

**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, 2018

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

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 6, 2018 there were 14,703,159 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 of 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, 2017 as filed with the Securities and Exchange Commission on February 23, 2018 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)

| | <u>September 30,</u> <u>2018</u> (Unaudited) | <u>December 31,</u> <u>2017</u> |
|--|--|------------------------------------|
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 23,249 | \$ 25,737 |
| Research and development incentive receivable | 937 | 1,744 |
| Prepaid expenses and other current assets | 191 | 177 |
| Total current assets | <u>24,377</u> | <u>27,658</u> |
| Property and equipment, net | 98 | 135 |
| Research and development incentive receivable, net of current portion | 1,131 | — |
| Deferred tax asset | 147 | 158 |
| Other assets | 1,373 | 1,111 |
| Total assets | <u>\$ 27,126</u> | <u>\$ 29,062</u> |
| Liabilities and Stockholders' Equity | | |
| Current liabilities: | | |
| Accounts payable | \$ 4,149 | \$ 2,622 |
| Accrued expenses | 1,897 | 3,461 |
| Total current liabilities | <u>6,046</u> | <u>6,083</u> |
| Non Current liabilities: | | |
| Warrant liability | 14,452 | 11,862 |
| Total liabilities | <u>20,498</u> | <u>17,945</u> |
| Commitments and contingencies (Note 10) | | |
| Stockholders' equity: | | |
| Common stock, \$0.001 par value; 100,000,000 shares authorized; 14,703,159 and 12,354,014 shares issued and outstanding as of September 30, 2018 and December 31, 2017, respectively | 15 | 12 |
| Additional paid-in capital | 161,468 | 141,770 |
| Accumulated other comprehensive income (loss) | 160 | (268) |
| Accumulated deficit | (155,015) | (130,397) |
| Total stockholders' equity | <u>6,628</u> | <u>11,117</u> |
| Total liabilities and stockholders' equity | <u>\$ 27,126</u> | <u>\$ 29,062</u> |

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 | |
|--|---------------------------------|------------|--------------------------------|-------------|
| | 2018 | 2017 | 2018 | 2017 |
| Operating expenses: | | | | |
| Research and development | \$ 6,457 | \$ 6,802 | \$ 14,922 | \$ 18,087 |
| General and administrative | 2,142 | 1,780 | 6,858 | 7,719 |
| Total operating expenses | 8,599 | 8,582 | 21,780 | 25,806 |
| Loss from operations | (8,599) | (8,582) | (21,780) | (25,806) |
| Interest income | 128 | 40 | 327 | 130 |
| Interest expense | (4) | (21) | (18) | (12) |
| Interest expense - related party | — | — | — | (121) |
| Australian research and development incentives | 299 | 961 | 1,188 | 1,852 |
| Foreign currency gains (loss) | (249) | 787 | (615) | 823 |
| Change in fair value of warrant liability | 1,793 | — | (3,720) | — |
| Net loss | (6,632) | (6,815) | (24,618) | (23,134) |
| Accretion of preferred stock to redemption value | — | — | — | (244) |
| Net loss attributable to common stockholders | \$ (6,632) | \$ (6,815) | \$ (24,618) | \$ (23,378) |
| Net loss per share | | | | |
| Basic | \$ (0.45) | \$ (0.73) | \$ (1.76) | \$ (2.72) |
| Diluted | \$ (0.55) | \$ (0.73) | \$ (1.76) | \$ (2.72) |
| Weighted average common shares outstanding | | | | |
| Basic | 14,701,785 | 9,395,920 | 13,955,949 | 8,584,558 |
| Diluted | 15,211,716 | 9,395,920 | 13,955,949 | 8,584,558 |

See notes to condensed consolidated financial statements.

LEAP THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(In thousands)

(Unaudited)

| | <u>Three Months Ended September 30,</u> | | <u>Nine Months Ended September 30,</u> | |
|--|---|-------------------|--|--------------------|
| | <u>2018</u> | <u>2017</u> | <u>2018</u> | <u>2017</u> |
| Net loss | \$ (6,632) | \$ (6,815) | \$ (24,618) | \$ (23,134) |
| Other comprehensive loss: | | | | |
| Foreign currency translation adjustments | 179 | (600) | 428 | (563) |
| Comprehensive loss | <u>\$ (6,453)</u> | <u>\$ (7,415)</u> | <u>\$ (24,190)</u> | <u>\$ (23,697)</u> |

See notes to condensed consolidated financial statements.

LEAP THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY

(In thousands, except share amounts)

(Unaudited)

| | Common Stock | | Additional Paid-in Capital | Accumulated Other Comprehensive Income (Loss) | Accumulated Deficit | Total Stockholders' Equity |
|---|-------------------|--------------|----------------------------------|--|------------------------|----------------------------------|
| | Shares | Amount | | | | |
| 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 | <u>14,703,159</u> | <u>\$ 15</u> | <u>\$ 161,468</u> | <u>\$ 160</u> | <u>\$ (155,015)</u> | <u>\$ 6,628</u> |

See notes to condensed consolidated financial statements.

