanding during the period and, if dilutive, the weighted average number of potential shares of common stock, including the assumed exercise of stock options and warrants.

Warrant Liability

In connection with entering into the Private Placement, the Company issued the 2017 Warrants with each share of common stock sold in the Private Placement. The Company classified the 2017 Warrants as a liability on its consolidated balance sheet prior to January 1, 2019, because each warrant represented a freestanding financial instrument that is not indexed to the Company's own shares. The warrant liability was initially recorded at fair value upon entering into the Private Placement agreement and was subsequently remeasured to fair value at each reporting date. Changes in the fair value of the warrant liability were recognized as gains (losses) in the condensed consolidated statement of operations through the year ended December 31, 2018.

Subsequent Events

The Company considers events or transactions that occur after the balance sheet date but prior to the issuance of the financial statements to provide additional evidence for certain estimates or to identify matters that require additional disclosure. Subsequent events have been evaluated as required.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board, or FASB, and are early adopted by the Company or adopted as of the specified effective date.

In June 2018, the FASB issued ASU No. 2018-07, Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting, which is intended to simplify the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payments to employees, with certain exceptions. The Company adopted this standard effective January 1, 2019, which had no impact on the Company's condensed consolidated financial statements.

3. Accrued Expenses

Accrued expenses consist of the following:

	September 30, 2019	December 31, 2018
Clinical trials	$ 1,621	$ 1,745
Professional fees	218	219
Payroll and related expenses	478	908
Accrued expenses	$ 2,317	$ 2,872

4. Leases

In February 2016, the FASB issued ASU 2016-02, Leases, or ASU 2016-02. ASU 2016-02 requires a lessee to recognize on its balance sheet (for both finance and operating leases) a liability to make lease payments and a right-of-use asset representing its right to use the underlying asset for the lease term. The Company adopted ASU 2016-02 on January 1, 2019, on the effective date, and used the effective date as its date of initial application. As such, the Company did not adjust prior period amounts. The Company also elected to adopt the practical expedients upon transition, which permit companies to not reassess lease identification, classification, and initial direct costs under ASU 2016-02 for leases that commenced prior to the effective date.

The Company has operating leases for real estate in the United States and does not have any finance leases. The Company's leases may contain options to renew and extend lease terms and options to terminate leases early. Reflected in the right-of-use asset and lease liability on the Company's consolidated balance sheets are the periods provided by renewal and extension options that the Company is reasonably certain to exercise, as well as the periods provided by termination options that the Company is reasonably certain to not exercise.

The Company has existing leases that include variable lease and non-lease components that are not included in the right-of-use asset and lease liability and are reflected as an expense in the period incurred. Such payments primarily include common area maintenance charges and increases in rent payments that are driven by factors such as future changes in an index (e.g., the Consumer Price Index).

In calculating the present value of future lease payments, the Company utilized its incremental borrowing rate based on the remaining lease term at the date of adoption. The Company has elected to account for each lease component and its associated non-lease components as a single lease component and has allocated all of the contract consideration across lease components only. This will potentially result in the initial and subsequent measurement of the balances of the right-of-use asset and lease liability for leases being greater than if the policy election was not applied. The Company has existing net leases in which the non-lease components (e.g. common area maintenance, maintenance, consumables, etc.) are paid separately from rent based on actual costs incurred and therefore are not included in the right-of-use asset and lease liability and are reflected as an expense in the period incurred. On January 1, 2019, the Company recorded a right-of-use asset of $1,755 and a lease liability of $1,720 on its consolidated balance sheets and reclassified a rent liability against the right-of-use asset of $35. As of September 30, 2019, a right-of-use asset of $1,214 and lease liability of $1,214 are reflected on the consolidated balance sheets. The Company recorded rent expense of $211 and $175, respectively, during the three months ended September 30, 2019 and 2018 and $629 and $467, respectively, for the nine months ended September 30, 2019 and 2018.

Future lease payments under non-cancelable operating leases as of September 30, 2019 are detailed as follows:

Future Operating Lease Payments	
2019	$ 210
2020	532
2021	434
2022	146
Total Lease Payments	**1,322**
Less: imputed interest	(108)
Total operating lease liabilities	**$ 1,214**

5. Warrants

As of September 30, 2019, outstanding warrants to purchase common stock consisted of the following:

	September 30, 2019			
	Number of Shares Issuable	Exercise Price	Exercisable for	Classification
Penny Warrants	54,516	$ 0.01	Common Stock	Equity
2017 Warrants	2,758,094	$ 1.75	Common Stock	Equity
2019 Warrants	7,557,142	$ 1.95	Common Stock	Equity
	10,369,752			

2017 Warrants

The 2017 Warrants contain full ratchet anti-dilution protection provisions. Prior to January 1, 2019, the Company classified the 2017 Warrants as a liability on its consolidated balance sheet because each warrant represented a freestanding financial instrument that, due to the potential variable nature of the exercise price, is not considered to be indexed to the Company's own shares. The warrant liability was initially recorded at fair value upon entering into the Private Placement and has been subsequently remeasured to fair value at each reporting date. Changes in the fair value of the warrant liability were recognized as gains (losses) in the Company's consolidated statement of operations.

On January 1, 2019, the Company adopted ASU 2017-11 and concluded that the 2017 Warrants now qualify for equity classification. The Company applied the guidance retrospectively to the 2017 Warrants by means of a cumulative-effect adjustment to its statement of financial position as of the beginning of the interim and annual period beginning January 1, 2019. The Company performed a final remeasurement of the warrant liability as of January 1, 2019 and reclassified $3,448 to additional paid in capital.

The Company will recognize on a prospective basis the value of the effect of the down round feature in the warrant when it is triggered (i.e., when the exercise price is adjusted downward). This value is measured as the difference between (1) the financial instrument's fair value (without the down round feature) using the pre-trigger exercise price and (2) the financial instrument's fair value (with the down round feature) using the reduced exercise price. The value of the effect of the down round feature will be treated as a dividend and a reduction to income available to common shareholders in the basic EPS calculation. In connection with the 2019 Public Offering, when the 2017 Warrants were repriced from $6.085 to $1.75, the Company recorded a dividend of $359 during the nine months ended September 30, 2019.

2019 Warrants

On February 5, 2019, in connection with the 2019 Public Offering, the Company issued immediately exercisable warrants (the "2019 Warrants") to purchase 7,557,142 shares of common stock to investors. The 2019 Warrants have an exercise price of $1.95 per share and expire on February 5, 2026. The 2019 Warrants qualify for equity classification.

6. Common Stock

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are entitled to receive dividends, as may be declared by the board of directors, if any, subject to the preferential dividend rights of the preferred stockholders. Through September 30, 2019, no dividends have been declared.