LEAP THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

| | <u>Nine Months Ended September 30,</u> | |
|--|--|------------------|
| | <u>2018</u> | <u>2017</u> |
| Cash flows from operating activities: | | |
| Net loss | \$ (24,618) | \$ (23,134) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation expense | 37 | 35 |
| Stock-based compensation expense | 2,544 | 4,905 |
| Non-cash interest expense - related party | — | 121 |
| Change in fair value of warrant liability | 3,720 | — |
| Changes in operating assets and liabilities, net of impact of assumed net assets of Macrocare: | | |
| Prepaid expenses and other assets | (115) | (148) |
| Research and development incentive receivable | (480) | 1,318 |
| Accounts payable and accrued expenses | (71) | 1,135 |
| Net cash used in operating activities | <u>(18,983)</u> | <u>(15,768)</u> |
| Cash flows from investing activities: | | |
| Purchases of property and equipment | — | (64) |
| Net cash used in investing activities | <u>—</u> | <u>(64)</u> |
| Cash flows from financing activities: | | |
| Proceeds from issuance of common stock in connection with merger with Macrocare | — | 21,165 |
| Proceeds from issuance of common stock in connection with Subscription Agreement | — | 10,000 |
| Proceeds from the issuance of common stock, net of underwriter commissions and discounts | 15,034 | — |
| Payment of deferred offering costs | (319) | (2,067) |
| Proceeds from exercise of common stock warrants | 1,217 | — |
| Proceeds from notes payable - related party | — | 750 |
| Proceeds from the exercise of stock options | 14 | 20 |
| Net cash provided by financing activities | <u>15,946</u> | <u>29,868</u> |
| Effect of exchange rate changes on cash and cash equivalents | <u>549</u> | <u>(626)</u> |
| Net increase (decrease) in cash and cash equivalents | <u>(2,488)</u> | <u>13,410</u> |
| Cash and cash equivalents at beginning of period | 25,737 | 793 |
| Cash and cash equivalents at end of period | <u>\$ 23,249</u> | <u>\$ 14,203</u> |
| 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 | \$ — |
| Deferred offering costs included in accounts payable | \$ 81 | \$ — |
| Accretion of preferred stock to redemption value | \$ — | \$ 244 |
| Conversion of notes payable - related party and accrued interest convertible preferred stock into common stock | \$ — | \$ 31,145 |
| Conversion of convertible preferred stock into common stock | \$ — | \$ 70,775 |
| Value of net assets acquired in connection with merger with Macrocare, excluding cash | \$ — | \$ 96 |

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 as Dekkun Corporation on January 3, 2011 and changed its name to HealthCare Pharmaceuticals, Inc. effective May 29, 2014, and then 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. During 2017, the Company merged with Macrocare Ltd. (now “Leap Therapeutics Ltd.”) and its wholly owned subsidiary Macrocare, Inc.

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, 2018 and for the three and nine months ended September 30, 2018 and 2017 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, 2017 included in the Company’s Annual Report on Form 10-K filed with the SEC on February 23, 2018.

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, 2018, statements of operations and statements of comprehensive loss for the three and nine months ended September 30, 2018 and 2017 and statements of cash flows for the nine months ended September 30, 2018 and 2017. Such adjustments are of a normal and recurring nature. The results of operations for the three and nine months ended September 30, 2018 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2018.

Liquidity and going concern

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, 2018, the Company had an accumulated deficit of \$155,015 and during the nine months ended September 30, 2018, the Company incurred a net loss of \$24,618. The Company expects to continue to generate operating losses in the foreseeable future. The Company had cash and cash equivalents of \$23,249 at September 30, 2018. The foregoing matters give rise to a substantial doubt about the Company’s ability to continue as a going concern for one year after the Company’s financial statements have been issued. 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 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 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, 2017 and for the nine months ended September 30, 2018.

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 \$2,068 and \$1,744 as of September 30, 2018 and December 31, 2017, respectively, in the condensed consolidated balance sheets and other income from Australian research and development incentives of \$299 and \$961, respectively, for the three months ended September 30, 2018 and 2017 and \$1,188 and \$1,852, respectively, for the nine months ended September 30, 2018 and 2017 in the condensed consolidated statements of operations related to refundable research and development incentive program payments in Australia.

The following table shows the change in the research and development incentive receivable from December 31, 2016 to September 30, 2018 (in thousands):

| | | |
|--|----|--------------|
| Balance at December 31, 2016 | \$ | 3,053 |
| Australian research and development incentive income | | 1,715(1) |
| Cash received for 2016 eligible expenses | | (3,245) |
| Foreign currency translation | | 221 |
| Balance at December 31, 2017 | | 1,744 |
| Australian research and development incentive income | | 1,188 |
| Cash received for 2016 eligible overseas research and development expenses | | (740) |
| Foreign currency translation | | (124) |
| Balance at September 30, 2018 | \$ | <u>2,068</u> |

- (1) Certain supporting research and development activity is performed outside of Australia when there are no Australian facilities that support the activity ("Overseas research and development activities"). In October 2017, the Commonwealth of Australia issued the Company a favorable ruling on its Overseas research and development activities, considering such activities to be eligible research and development activities under the Australian Incentive Program. As such, the Company recorded Australian research and development incentives during the three months ended September 30, 2017 for its Overseas research and development activities performed during the year ended December 31, 2016 and the six months ended June 30, 2017, of \$347 and \$412, respectively.

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, 2018 and December 31, 2017 included \$1,176 and \$1,076, 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, 2018, other assets included \$162 of deferred issuance costs and a deposit of \$35 related to the operating lease for the Company's office space in Cambridge, Massachusetts.

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. The Company recognizes transfers between levels of the fair value hierarchy as of the end of the reporting period. There were no transfers within the hierarchy during the nine months ended September 30, 2018 and the year ended December 31, 2017.

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, 2018 | | | | |
| Assets: | | | | |
| Cash equivalents | \$ 23,249 | \$ 23,249 | \$ — | \$ — |
| Total assets | <u>\$ 23,249</u> | <u>\$ 23,249</u> | <u>\$ —</u> | <u>\$ —</u> |
| Liabilities: | | | | |
| Warrant liability | \$ 14,452 | \$ — | \$ — | \$ 14,452 |
| Total liabilities | <u>\$ 14,452</u> | <u>\$ —</u> | <u>\$ —</u> | <u>\$ 14,452</u> |
| December 31, 2017 | | | | |
| Assets: | | | | |
| Cash equivalents | \$ 25,737 | \$ 25,737 | \$ — | \$ — |
| Total assets | <u>\$ 25,737</u> | <u>\$ 25,737</u> | <u>\$ —</u> | <u>\$ —</u> |
| Liabilities: | | | | |
| Warrant liability | \$ 11,862 | \$ — | \$ — | \$ 11,862 |
| Total liabilities | <u>\$ 11,862</u> | <u>\$ —</u> | <u>\$ —</u> | <u>\$ 11,862</u> |

Cash equivalents of \$23,249 and \$25,737 as of September 30, 2018 and December 31, 2017, 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):

| | |
|-----------------------------------|------------------|
| Balance—December 31, 2017 | \$ 11,862 |
| Change in fair value | 4,851 |
| Balance—March 31, 2018 | <u>16,713</u> |
| Exercise of warrants | (1,130) |
| Change in fair value | 662 |
| Balance—June 30, 2018 | <u>16,245</u> |
| Change in fair value | (1,793) |
| Balance—September 30, 2018 | <u>\$ 14,452</u> |

The warrant liability in the table above is composed of the fair value of warrants to purchase common shares that the Company issued in connection with the private placement of common stock in November 2017. 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 develop a 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.

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 (as defined below), the Company issued a warrant to purchase common stock with each share of common stock sold in the Private Placement (as defined below). The Company classified the warrants as a liability on its consolidated balance sheet because each warrant represents 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 (as defined below) agreement and is subsequently remeasured to fair value at each reporting date. Changes in the fair value of the warrant liability are recognized as gains (losses) in the condensed consolidated statement of operations. Changes in the fair value of the warrant liability will continue to be recognized until the warrants are exercised, expire or qualify for equity classification.

If the Company issues shares to discharge the liability, the derivative financial liability is derecognized and common stock and additional paid-in capital are recognized on the issuance of those shares. Warrants are valued using the Monte Carlo simulation model. If the terms of warrants that initially require the warrant to be classified as a liability lapse, the liability is reclassified out of financial liabilities into equity at its fair value on that date. The cash proceeds received from exercises of warrants are recorded in common stock and additional paid-in capital.

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 March 2016, the FASB issued ASU 2016-09, Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting. The new standard involves several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities and classification on the statement of cash flows. The Company adopted this standard effective January 1, 2018, which had no impact on the Company's condensed consolidated financial statements.

In August 2016, the FASB issued ASU No. 2016-15, Statement of Cash Flows: Classification of Certain Cash Receipts and Cash Payments ("ASU 2016-15"), to address diversity in practice in how certain cash receipts and cash payments are presented and classified in the statement of cash flows. The standard is effective for the Company for annual periods beginning after December 15, 2018, including interim periods within those fiscal years. The Company is currently evaluating the impact that the adoption of ASU 2016-15 will have on its consolidated financial statements.

In May 2017, the FASB issued ASU No. 2017-09, Compensation—Stock Compensation (Topic 718): Scope of Modification Accounting ("ASU 2017-09"), which clarifies when to account for a change to the terms or conditions of a share-based payment award as a modification. Under the new guidance, modification accounting is required only if the fair value, the vesting conditions, or the classification of the award (as equity or liability) changes as a result of the change in terms or conditions. The Company adopted this standard effective January 1, 2018, which had no impact on the Company's condensed consolidated financial statements.

In July 2017, the FASB issued 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 new standard is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. The Company does not expect that the adoption of ASU 2017-11 will have a material impact on its consolidated financial statements.

The Company also considered the following recent accounting pronouncements which were not yet adopted as of September 30, 2018:

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 new guidance is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption is permitted. The Company has evaluated the accounting, transition and disclosure requirements of this standard and does not expect it to have a material impact on the Company's consolidated financial statements.