Public Offering of Common Stock — March 2018

On March 27, 2018, the Company completed a public offering whereby the Company issued 2,146,667 shares of its common stock at a price of $7.50 per share, which included 280,000 shares issued pursuant to the underwriters' exercise of their option to purchase additional shares of common stock. The aggregate net proceeds received by the Company from the offering were approximately $14,796, net of underwriting discounts and commissions and estimated offering expenses payable by the Company.

Public Offering of Common Stock — February 2019

On February 5, 2019, the Company completed the 2019 Public Offering whereby the Company issued 7,557,142 shares of its common stock at a price of $1.75 per share, which included 985,714 shares issued pursuant to the underwriters' exercise of their option to purchase additional shares of common stock, each share issued with a warrant to purchase one share of common stock. Each warrant has an exercise price of $1.95 per share with an exercise period expiring seven years from the date of issuance. The aggregate net proceeds received by the Company from the 2019 Public Offering were approximately $12,122, net of underwriting discounts and commissions and estimated offering expenses payable by the Company.

Issuance of Common Stock under Distribution Agreement — April through September 2019

On September 7, 2018, the Company filed a Prospectus Supplement to register the offer and sale of shares of common stock having an aggregate offering price of up to $30,000 pursuant to the terms of a distribution agreement, or the Distribution Agreement, with Raymond James & Associates, Inc. During the nine months ended September 30, 2019, the Company issued 1,033,147 shares under the Distribution Agreement, for net proceeds of $1,923.

Lincoln Park Purchase Agreements

On July 10, 2019, the Company entered into a Commitment Purchase Agreement and a Registration Rights Agreement with Lincoln Park, pursuant to which the Company has the right to sell to Lincoln Park up to $20,000 in shares of its Common Stock, $0.001 par value per share, subject to certain limitations and conditions set forth in the Commitment Purchase Agreement. As consideration for Lincoln Park's commitment to purchase shares of Common Stock pursuant to the Commitment Purchase Agreement, the Company issued to Lincoln Park 330,000 shares of Common Stock. The Company did not receive any cash proceeds from the issuance of such shares.

On July 11, 2019, the Company entered into a Registered Offering Purchase Agreement and together with the Commitment Purchase Agreement, under which the Company agreed to sell to Lincoln Park, and Lincoln Park agreed to purchase 571,429 shares of its Common Stock, at a price of $1.75 per share for an aggregate purchase price of $1,000, pursuant to the Company's effective shelf registration statement on Form S-3 (Registration No. 333-223419), including the prospectus supplement thereto dated July 11, 2019.

7. Equity Incentive Plans

Equity Incentive Plans

In September 2012, the Company adopted the 2012 Equity Incentive Plan, as amended (the "Plan"), which provides designated employees of the Company and its affiliates, certain consultants and advisors who perform services for the Company and its affiliates, and nonemployee members of the Board of Directors of the Company and its affiliates with the opportunity to receive grants of incentive stock options, nonqualified stock options and stock awards. As of September 30, 2019, there were 1,361,952 outstanding options issued under the 2012 Plan.

On January 20, 2017, the Company's stockholders approved the 2016 Equity Incentive Plan (the "2016 Plan"). Beginning on January 1, 2018, the number of shares of common stock authorized for issuance pursuant to the 2016 Plan was increased each January 1 by an amount equal to four percent (4%) of the Company's outstanding common stock as of the end of the immediately preceding calendar year or such other amount as determined by the compensation committee of the Company's Board of Directors. During the nine months ended September 30, 2019, the compensation committee of the board of directors authorized an additional 3,000,000 shares of Common Stock to be added to the shares authorized for issuance under the 2016 Plan. As of September 30, 2019, there were 2,441,910 outstanding options issued under the 2016 Plan.

As of September 30, 2019, there were 2,464,373 shares available for grant under the Company's Equity Incentive Plans.

A summary of stock option activity under the Equity Plans is as follows:

	Options	Weighted Average Exercise Price Per Share	Weighted Average Remaining Life in Years	Aggregate Intrinsic Value
Outstanding at December 31, 2018	2,761,912	$ 11.30	8.01	$ —
Granted	1,476,975	$ 1.48		
Forfeited	(219,321)	$ 15.14		
Outstanding at September 30, 2019	4,019,566	$ 7.48	8.22	$ —
Options exercisable at September 30, 2019	2,119,678	$ 11.17	7.35	$ —
Options vested and expected to vest at September 30, 2019	4,019,566	$ 7.48	8.22	$ —

The grant date fair value of the options granted during the year ended December 31, 2018 and the nine months ended September 30, 2019, was estimated at the date of grant using the Black-Scholes option valuation model. The expected life was estimated using the "simplified" method as defined by the Securities and Exchange Commission's Staff Accounting Bulletin 107, Share-Based Payment. The expected volatility was based on the historical volatility of comparable public companies from a representative peer group selected based on industry and market capitalization data. The risk-free interest rate was based on the continuous rates provided by the U.S. Treasury with a term approximating the expected life of the option. The expected dividend yield was 0% because the Company does not expect to pay any dividends for the foreseeable future. The Company elected the straight-line attribution method in recognizing the grant date fair value of options issued over the requisite service periods of the awards, which are generally the vesting periods.

The assumptions that the Company used to determine the grant-date fair value of stock options granted to employees and directors during the year ended December 31, 2018 and the nine months ended September 30, 2019 were as follows, presented on a weighted average basis:

	Nine Months Ended September 30, 2019	Year Ended December 31, 2018
Expected volatility	66.94%	66.94%
Weighted average risk-free interest rate	2.07%	2.80%
Expected dividend yield	0.00%	0.00%
Expected term (in years)	6.79	6.95

Stock options generally vest over a three or four year period, as determined by the Compensation Committee of the Board of Directors at the time of grant. The options expire ten years from the grant date. As of September 30, 2019, there was approximately $4,004 of unrecognized compensation cost related to non-vested stock options, which is expected to be recognized over a remaining weighted-average period of approximately 2.11 years.

The Company recognized stock-based compensation expense related to the issuance of stock option awards to employees and non-employees in the condensed consolidated statements of operations and comprehensive loss as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Research and development	$ 181	$ 180	$ 536	$ 460
General and administrative	769	752	2,260	2,084
Total	$ 950	$ 932	$ 2,796	$ 2,544

Restricted Stock Units

During the three months ended September 30, 2019, the Company issued 181,000 restricted stock units (“RSUs”) to employees under the 2016 Plan. Upon vesting of the RSUs, the Company has the option to settle the award by either issuing shares of the Company’s common stock or an amount of cash equal to the fair value of the Company’s common stock on the vesting date. As of September 30, 2019, the Company recorded a restricted stock liability on its condensed consolidated balance sheets of $0.2 million.

The following table presents a summary of outstanding RSU’s under the 2016 Plan as of September 30, 2019:

	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2018	—	$ —
Awarded	181,000	$ 1.74
Outstanding at September 30, 2019	181,000	$ 1.74

As of September 30, 2019, there were 181,000 shares outstanding covered by RSUs that are expected to vest. The weighted average grant date fair value of these shares of restricted stock was $1.74 per share and the aggregate grant date fair value of these shares of restricted stock was approximately $0.3 million. As of September 30, 2019, there were approximately $0.1 million of unrecognized compensation costs, net of estimated forfeitures, related to RSU’s granted to employees, which are expected to be recognized as expense over a remaining weighted average period of 0.25 years.

8. Net Loss Per Share

Basic and diluted net loss per share for the three and nine months ended September 30, 2019 and 2018 was calculated as follows (in thousands except share and per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Numerator:				
Net loss	$ (7,935)	$ (6,632)	$ (24,904)	$ (24,618)
Dividend attributable to down round feature of warrants	—	—	(359)	—
Net loss attributable to common stockholders for basic loss per share	$ (7,935)	$ (6,632)	$ (25,263)	$ (24,618)
Less change in fair value of warrant liability		1,793		
Net loss attributable to common stockholders for diluted loss per share	$ (7,935)	$ (8,425)	$ (25,263)	$ (24,618)
Denominator:				
Weighted average number of common shares outstanding - basic	23,923,196	14,701,785	22,039,386	13,955,949
Assumed conversion of dilutive securities:				
Private Placement Warrants	—	509,931	—	—
Denominator for diluted loss per share - adjusted weighted average shares	23,923,196	15,211,716	22,039,386	13,955,949
Net loss per share attributable to common stockholders - basic	$ (0.33)	$ (0.45)	$ (1.15)	$ (1.76)
Net loss per share attributable to common stockholders - diluted	$ (0.33)	$ (0.55)	$ (1.15)	$ (1.76)

The Company's potentially dilutive securities include stock options and warrants. These securities were excluded from the computations of diluted net loss per share for the three and nine months ended September 30, 2019 and 2018, as the effect would be to reduce the net loss per share. The following table includes the potential shares of common stock, presented based on amounts outstanding at each period end, that were excluded from the computation of diluted net loss per share attributable to common stockholders for the periods indicated because including them would have had an anti-dilutive effect:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Options to purchase common stock	4,019,566	2,631,446	4,019,566	2,631,446
Warrants to purchase common stock	10,369,752	54,516	10,369,752	2,812,610
	14,389,318	2,685,962	14,389,318	5,444,056

9. Commitments and Contingencies

Manufacturing Agreements—The Company is party to manufacturing agreements with vendors to manufacture TRX518 and DKN-01, its lead product candidates, for use in clinical trials. As of September 30, 2019, noncancelable commitments under these agreements totaled $532.

License and Service Agreement—On January 3, 2011, the Company entered into a license agreement with Eli Lilly and Company ("Lilly") to grant a license to the Company for certain intellectual property rights relating to pharmaceutically active compounds that may be useful in the treatment of bone healing, cancer and, potentially, other medical conditions. The Company previously issued 9,000,000 shares of Series A Stock to Lilly in consideration for the grant of the license. As defined in the license agreement, the Company would be required to pay royalties to Lilly based upon a percentage in the low single digits of net sales of developed products, if and when achieved. However, there can be no assurance that clinical or commercialization success of developed products will occur, and no royalties have been paid or accrued through September 30, 2019.

License Agreement—On May 28, 2015, the Company entered into a license agreement with Lonza Sales AG ("Lonza"), pursuant to which Lonza granted the Company a world-wide, non-exclusive license for certain intellectual property relating to a gene expression system for manufacturing DKN-01. As defined in the license agreement, the Company would be required to pay royalties to Lonza based on a percentage in the low single digits of net sales of DKN-01, if and when achieved. However, there can be no assurance that clinical or commercialization success will occur, and no royalties have been paid or accrued through September 30, 2019.

Legal Proceedings—At each reporting date, the Company evaluates whether or not a potential loss amount or a potential range of loss is probable and reasonably estimable under the provisions of the authoritative guidance that addresses accounting for contingencies. The Company expenses as incurred the costs related to its legal proceedings.

A patent covering the TRX518 antibody and its uses in methods of inducing or enhancing an immune response in a subject was granted in 2013 to the Company by the European Patent Office (EPO). Three notices of opposition to this patent were filed: two by major pharmaceutical companies and a third by an individual, possibly on behalf of a major pharmaceutical company. At the conclusion of the opposition proceedings before the Opposition Division of the EPO, the Opposition Division issued a decision indicating that the Company's patent was maintained with modified claims that differ from the claims as originally granted. These narrowed claims cover the TRX518 antibody and uses of the TRX518 antibody in methods of inducing or enhancing an immune response in a subject. The Company has filed an appeal of the decision of the Opposition Division seeking to obtain broader claims that more closely reflect the claims as granted in the patent. The EPO Board of Appeal has not yet scheduled a date for the appeal hearing.

In 2016, a patent covering the use of the TRX518 antibody in combination with a chemotherapeutic agent for treating cancer was granted to the Company by the EPO. In March 2017, notices of opposition to this patent were filed at the EPO by ten different entities, including several major pharmaceutical companies. Oral proceedings at the EPO took place on December 4 and 5, 2018. At the conclusion of the oral proceedings, the Opposition Division decided that the patent should be revoked in its entirety on the ground that the claims as granted contained added matter. Subsequently, the Opposition Division issued an interlocutory decision restating its conclusion that the claims as granted contained added matter and revoking the patent. The Company has filed an appeal of the decision of the Opposition Division seeking to obtain a reversal of the Opposition Division's decision on added matter. The EPO Board of Appeal has not yet scheduled a date for the appeal hearing.

Indemnification Agreements—In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company is not aware of any claims under indemnification arrangements, and it has not accrued any liabilities related to such obligations in its condensed consolidated financial statements as of September 30, 2019 or December 31, 2018.

10. Related Party Transactions

The Company has a license agreement with a stockholder (See Note 9).

On February 5, 2019, the Company completed the 2019 Public Offering pursuant to which the Company issued 7,557,142 shares of its common stock at a price of $1.75 per share, which included 985,714 shares issued pursuant to the underwriters' exercise of their option to purchase additional shares of common stock, each share issued with a warrant to purchase one share of common stock. Each warrant has an exercise price of $1.95 per share with an exercise period expiring seven years from the date of issuance. The aggregate net proceeds received by the Company from the offering were approximately $12,122, net of underwriting discounts and commissions and estimated offering expenses payable by the Company. HealthCare Ventures IX, L.P. purchased common stock and warrants in the 2019 Public Offering on the same terms and conditions as the other Purchasers. Three of the Company's directors and executive officers are affiliated with HealthCare Ventures IX, L.P. and its affiliates.