In February 2016, the FASB established Topic 842, Leases, by issuing Accounting Standards Update (ASU) No. 2016-02, which requires lessees to recognize leases on the balance sheet and disclose key information about leasing arrangements. The new standard establishes a right-of-use model (ROU) that requires a lessee to recognize a ROU asset and lease liability on the balance sheet for all leases with a term longer than 12 months. Leases will be classified as finance or operating, with classification affecting the pattern and classification of expense recognition in the income statement. The new standard is effective for the Company on January 1, 2019, with early adoption permitted. The Company expects to adopt the new standard on its effective date. A modified retrospective transition approach is required, applying the new standard to all leases existing at the date of initial application. An entity may choose to use either (1) its effective date or (2) the beginning of the earliest comparative period presented in the financial statements as its date of initial application. The Company expects that this standard will have a material effect on its financial statements. While the Company continues to assess all of the effects of adoption, it currently believes the most significant effects relate to (1) the recognition of new ROU assets and lease liabilities on its balance sheet for its office and equipment operating leases; and 2) providing significant new disclosures about its leasing activities.

The Company believes that the impact of other recently issued but not yet adopted accounting pronouncements will not have a material impact on the Company's consolidated financial position, results of operations, and cash flows, or do not apply to the Company's operations.

3. Merger with Macrocare and Related Transactions

Merger with Macrocare Ltd.

The Company entered into a definitive merger agreement (the "Merger Agreement"), dated as of August 29, 2016, with Macrocare Ltd. ("Macrocare"), a publicly held, clinical-stage biotechnology company based in Petach Tikva, Israel, and M-Co Merger Sub Ltd. ("Merger Sub"), a wholly owned subsidiary of the Company which provided for the merger of Macrocare with and into Merger Sub, with Macrocare continuing after the merger as a wholly owned subsidiary of the Company.

On January 23, 2017, the Company issued 3,256,898 shares of its common stock, net of fractional shares paid in cash, in exchange for 100% of the outstanding ordinary shares of Macrocare Ltd. upon consummation of the merger. Pursuant to the terms of the merger agreement, each holder of Macrocare's ordinary shares received approximately 0.1815 shares of the Company's common stock, plus cash in lieu of fractional shares based on a value of the Company's common stock of \$9.90 per share. The exchange ratio was based on a final net cash calculation, as of the closing, of \$21,875. The merger was accounted for as an in-substance recapitalization of the Company, as the transaction was, in essence, an exchange of shares of the Company's common stock (and options and warrants exercisable therefor) for cash. Apart from cash, the net assets acquired were \$96, and all Macrocare employees were terminated as of the effective time of the merger. Macrocare's cash and nominal assets and liabilities were measured and recognized at their fair values as of the date of the merger, and combined with the assets, liabilities and results of operations of the Company.

All Macrocare stock options granted under the Macrocare stock option plans (whether or not then exercisable) and all warrants to purchase Macrocare ordinary shares that were outstanding prior to the effective time of the merger became options and warrants, respectively, to purchase the Company's common stock equal to the number of ordinary shares of Macrocare issuable upon exercise of such stock options and warrants multiplied by the exchange ratio, with a corresponding exercise price equal to the exercise price of such stock options or warrants divided by the exchange ratio. All outstanding and unexercised Macrocare stock options and warrants assumed by the Company may be exercised solely for shares of the Company's common stock.

Vesting of all unvested Macrocare equity awards issued and outstanding was accelerated at the effective time of the merger, and all such equity awards issued and outstanding at the time of the merger remained issued and outstanding. For accounting purposes, since the acceleration of vesting was negotiated in contemplation of the merger, the remaining unrecognized compensation expense associated with the original grant date fair value of the awards of \$280 was recognized as a charge in the Company's condensed consolidated statement of operations and comprehensive loss for the nine months ended September 30, 2017. In addition, the exercise period for all Macrocare options outstanding at the effective time of the merger was extended beyond the respective periods provided in the original awards. The Company recorded a charge of \$504 in connection with the extension of the exercise periods in the unaudited consolidated statement of operations and comprehensive loss for the nine months ended September 30, 2017 equal to the difference in the fair value of the options immediately prior to and immediately following the modification of the exercise period.

In connection with the merger, the Company applied to be listed on the NASDAQ Global Market. NASDAQ approved the listing, and trading in the Company's common stock commenced on January 24, 2017, under the trading symbol "LPTX".

Recapitalization and Amendments to Certificate of Incorporation

On January 20, 2017, in connection with and prior to the completion of the merger with Macrocare, (a) all of the Company's outstanding shares of convertible preferred stock were converted into 3,174,523 shares of common stock, (b) the outstanding note payable and accrued interest was converted into 1,950,768 shares of common stock, and (c) the Company amended and restated its certificate of incorporation and bylaws to, among other things: (i) authorize 100,000,000 shares of common stock; (ii) eliminate all references to the previously existing series of the Company's preferred stock; (iii) authorize 10,000,000 shares of undesignated preferred stock that may be issued from time to time by the Company's board of directors and (iv) effect a one for 19.86754 reverse stock split of the Company's common stock outstanding immediately prior to the filing of the amended and restated certificate of incorporation.