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

The following Management's Discussion and Analysis of Financial Condition and Results of Operations ("MD&A") is intended to help the reader understand our results of operations and financial condition. This MD&A is provided as a supplement to, and should be read in conjunction with, our condensed consolidated financial statements and the accompanying notes thereto and other disclosures included in this Quarterly Report on Form 10-Q, including the disclosures under Part II, Item IA "Risk Factors", and our audited condensed consolidated financial statements and the accompanying notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2018, which was filed with the Securities and Exchange Commission, or the SEC, on April 1, 2019. Our condensed consolidated financial statements have been prepared in accordance with U.S. GAAP and, unless otherwise indicated, amounts are presented in U.S. dollars.

Company Overview

We are a biopharmaceutical company developing novel therapies designed to treat patients with cancer by inhibiting fundamental tumor-promoting pathways and by harnessing the immune system to attack cancer cells. Our strategy is to identify, acquire, and develop molecules that will rapidly translate into high impact therapeutics that generate durable clinical benefit and enhanced patient outcomes. Our two clinical stage programs are:

- *DKN-01:* A monoclonal antibody that inhibits Dickkopf-related protein 1, or DKK1. DKK1 is a protein that regulates the Wnt signaling pathways and enables tumor cells to proliferate and spread, as well as suppresses the immune system from attacking the tumor. When DKN-01 binds to DKK1, an anti-tumor effect can be generated. DKN-01-based therapies have generated responses and clinical benefit in several patient populations. We are currently studying DKN-01 in multiple ongoing clinical trials in patients with esophagogastric cancer, hepatobiliary cancer, gynecologic cancers, or prostate cancer

- *TRX518:* A monoclonal antibody targeting the glucocorticoid-induced tumor necrosis factor-related receptor, or GITR. GITR is a receptor found on the surface of a wide range of immune cells. GITR stimulation activates tumor fighting white blood cells and decrease the activity of potentially tumor-protective immunosuppressive cells. TRX518 has been specifically engineered to enhance the immune system's anti-tumor response by activating GITR signaling without causing the immune cells to be destroyed.

Recent Developments

During the quarter, we have continued to make progress with the development of our product candidates:

- ***DKN-01 plus KEYTRUDA in ESOPHAGOGASTRIC CANCER***: We presented data from the KEYNOTE-731 clinical study evaluating DKN-01 in combination with KEYTRUDA® (pembrolizumab) in patients with advanced esophagogastric cancer. In gastroesophageal junction and gastric cancer patients who had not received prior PD-1/PD-L1 therapy, the combination of DKN-01 plus KEYTRUDA demonstrated improved outcomes in patients whose tumors express high levels of DKK1, or DKK1-high. DKK1-high patients experienced 22.1 weeks median progression free survival, or PFS, and 31.6 weeks median overall survival, or OS, with a 50% overall response rate, or ORR, and 80% disease control rate, or DCR, in ten evaluable patients. DKK1-low patients experienced 5.9 weeks PFS and 17.4 weeks OS, with a 20% DCR in fifteen evaluable patients. PD-L1 Combined Positive Scores, or CPS, did not predict efficacy to the combination of DKN-01 plus KEYTRUDA. In multi-variate analysis, DKK1-high status correlated with longer PFS independent of PD-L1 CPS.

- ***DKN-01 in GYNECOLOGICAL CANCERS***: At the International Gynecologic Cancer Society meeting, we presented data from the clinical study of DKN-01 as a monotherapy and in combination with paclitaxel in patients with advanced gynecological cancers. In the cohort of 16 evaluable monotherapy patients with epithelial endometrial cancer (EEC) with identified Wnt signaling mutations, one patient had a complete response and one patient had a partial response, representing a 12.5% single agent ORR, seven patients had a best response of stable disease, and seven patients had progressive disease. In the six evaluable monotherapy EEC patients who did not have any identified Wnt signaling mutations, none had clinical benefit. Across the study, patients with Wnt signaling mutations have had higher response rates and demonstrated a longer PFS as compared to patients without Wnt signaling mutations. Patient follow-up is continuing in this study, which has been expanded to include focused cohorts of patients with carcinosarcoma.

- ***DKN-01 plus OPDIVO in BILIARY TRACT CANCER***: The first patients have been dosed in an investigator-initiated clinical study to evaluate DKN-01 in combination with Bristol-Myers Squibb's OPDIVO® (nivolumab) in previously-treated patients with advanced biliary tract cancer. The study is being conducted by Massachusetts General Hospital, and will enroll up to 36 biliary tract cancer patients who have progressed after one or more lines of systemic therapy for advanced biliary tract cancer. The primary endpoint of the study will be ORR, which will be assessed in the overall population as well as in subgroups stratified by tumor DKK1 and PD-L1 expression. Bristol-Myers Squibb is providing OPDIVO drug supply and partial funding for the study. We are providing DKN-01 drug supply and partial funding for the study.

- ***TRX518 PROGRAM***: Enrollment in the dose escalation phase is complete in our clinical trial evaluating TRX518 in combination with cyclophosphamide chemotherapy and BAVENCIO® (avelumab). However, instead of pursuing additional enrollment through the expansion cohorts in this study as initially planned, we have decided to reprioritize resources on the further development of the DKN-01 program. There were no safety or efficacy concerns leading to the decision, and patients who are receiving benefit from the combination will continue to be treated in the study.

Financial Overview

Research and Development Expenses

Our research and development activities have included conducting nonclinical studies and clinical trials, manufacturing development efforts and activities related to regulatory filings for DKN-01 and TRX518. We recognize research and development expenses as they are incurred. Our research and development expenses consist primarily of:

- salaries and related overhead expenses for personnel in research and development functions, including costs related to stock-based compensation;
- fees paid to consultants and CROs for our nonclinical and clinical trials, and other related clinical trial fees, including but not limited to laboratory work, clinical trial database management, clinical trial material management and statistical compilation and analysis;
- costs related to acquiring and manufacturing clinical trial material; and
- costs related to compliance with regulatory requirements.

We plan to increase our research and development expenses for the foreseeable future as we continue the development of DKN-01 and any other product candidates, subject to the availability of additional funding.

Our direct research and development expenses are tracked on a program-by-program basis and consist primarily of internal and external costs, such as employee costs, including salaries and stock-based compensation, other internal costs, fees paid to consultants, central laboratories, contractors and CROs in connection with our clinical and preclinical trial development activities. We use internal resources to manage our clinical and preclinical trial development activities and perform data analysis for such activities.