Subscription Agreement

On January 20, 2017, prior and subject to the consummation of the merger, the Company and HealthCare Ventures IX, L.P. ("HCV IX") entered into a subscription agreement pursuant to which HCV IX purchased 1,010,225 shares of the Company's common stock for \$10,000, at a purchase price per share of \$9.90.

Stock Option Grants

On January 20, 2017, in connection with the consummation of the merger with Macrocare, the Company made an option grant to each of three executives to purchase 330,303 of shares of common stock, for a total of 990,909 shares of common stock, pursuant to our Amended and Restated 2012 Equity Incentive Plan. The options were granted at an exercise price \$9.90 per share. The options vested 33% on the first anniversary of the date of grant, and vest thereafter in equal monthly installments over a period of two years, generally subject to the executive's continued employment.

Royalty Agreement and Letter Agreement

On January 23, 2017, immediately prior to the merger, the Company entered into a royalty agreement with Leap Shareholder Royalty Vehicle, LLC, a Delaware limited liability company (the “Royalty Vehicle”), a special purpose vehicle formed for the specific purpose of entering into the royalty agreement. In connection with the transactions contemplated by the merger agreement, the Company declared a special distribution of certain royalty rights to each of its holders of common stock outstanding immediately prior to the effective time of the merger. These holders collectively beneficially owned or controlled 100% of the Company’s outstanding common stock at the time of the merger. Pursuant to the royalty agreement, the Company will pay to the special purpose vehicle (i) 5% of the Company’s net sales of products incorporating its TRX518 compound and (ii) 2% of the Company’s net sales of products incorporating its DKN-01 compound. The royalty agreement has an indefinite term, and neither the Company nor the special purpose vehicle has the right to terminate. The Company accounted for the royalty rights as a contingent liability.

4. Accrued Expenses

Accrued expenses consist of the following:

| | <u>September 30,</u> <u>2018</u> | <u>December 31,</u> <u>2017</u> |
|------------------------------|-------------------------------------|------------------------------------|
| Clinical trials | \$ 980 | \$ 2,116 |
| Professional fees | 146 | 390 |
| Payroll and related expenses | 771 | 955 |
| Accrued expenses | <u>\$ 1,897</u> | <u>\$ 3,461</u> |

5. Notes Payable—Related Party

During 2014, the Company entered into a convertible promissory note with a stockholder, and made multiple drawdowns under the note throughout 2014, 2015 and 2016. The note accrued interest at a rate of 8% per year until the principal of the note was either repaid or otherwise converted. As of December 31, 2016, the Company owed \$29,000 aggregate principal and \$1,274 of accrued interest in connection with the promissory note. Interest expense from the related-party note was \$0 and \$121 for the nine months ended September 30, 2018 and 2017, respectively.

On January 13, 2017, the Company received aggregate proceeds of \$750 from an amendment and restatement of the promissory note. On January 20, 2017, in accordance with its terms and in connection with and prior and subject to the consummation of the merger with Macrocare, the outstanding note payable, including principal and accrued interest totaling \$31,145, was converted into 1,950,768 shares of common stock.

6. Warrants

As of September 30, 2018, outstanding warrants to purchase common stock consisted of the following:

| <u>September 30, 2018</u> | | | |
|--|---------------------------------|------------------------|-----------------------|
| <u>Number of Shares</u> <u>Issuable</u> | <u>Exercise</u> <u>Price</u> | <u>Exercisable for</u> | <u>Classification</u> |
| 54,516 | \$ 0.01 | Common Stock | Equity |
| 2,758,094 | \$ 6.085 | Common Stock | Liability |
| <u>2,812,610</u> | | | |

2017 Warrants

On November 14, 2017, in connection with the Private Placement (as defined below), the Company issued immediately exercisable warrants to purchase 2,958,094 shares of common stock to investors. The warrants have an exercise price of \$6.085 per share and expire on November 14, 2024. During the nine months ended September 30, 2018, 200,000 warrants were exercised resulting in gross proceeds to the Company of \$1,217.

The warrants contain full ratchet anti-dilution protection provisions. The Company classifies the warrants as a liability on its consolidated balance sheet because each warrant represents 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 (as defined below) and is subsequently remeasured to fair value at each reporting date. Changes in the fair value of the warrant liability are recognized as gains (losses) in the Company’s consolidated statement of operations. Changes in the fair value of the warrant liability will continue to be recognized until the warrants are exercised, expire or qualify for equity classification.

The fair value of the warrant liability was determined to be \$11,862 as of December 31, 2017. The Company remeasured the liability at the end of each reporting period, resulting in a gain (loss) of \$1,793 and (\$3,720), respectively, recorded in the condensed consolidated statements of operations for the three and nine months ended September 30, 2018.

7. 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, 2018 no dividends have been declared.

As of September 30, 2018, the Company had reserved shares of common stock for the exercise of outstanding stock options and warrants, and the number of shares remaining for grant under the Company's 2012 Equity Incentive Plan.

Private Placement of Common Stock

On November 14, 2017, the Company entered into purchase agreements (collectively, the "Purchase Agreements") with certain accredited institutional investors (collectively, the "Purchasers"), each with substantially similar terms and conditions. Pursuant to the Purchase Agreements, the Company agreed to issue and sell to the Purchasers an aggregate of 2,958,094 shares of unregistered common stock at a price per share of \$6.085, for gross proceeds of \$18,000 (the "Private Placement"). Each common share was issued with a detachable warrant to purchase one share of common stock at an exercise price of \$6.085 per share, expiring seven years after the closing of the Purchase Agreements. The common shares issued in the Private Placement have the same rights and privileges as all other issued and outstanding common shares.

The gross proceeds of \$18,000 were first allocated to the fair value of the warrants of \$14,344 with the remaining proceeds of \$3,656 being allocated to the common stock. After giving effect to issuance costs related to the Private Placement, net proceeds were \$17,250. If all of the Warrants are exercised in cash at the stated exercise price during the term, the Company will receive additional proceeds of approximately \$18,000 and will issue an aggregate of 2,958,094 shares of common stock (the "Warrant Shares"). During the nine months ended September 30, 2018, there were 200,000 warrants exercised, resulting in gross proceeds to the Company of \$1,217.

The Company incurred \$750 of issuance costs associated with the Private Placement which consisted of legal, consulting and regulatory fees. The costs were allocated between the issuance of the common stock and warrants on a pro rata basis with the allocation of the proceeds, with approximately 80% of the costs allocated to the warrants and approximately 20% allocated to the common stock. The issuance costs associated with the common stock totaled \$152 and were recorded as a reduction to additional paid-in capital on the consolidated balance sheet. The issuance costs associated with the warrants totaled \$598 and were recorded within other expense on the consolidated statement of operations for the year ended December 31, 2017.

HealthCare Ventures IX, L.P. and Eli Lilly and Company, each a holder of more than 5% of the Company's outstanding common stock, also purchased common stock and warrants in the Private Placement. Each of HealthCare Ventures IX, L.P. and Eli Lilly and Company agreed to purchase the common stock and warrants on the same terms and conditions as the other Purchasers in the Private Placement. Three of the Company's directors and executive officers are affiliated with HealthCare Ventures IX, L.P. and its affiliates.

Public Offering of Common Stock

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.

The shares were offered pursuant to an effective shelf registration statement on Form S-3 (File No. 333-223419) that was previously filed by the Company with the SEC on March 2, 2018 and was declared effective by the SEC on March 16, 2018.

8. 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. On January 20, 2017, the Company's stockholders approved the amended and restated 2012 Equity Incentive Plan (the "2012 Plan"), which amended and restated the Plan and was effective in connection with the completion of the Company's merger with Macrocare. As of September 30, 2018, there were 1,353,152 outstanding options issued under the 2012 Plan.

On January 20, 2017, the Company's stockholders approved the 2016 Equity Incentive Plan (the "2016 Plan"), which was effective in connection with the completion of the Company's merger with Macrocare. The number of shares of common stock issuable pursuant to outstanding awards granted under the 2016 Plan may not exceed the number that is equal to the sum of (i) 854,321 shares of common stock plus (ii) the number of shares of common stock (not to exceed 103,023 shares) subject to out-of-the-money options issued by Macrocare prior to the closing of the merger and assumed by the Company pursuant to the merger agreement upon consummation of the merger that expire unexercised. Beginning on January 1, 2018, the number of shares of common stock authorized for issuance pursuant to the 2016 Plan will be 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.

In connection with the merger with Macrocare in January 2017, the Company assumed the Macrocare 2013 Share Incentive Plan (the "2013 Plan"), the Macrocare 2008 Stock Option Plan (the "2008 Plan") and all stock options outstanding under each of the 2013 Plan and the 2008 Plan immediately prior to the consummation of the merger. By virtue of the terms of the Merger Agreement and the 2013 Plan or the 2008 Plan, as applicable, each stock option outstanding immediately prior to the consummation of the merger was automatically converted into a stock option exercisable for a number of shares of the Company's common stock calculated based on the exchange ratio and the exercise price per share of such outstanding stock option.

The Company could also make awards of restricted stock under the 2016 Plan. Restricted stock may be issued for such consideration, in cash, other property or services, or any combination thereof, as is determined by the Board of Directors. During the restriction period applicable to the shares of restricted stock, such shares shall be subject to limitations on transferability, subject to forfeiture or repurchase by the Company and/or subject to other terms and conditions. Upon lapse of such restrictions, the stock certificates representing shares of common stock shall be delivered to the grantee.