We participate, through our subsidiary in Australia, in the Australian government's research and development ("R&D") Incentive program, such that a percentage of our eligible research and development expenses are reimbursed by the Australian government as a refundable tax offset and such incentives are reflected as other income.

The table below summarizes our research and development expenses incurred by development program and the R&D Incentive income for the three and nine months ended September 30, 2019 and 2018:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
	(in thousands)		(in thousands)	
Direct research and development by program:				
DKN-01 program	$ 3,806	$ 3,929	$ 12,428	$ 10,774
TRX518 program	1,966	2,528	6,270	4,148
Total research and development expenses	$ 5,772	$ 6,457	$ 18,698	$ 14,922
Australian research and development incentives	$ (7)	$ 299	$ 129	$ 1,188

The successful development of our clinical product candidates is highly uncertain. At this time, we cannot reasonably estimate the nature, timing or costs of the efforts that will be necessary to complete the remainder of the development of any of our product candidates or the period, if any, in which material net cash inflows from these product candidates may commence. This is due to the numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

- the scope, rate of progress and expense of our ongoing, as well as any additional, clinical trials and other research and development activities;
- future clinical trial results; and

- the timing and receipt of any regulatory approvals.

A change in the outcome of any of these variables with respect to the development of a product candidate could result in a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those that we currently anticipate will be required for the completion of clinical development of a product candidate, or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs, including stock-based compensation, for personnel in executive, finance and administrative functions. General and administrative expenses also include direct and allocated facility-related costs as well as professional fees for legal, patent, consulting, accounting and audit services.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research activities and development of our product candidates. We also anticipate that we will incur increased accounting, audit, legal, regulatory, compliance, director and officer insurance costs as well as investor and public relations expenses associated with being a public company.

Interest income

Interest income consists primarily of interest income earned on cash and cash equivalents.

Research and development incentive income

Research and development incentive income includes payments under the R&D Incentive program from the government of Australia. The R&D Incentive is one of the key elements of the Australian Government's support for Australia's innovation system. It was developed to assist businesses to recover some of the costs of undertaking research and development. The research and development tax incentive provides a tax offset to eligible companies that engage in research and development activities.

Companies engaged in research and development may be eligible for either:

- a 43.5% refundable tax offset for entities with an aggregated turnover of less than A$20 million per annum, or

- a 38.5% non-refundable tax offset for all other entities.

We recognize as income the amount we expect to be reimbursed for qualified expenses.

Foreign currency translation adjustment

Foreign currency translation adjustment consists of gains (losses) due to the revaluation of foreign currency transactions attributable to changes in foreign currency exchange rates associated with our Australian subsidiary.

Critical Accounting Policies and Estimates

Our condensed consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States, or GAAP. The preparation of our financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue, costs and expenses, and the disclosure of contingent assets and liabilities in our financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are 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. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

On January 1, 2019, we adopted ASU No. 2017-11, *Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480), and Derivatives and Hedging (Topic 815)* ("ASU 2017-11"), which changes the classification analysis of certain equity-linked financial instruments (or embedded features) with down round features, and Topic 842, Leases, ("ASU 2016-02), which requires lessees to recognize leases on the balance sheet and disclose key information about leasing arrangements.

Our critical accounting policies are described under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations — Critical Accounting Policies and Significant Judgments and Estimates" in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on April 1, 2019 and the notes to the condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q. We believe that of our critical accounting policies, the following accounting policies involve the most judgment and complexity:

- accrued research and development expenses;
- research and development incentive receivable; and
- stock-based compensation.

Results of Operations

Comparison of the Three Months Ended September 30, 2019 and 2018

The following table summarizes our results of operations for the three months ended September 30, 2019 and 2018:

	Three Months Ended September 30, 2019	Three Months Ended September 30, 2018	Change
	(in thousands)		
Operating expenses:			
Research and development	$ 5,772	$ 6,457	$ (685)
General and administrative	2,151	2,142	9
Total operating expenses	7,923	8,599	(676)
Loss from operations	(7,923)	(8,599)	676
Interest income	80	128	(48)
Interest expense	(5)	(4)	(1)
Australian research and development incentives	(7)	299	(306)
Foreign currency loss	(80)	(249)	169
Gain on change in fair value of warrant liability	—	1,793	(1,793)
Net loss	$ (7,935)	$ (6,632)	$ (1,303)

Research and Development Expenses

	Three Months Ended September 30, 2019	2018	Increase (Decrease)
	(in thousands)		
Direct research and development by program:			
DKN-01 program	$ 3,806	$ 3,929	$ (123)
TRX518 program	1,966	2,528	(562)
Total research and development expenses	$ 5,772	$ 6,457	$ (685)

Research and development expenses were $5.8 million for the three months ended September 30, 2019, compared to $6.5 million for the three months ended September 30, 2018. The decrease of $0.7 million was primarily due to a decrease of $0.4 million in clinical trial costs due to timing of patient enrollment and a decrease of $0.3 million in manufacturing costs related to clinical trial material due to timing of manufacturing campaigns. There was also a $0.3 million decrease in consulting fees associated with research and development activities during the three months ended September 30, 2019 as compared to the same period in 2018. These decreases were partially offset by a $0.2 million increase in payroll and other related expenses due to an increase in headcount in our research and development full time employees and a $0.1 million increase in stock based compensation expense due to new stock options granted to employees in 2019.

General and Administrative Expenses

General and administrative expenses were $2.2 million for the three months ended September 30, 2019, compared to $2.1 million for the three months ended September 30, 2018. The increase of $0.1 million in general and administrative expenses was primarily due to a $0.1 million increase in stock based compensation due to new stock options granted to employees and directors in 2019.

Interest Income

We recorded interest income of $0.1 million and $0.1 million in the three months ended September 30, 2019 and 2018, respectively.

Australian Research and Development Incentives

We recorded R&D incentive income of $0.3 million in the three months ended September 30, 2018, based upon the applicable percentage of eligible research and development activities under the Australian Incentive Program, which expenses included the cost of manufacturing clinical trial material. During the three months ended September 30, 2019, the Australian research and development incentives recognized were offset by an adjustment to the prior year estimated Australian research and development incentives, resulting in a net expense for the period.

The R&D incentive receivable has been recorded as “Research and development incentive receivable” in the condensed consolidated balance sheets.

Foreign Currency Gains (loss)

During the three months ended September 30, 2019 and 2018 we recorded foreign currency losses of 0.1 million and $0.2 million, respectively. Foreign currency gains and losses are due to changes in the Australian dollar exchange rate related to activities of the Australian entity.

Gain on Change in Fair Value of Warrant Liability

We recorded a gain on the change in fair value of the warrant liability during the three months ended September 30, 2018 of $1.8 million. As of January 1, 2019, we adopted ASU No. 2017-11, *Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480), and Derivatives and Hedging (Topic 815)* (“ASU 2017-11”), which changes the classification analysis of certain equity-linked financial instruments (or embedded features) with down round features. The amendments require entities that present earnings per share (“EPS”) in accordance with Topic 260 to recognize the effect of the down round feature when triggered with the effect treated as a dividend and as a reduction of income available to common shareholders in basic EPS.

We concluded that the 2017 Warrants now qualify for equity classification. As the adoption of ASU 2017-11 provides for a modified retrospective adoption, we applied the guidance to the 2017 Warrants by means of a cumulative-effect adjustment as of January 1, 2019.

Comparison of the Nine Months Ended September 30, 2019 and 2018

The following table summarizes our results of operations for the nine months ended September 30, 2019 and 2018:

	Nine Months Ended September 30,		
	2019	2018	Change
	(in thousands)		
Operating expenses:			
Research and development	$ 18,698	$ 14,922	$ 3,776
General and administrative	6,481	6,858	(377)
Total operating expenses	25,179	21,780	3,399
Loss from operations	(25,179)	(21,780)	(3,399)
Interest income	281	327	(46)
Interest expense	(21)	(18)	(3)
Australian research and development incentives	129	1,188	(1,059)
Foreign currency loss	(114)	(615)	501
Loss on change in fair value of warrant liability	—	(3,720)	3,720
Net loss	$ (24,904)	$ (24,618)	$ (286)

Research and Development Expenses

	Nine Months Ended September 30, 2019	2018	Increase (Decrease)
	(in thousands)		
Direct research and development by program:			
DKN-01 program	$ 12,428	$ 10,774	$ 1,654
TRX518 program	6,270	4,148	2,122
Total research and development expenses	$ 18,698	$ 14,922	$ 3,776

Research and development expenses were $18.7 million for the nine months ended September 30, 2019, compared to $14.9 million for the nine months ended September 30, 2018. The increase of $3.8 million was primarily due to an increase of $4.4 million in clinical trial costs due to an increase in patient enrollment, a $0.6 million increase in payroll and other related expenses due to an increase in headcount in our research and development full time employees and an increase of $0.2 million in consulting fees associated with research and development activities. Additionally, stock based compensation expense increased $0.2 million due to new stock options granted to employees during the nine months ended September 30, 2019 and rent expense increased $0.1 million due to a new research laboratory. These increases were partially offset by a decrease of $1.7 million in manufacturing costs related to clinical trial material due to timing of manufacturing campaigns.

General and Administrative Expenses

General and administrative expenses were $6.5 million for the nine months ended September 30, 2019, compared to $6.9 million for the nine months ended September 30, 2018. The decrease of $0.4 million in general and administrative expenses was primarily due to a decrease of $0.6 million in payroll and other related expenses due to a decrease in bonus expense in the nine months ending September 30, 2019 as compared to the same period in 2018. This decrease was partially offset by an increase of $0.2 million of stock based compensation expense due to new stock options granted to employees and directors during the nine months ended September 30, 2019.

Interest Income

We recorded interest income of $0.3 million and $0.3 million in the nine months ended September 30, 2019 and 2018, respectively.

Australian Research and Development Incentives

We recorded R&D incentive income of $0.1 million and $1.2 million in the nine months ended September 30, 2019 and 2018, respectively, based upon the applicable percentage of eligible research and development activities under the Australian Incentive Program, which expenses included the cost of manufacturing clinical trial material. The decrease of $1.1 million was primarily due to a decrease of $1.7 million in manufacturing costs related to clinical trial material due to timing of manufacturing campaigns.

The R&D incentive receivable has been recorded as "Research and development incentive receivable" in the condensed consolidated balance sheets.

Foreign Currency Gains (loss)

During the nine months ended September 30, 2018, we recorded foreign currency losses of ($0.6) million. During the nine months ended September 30, 2019 we recorded ($0.1) million of foreign currency losses. Foreign currency gains and losses are due to changes in the Australian dollar exchange rate related to activities of the Australian entity.

Loss on Change in Fair Value of Warrant Liability

We recorded a loss on the change in fair value of the warrant liability during the nine months ended September 30, 2018 of $3.7 million. As of January 1, 2019, we adopted ASU No. 2017-11, *Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480), and Derivatives and Hedging (Topic 815)* ("ASU 2017-11"), which changes the classification analysis of certain equity-linked financial instruments (or embedded features) with down round features. The amendments require entities that present earnings per share ("EPS") in accordance with Topic 260 to recognize the effect of the down round feature when triggered with the effect treated as a dividend and as a reduction of income available to common shareholders in basic EPS.

We concluded that the 2017 Warrants now qualify for equity classification. As the adoption of ASU 2017-11 provides for a modified retrospective adoption, we applied the guidance to the 2017 Warrants by means of a cumulative-effect adjustment as of January 1, 2019.

Financial Position, Liquidity and Capital Resources

Since our inception, we have been engaged in organizational activities, including raising capital, and research and development activities. We do not yet have a product that has been approved by the Food and Drug Administration (the "FDA"), have not generated any revenues and have not yet achieved profitable operations, nor have we ever generated positive cash flows from operations. There is no assurance that profitable operations, if achieved, could be sustained on a continuing basis. Further, our future operations are dependent on the success of efforts to raise additional capital, our research and commercialization efforts, regulatory approval, and, ultimately, the market acceptance of our products.

In accordance with Accounting Standards Codification ("ASC") 205-40, Going Concern, we have evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern within one year after the date that the condensed consolidated financial statements are issued. As of September 30, 2019, we had cash and cash equivalents of $10.1 million and expect to receive $0.8 million of research and development tax incentive payments in 2019 from the Commonwealth of Australia as a result of the 2018 research and development activities of our Australian subsidiary, HCP Australia. Additionally, we had an accumulated deficit of $187.2 million at September 30, 2019, and during the nine months ended September 30, 2019, we incurred a net loss of $24.9 million. We expect to continue to generate operating losses in the foreseeable future. Due to our need for additional capital and the uncertainties surrounding our ability to raise such funding, substantial doubt exists as to our ability to continue as a going concern for a period through one year after the financial statements have been issued.

On July 10, 2019, we entered into a Commitment Purchase Agreement and a Registration Rights Agreement with Lincoln Park, pursuant to which we have the right to sell to Lincoln Park up to $20.0 million in shares of our Common Stock, $0.001 par value per share, subject to certain limitations and conditions set forth in the Commitment Purchase Agreement. On July 11, 2019, we entered into Purchase Agreements, under which we sold to Lincoln Park 571,429 shares of our Common Stock, at a price of $1.75 per share for an aggregate purchase price of $1.0 million, pursuant to our effective shelf registration statement on Form S-3 (Registration No. 333-223419), filed with the SEC in accordance with the provisions of the Securities Act, on March 2, 2018 and was declared effective by the SEC on March 16, 2018, and the prospectus supplement thereto dated July 11, 2019.