A summary of 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, 2017 | 2,257,621 | \$ 12.38 | 8.66 | \$ 68 |
| Granted | 444,800 | \$ 7.72 | | |
| Exercised | (2,478) | \$ 5.56 | | |
| Forfeited | (68,497) | \$ 8.22 | | |
| Outstanding at September 30, 2018 | 2,631,446 | \$ 11.71 | 8.17 | \$ 692 |
| Options exercisable at September 30, 2018 | 1,440,904 | \$ 14.46 | 7.56 | \$ 260 |
| Options vested and expected to vest at September 30, 2018 | 2,631,446 | \$ 11.71 | 8.17 | \$ 692 |

The grant date fair value of the options granted during the year ended December 31, 2017 and the nine months ended September 30, 2018, 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, 2017 and the nine months ended September 30, 2018 were as follows, presented on a weighted average basis:

| | Year Ended December 31, 2017 | Nine Months Ended September 30, 2018 |
|--|------------------------------------|--|
| Expected volatility | 68.7% | 66.9% |
| Weighted average risk-free interest rate | 2.1% | 2.8% |
| Expected dividend yield | 0.0% | 0.0% |
| Expected term (in years) | 6.6 | 7.0 |

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, 2018, there was approximately \$6,375 of unrecognized compensation cost related to non-vested stock options, which is expected to be recognized over a remaining

weighted-average period of approximately 2.25 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, | |
|----------------------------|----------------------------------|---------------|---------------------------------|-----------------|
| | 2018 | 2017 | 2018 | 2017 |
| Research and development | \$ 180 | \$ 42 | \$ 460 | \$ 1,758 |
| General and administrative | 752 | 607 | 2,084 | 3,147 |
| Total | <u>\$ 932</u> | <u>\$ 649</u> | <u>\$ 2,544</u> | <u>\$ 4,905</u> |

9. Net Loss Per Share

Basic and diluted net loss per share for the three and nine months ended September 30, 2018 and 2017 was calculated as follows (in thousands except share and per share amounts):

| | Three Months Ended September 30, | | Nine Months Ended June 30, | |
|---|----------------------------------|-------------------|----------------------------|--------------------|
| | 2018 | 2017 | 2018 | 2017 |
| Numerator: | | | | |
| Net loss | \$ (6,632) | \$ (6,815) | \$ (24,618) | \$ (23,134) |
| Accretion of preferred stock to redemption value | — | — | — | (244) |
| Net loss attributable to common stockholders for basic loss per share | (6,632) | (6,815) | (24,618) | (23,378) |
| Less change in fair value of warrant liability | 1,793 | — | — | — |
| Net loss attributable to common stockholders for diluted loss per share | <u>\$ (8,425)</u> | <u>\$ (6,815)</u> | <u>\$ (24,618)</u> | <u>\$ (23,378)</u> |
| Denominator: | | | | |
| Weighted average number of common shares outstanding - basic | 14,701,785 | 9,395,920 | 13,955,949 | 8,584,558 |
| Assumed conversion of dilutive securities: | | | | |
| Private Placement Warrants | 509,931 | — | — | — |
| Denominator for diluted loss per share — adjusted weighted average shares | <u>15,211,716</u> | <u>9,395,920</u> | <u>13,955,949</u> | <u>8,584,558</u> |
| Net loss per share attributable to common stockholders - basic | <u>\$ (0.45)</u> | <u>\$ (0.73)</u> | <u>\$ (1.76)</u> | <u>\$ (2.72)</u> |
| Net loss per share attributable to common stockholders - diluted | <u>\$ (0.55)</u> | <u>\$ (0.73)</u> | <u>\$ (1.76)</u> | <u>\$ (2.72)</u> |

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 nine months ended September 30, 2018 and for the three and nine months ended September 30, 2017, as the effect would be to reduce the net loss per share. During the three months ended September 30, 2018, the outstanding warrants issued with the Private Placement is reflected in the diluted net loss per share computation by applying the treasury stock method. The following table includes the potential common shares, 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, | |
|--|----------------------------------|------------------|---------------------------------|------------------|
| | 2018 | 2017 | 2018 | 2017 |
| Options to purchase common stock | 2,631,446 | 1,862,621 | 2,631,446 | 1,862,621 |
| Warrants assumed from Macrocore | 54,516 | 54,516 | 54,516 | 54,516 |
| Warrants issued with the Private Placement | — | — | 2,758,094 | — |
| | <u>2,685,962</u> | <u>1,917,137</u> | <u>5,444,056</u> | <u>1,917,137</u> |

10. Commitments and Contingencies

Lease Agreement—Effective January 1, 2017, the Company entered into an assignment agreement to assume an operating lease for its office space in Cambridge, Massachusetts. Annual rent under the lease, exclusive of operating expenses and real estate taxes, was \$289 for the 12-month period ending July 31, 2017, increasing to \$297 for the 12-month period ending July 31, 2018 and increasing to \$305 for the period ending April 30, 2019. The lease agreement expires April 30, 2019, and the Company has the option to extend the term through April 30, 2022.

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, 2018, noncancelable commitments under these agreements totaled \$416.

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, 2018.

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, 2018.

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 modified 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. The Company has filed responses to all grounds of opposition argued by the Opponents. Subsequently, the Opposition Division scheduled oral proceedings to begin at the EPO on December 4, 2018. The Opposition Division also rendered a preliminary opinion that many of the claims of the patent did not comply with certain requirements for patentability at the EPO. The Company has developed and filed arguments and evidence to rebut certain adverse preliminary opinions of the Opposition Division. Further, the Company’s attorneys will attend the oral proceedings to further defend the patent as it was granted.