We have suspended enrollment of a TRX518 clinical trial until additional funding is available. In addition, we will seek additional funding through public or private equity financings or government programs and will seek funding or development program cost-sharing through collaboration agreements or licenses with larger pharmaceutical or biotechnology companies. If we do not obtain additional funding or development program cost-sharing, we will be forced to delay, reduce or eliminate certain clinical trials or research and development programs, reduce or eliminate discretionary operating expenses, and delay company and pipeline expansion, which would adversely affect our business prospects. The inability to obtain funding, as and when needed, would have a negative impact on our financial condition and ability to pursue our business strategies.

Cash Flows

The following table summarizes our sources and uses of cash for each of the periods presented:

	Nine Months Ended September 30,	
	2019	**2018**
	(in thousands)	
Cash used in operating activities	$ (21,008)	$ (18,983)
Cash used in investing activities	(100)	—
Cash provided by financing activities	14,836	15,946
Effect of exchange rate changes on cash and cash equivalents	46	549
Net decrease in cash and cash equivalents	$ (6,226)	$ (2,488)

Operating activities. Net cash used in operating activities for the nine months ended September 30, 2019 was primarily related to our net loss from the operation of our business of $24.9 million and net changes in working capital, including a decrease in lease liabilities of $0.5 million due to rent payments and an increase in research and development receivable of $0.1 million. These changes were partially offset by an increase in accounts payable and accrued expenses of $0.7 million, a decrease of $0.3 million in prepaid expenses and other assets, noncash stock based compensation expense of $2.8 million, noncash lease expense of $0.5 million and change in restricted stock liability of $0.2 million.

Net cash used in operating activities for the nine months ended September 30, 2018 was primarily related to our net loss from the operation of our business of $24.6 million and net changes in working capital, including an increase in research and development receivable of $0.5 million, an increase of $0.1 million in prepaid expenses and other assets and a decrease of $0.1 million in accounts payable and accrued expenses, partially offset by a noncash change in the fair value of the warrant liability of $3.7 million and noncash stock based compensation expense of $2.5 million.

Investing Activities. Net cash used in investing activities during the nine months ended September 30, 2019 was related to purchases of equipment. There were no investing activities during the nine months ended September 30, 2018.

Financing Activities. Net cash provided by financing activities for the nine months ended September 30, 2019 consisted of $12.3 million in proceeds from the issuance of common stock in connection with the 2019 Public Offering, net of underwriter commissions and discounts, $1.9 million in proceeds from the issuance of common stock under our Distribution Agreement with Raymond James & Associates, Inc. and $1.0 million in proceeds from the issuance of common stock under the Distribution Agreement with Lincoln Park Capital. These increases were partially offset by payments of $0.4 million for deferred offering costs.

Net cash provided by financing activities for the nine months ended September 30, 2018 consisted of $15.0 million in gross proceeds from the issuance of common stock in connection with the March 2018 public offering, net of underwriter commissions and discounts, and $1.2 million in proceeds from the exercise of common stock warrants, partially offset by payments of $0.3 million for deferred offering costs.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Not Applicable.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Securities and Exchange Act of 1934 is (1) recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management, including our President and Chief Executive Officer, who is our principal executive officer, and Chief Financial Officer, who is also our principal financial and accounting officer, as appropriate, to allow timely decisions regarding required disclosure.

As of September 30, 2019, our management, with the participation of our principal executive officer and principal financial and accounting officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities and Exchange Act of 1934) using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control—Integrated Framework (2013 Framework). Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our principal executive officer and principal financial and accounting officer have concluded based upon the evaluation described above that, as of September 30, 2019, our disclosure controls and procedures were effective to ensure that information required to be disclosed by it in reports the Company files or submits 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 material information is accumulated and communicated to the Company's management, including its Principal Executive Officer and Principal Financial Officer, to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

During the three and nine months ended September 30, 2019, there were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) that materially affected, or are reasonably likely to affect, internal control over financial reporting.

Part II — OTHER INFORMATION

Item 1. Legal Proceedings

None.

Item 1A. Risk Factors

An investment in our ordinary shares involves a high degree of risk. In addition to the other information contained elsewhere in this report, you should carefully consider the risk factors discussed in Part I, Item 1A “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2018 as filed with the SEC on April 1, 2019, which could materially affect our business, financial condition, operating results or cash flows. We operate in a dynamic and rapidly changing industry that involves numerous risks and uncertainties. In addition to those risk factors, you should consider the following:

Risks Related to Leap’s Financial Position and Capital Needs

We have incurred significant losses since our inception and anticipate that we will continue to incur losses in the future.

We are a clinical-stage biopharmaceutical company. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that our two product candidates, DKN-01 and TRX518, or any other products will fail to gain regulatory approval or become commercially viable. We have only two clinical-stage product candidates, which are at the early stages of clinical development. We do not have any products approved by regulatory authorities for marketing and have not generated any revenue from product sales. We incur significant research, development and other expenses related to our ongoing operations.

As a result, we are not profitable and have incurred losses in every reporting period since our inception in 2011. For the year ended December 31, 2018, we reported a net loss of $23.1 million, and had an accumulated deficit of $153.5 million at December 31, 2018. For the nine months ended September 30, 2019, we reported a net loss of $24.9 million and had an accumulated deficit of $187.2 million at September 30, 2019.

We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate these losses to increase as we continue the research and development of and seek regulatory approvals for DKN-01, and we potentially begin to commercialize DKN-01, if it receives regulatory approval. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues. If DKN-01 fails in clinical trials or does not gain regulatory approval, or if approved, fails to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods.

Our management as of September 30, 2019 has concluded that due to our need for additional capital, and the uncertainties surrounding our ability to raise such funding, substantial doubt exists as to our ability to continue as a going concern.

Our financial statements for the quarter ended September 30, 2019 were prepared assuming that we will continue as a going concern. The going concern basis of presentation assumes that we will continue in operation for the foreseeable future and will be able to realize our assets and discharge our liabilities and commitments in the normal course of business and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from our inability to continue as a going concern. Our management concluded as of September 30, 2019 that due to our need for additional capital and the uncertainties surrounding our ability to raise such funding, substantial doubt exists as to our ability to continue as a going concern for a period from one year after our financial statements have been issued.

We have based these estimates on assumptions that may prove to be wrong, and we could exhaust our available financial resources sooner than we currently anticipate. We have deprioritized the development of TRX518 and suspended enrollment in a clinical trial in order to reprioritize resources. We may be forced to reduce further our operating expenses and raise additional funds to meet our working capital needs, principally through the additional sales of our securities or debt financings. However, we cannot guarantee that we will be able to obtain sufficient additional funds when needed or that such funds, if available, will be obtainable on terms satisfactory to us. If we are unable to raise sufficient additional capital or complete a strategic transaction, we may be unable to continue to fund our operations, develop our product candidates, or realize value from our assets and discharge our liabilities in the normal course of business. If we cannot raise sufficient funds, we may have to liquidate our assets, and might realize significantly less than the values at which they are carried on our financial statements, and stockholders may lose all or part of their investment in our common stock.

We will require additional capital to fund our operations and if we fail to obtain necessary financing, we may be unable to complete the development and potential commercialization of DKN-01.

Our operations have consumed substantial amounts of cash since inception. As of September 30, 2019, we had cash and cash equivalents of $10.1 million. We expect to continue to spend substantial amounts to advance the clinical development of DKN-01. We will require additional capital for the further development. If we are unable to raise capital when needed or at all, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts. We have deprioritized the development of TRX518 and suspended enrollment in a clinical trial in order to reprioritize resources.

Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to the:

- initiation, progress, timing, costs and results of pre-clinical studies and clinical trials for our product candidates;
- costs and timing of additional clinical trial and commercial manufacturing activities;
- clinical development plans we establish for DKN-01 and any other future product candidates;
- number and characteristics of any new product candidates that we in-license and develop;
- outcome, timing and cost of regulatory review by the FDA and comparable foreign regulatory authorities, including the potential for the FDA or comparable foreign regulatory authorities to require that we perform more studies than those that we currently expect;
- costs of filing, prosecuting, defending and enforcing any patent claims and maintaining and enforcing other intellectual property rights;
- effect of competing product candidates and market developments; and
- costs and timing of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval.

If we are unable to fund our operations or otherwise capitalize on our business opportunities due to a lack of capital, our ability to become profitable will be compromised.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our product candidates.

Until we can generate substantial revenue from product sales, if ever, we expect to seek additional capital through a combination of private and public equity offerings, debt financings, strategic collaborations and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of existing stockholders will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of existing stockholders. Debt financing, if available, may involve agreements that include liens or other restrictive covenants limiting our ability to take important actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we are unable to raise additional funds through equity or debt financing when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts or grant rights to develop and market our product candidates that we would otherwise prefer to develop and market ourselves. If we raise additional funds through strategic collaborations and alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates in particular countries, or grant licenses on terms that are not favorable to us.

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

None.

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Item 5. Other Information

None.

Item 6. Exhibits

See the Exhibit Index immediately prior to the signature page to this Quarterly Report on Form 10-Q for a list of exhibits filed or furnished with this report, which Exhibit Index is incorporated herein by reference.

EXHIBIT INDEX

10.1	Purchase Agreement dated as of July 11, 2019, by and between the Company and Lincoln Park Capital Fund, LLC (filed as Exhibit 10.1 to the Registrant's current report on Form 8-K as filed on July 11, 2019).
10.2	Purchase Agreement dated as of July 10, 2019, by and between the Company and Lincoln Park Capital Fund, LLC (filed as Exhibit 10.2 to the Registrant's current report on Form 8-K as filed on July 11, 2019).
10.3	Registration Rights Agreement dated as of July 10, 2019, by and between the Company and Lincoln Park Capital Fund, LLC (filed as Exhibit 10.3 to the Registrant's current report on Form 8-K as filed on July 11, 2019).
31.1 ±	Certification of Principal Executive Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.
31.2 ±	Certification of Principal Financial Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.
32.1 ±**	Principal Executive Officer Certification 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.
101 ±	The following materials from Leap Therapeutics, Inc.'s Quarterly Report on Form 10-Q for the quarter ended September 30, 2019, formatted in XBRL (Extensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets at September 30, 2019 and December 31, 2018, (ii) Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2019 and 2018, (iii) Condensed Consolidated Statements of Comprehensive Loss for the three and nine months ended September 30, 2019 and 2018, (iv) Condensed Consolidated Statements of Shareholders' Equity for the three and nine months ended September 30, 2019 and 2018 (v) Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2019 and 2018, and (vi) Notes to Condensed Consolidated Financial Statements, tagged as blocks of text.

± Filed herewith.

** This exhibit shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference in any filings under the Securities Act of 1933 or the Securities and Exchange Act of 1934, whether made before or after the date hereof and irrespective of any general incorporation language in any filing.

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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.

LEAP THERAPEUTICS, INC.

Date:	November 14, 2019	By:	/s/ Christopher K. Mirabelli
			Christopher K. Mirabelli President, Chief Executive Officer and Chairman of the Board of Directors (Principal Executive Officer)
Date:	November 14, 2019	By:	/s/ Douglas E. Onsi
			Douglas E. Onsi Chief Financial Officer, General Counsel, Treasurer and Secretary (Principal Financial Officer and Principal Accounting Officer)

Exhibit 31.1

CERTIFICATION PURSUANT TO
SECURITIES EXCHANGE ACT RULES 13a-14(a) AND 15d-14(a)

I, Christopher K. Mirabelli, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Leap Therapeutics, 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. The registrant's other certifying officer and I are 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 our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us 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 our 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. The registrant's other certifying officer and I have disclosed, based on our 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.

November 14, 2019	/s/ CHRISTOPHER K. MIRABELLI
Date	Christopher K. Mirabelli Chief Executive Officer, President and Chairman of the Board (Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
SECURITIES EXCHANGE ACT RULES 13a-14(a) AND 15d-14(a)

I, Douglas E. Onsi, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Leap Therapeutics, 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. The registrant's other certifying officer and I are 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 our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us 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 our 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. The registrant's other certifying officer and I have disclosed, based on our 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.

November 14, 2019	/s/ DOUGLAS E. ONSI
Date	Douglas E. Onsi Chief Financial Officer, General Counsel, Treasurer and Secretary (Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.1

CERTIFICATIONS PURSUANT TO

18 U.S.C. SECTION 1350,

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Leap Therapeutics, Inc. (the "Corporation") on Form 10-Q for the quarter ended September 30, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Christopher K. Mirabelli, as Chief Executive Officer, President and Chairman of the Board of the Corporation, and I, Douglas E. Onsi, the Chief Financial Officer, General Counsel, Treasurer and Secretary of the Corporation, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my 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 Corporation.

Date: November 14, 2019

By: /s/ CHRISTOPHER K. MIRABELLI

Christopher K. Mirabelli
Chief Executive Officer, President and Chairman of the Board

(Principal Executive Officer)

Date: November 14, 2019

By: /s/ DOUGLAS E. ONSI

Douglas E. Onsi
Chief Financial Officer, General Counsel, Treasurer and Secretary

(Principal Financial Officer and Principal Accounting Officer)

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.