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, 2018 or December 31, 2017.

11. Related Party Transactions

During the nine months ended September 30, 2017, the Company executed promissory notes with stockholders (See Note 5).

The Company has a license agreement with a stockholder (See Note 10).

On November 14, 2017, the Company entered into Purchase Agreements with certain Purchasers. Each of the Purchase Agreements was on terms and conditions substantially similar to each other Purchase Agreement and pursuant to such Purchase Agreements, the Company, in a private placement, agreed to issue and sell to the Purchasers an aggregate of 2,958,094 Shares of unregistered Common Stock, at a price per share of \$6.085, each share issued with a Warrant to purchase one share of Common Stock at an exercise price of \$6.085. HealthCare Ventures IX, L.P. and Eli Lilly and Company, each a more than 5% direct holder of the Company’s Common Stock, purchased Common Stock and Warrants in the Private Placement. Each of HealthCare Ventures IX, L.P. and Eli Lilly and Company agreed to purchase the Common Stock and Warrants 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.

12. Subsequent Events

On October 25, 2018, the Company received \$800 of research and development tax incentive payments from the Commonwealth of Australia as a result of the research and development activities of its Australian subsidiary, HCP Australia.

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, 2017, which was filed with the Securities and Exchange Commission, or the SEC, on February 23, 2018. 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, or gynecologic cancers.
- **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. We are conducting clinical trials of TRX518 in patients with advanced solid tumors in combination with gemcitabine chemotherapy or with cancer immunotherapies known as PD-1 antagonists.

We intend to apply our extensive experience identifying and developing transformational products to aggressively develop these antibodies and build a pipeline of programs that has the potential to change the practice of cancer medicine.

Recent Developments

Since the end of the second quarter, we have continued to make strong progress with the development of our product candidates:

- **DKN-01/KEYTRUDA:** At the European Society for Molecular Oncology (ESMO) 2018 Annual Congress, we presented clinical data from our study evaluating DKN-01 in combination with KEYTRUDA® (pembrolizumab) in patients with advanced esophagogastric cancer. As of the cut-off date for the poster, DKN-01 and pembrolizumab had a 23.5% overall response rate and 58.8% disease control rate in evaluable gastric or gastroesophageal junction cancer patients who have been heavily pre-treated and not received any prior anti-PD-1/PD-L1 therapy. All four of the responding patients had tumors that were microsatellite stable, which is a subgroup of patients who have historically experienced a less than ten percent response rate to KEYTRUDA monotherapy.
- **DKN-01/PACLITAXEL:** At the Society for Immunotherapy of Cancer 33rd Annual Meeting, we presented an update on our clinical study evaluating DKN-01 in combination with paclitaxel in patients with advanced esophagogastric cancer. The combination of DKN-01 and paclitaxel generated a 46.7% overall response rate, 19.6 weeks median progression free survival, and 61.1 weeks median overall survival in fifteen evaluable patients as a second line therapy. In the benchmark RAINBOW study, paclitaxel monotherapy in second line gastroesophageal junction or gastric cancer patients generated a 16.1% overall response rate, 2.9 months median progression free survival, and 7.4 months median overall survival. Additionally, in our study in the subgroup of twelve evaluable patients with heavily pre-treated esophageal squamous cell carcinoma, the combination of DKN-01 and paclitaxel produced a 33.3% overall response rate, 13.7 weeks median progression free survival, and 31.0 weeks median overall survival.
- **DKN-01 in HCC:** The first patient has been enrolled in our investigator-initiated study of DKN-01 as a monotherapy and in combination with NEXAVAR® (sorafenib) in hepatocellular carcinoma patients with Wnt pathway activation.

- **TRX518/BAVENCIO:** In July, we announced a collaboration agreement with Pfizer and Merck KGaA, Darmstadt, Germany to evaluate TRX518 in combination with BAVENCIO® (avelumab) and cyclophosphamide chemotherapy. Under the terms of the collaboration, we will be conducting a Phase I/II clinical trial in advanced solid tumors including expansion populations in patients with relapsed/refractory ovarian, breast, and prostate cancers.
- **TRX518/KEYTRUDA or OPDIVO or GEMCITABINE:** During the third quarter, we presented initial data from our clinical trial evaluating TRX518 in combination with gemcitabine chemotherapy or in combination with KEYTRUDA® (pembrolizumab) or OPDIVO® (nivolumab). Three patients treated with TRX518 in combination with anti-PD1 antibodies have experienced clinical benefit. An esophageal squamous cell carcinoma patient treated with TRX518 and KEYTRUDA demonstrated a partial response with a 77% reduction in tumor volume, and an ocular melanoma patient experienced stable disease with a 23% reduction in tumor volume. An urothelial carcinoma patient who had progressed while on KEYTRUDA has had a partial response with TRX518 and OPDIVO with a 39% reduction in tumor volume. We have also fully enrolled the TRX518 and gemcitabine expansion cohort. We plan to present additional data from this trial at the ESMO Immuno-Oncology Congress in December 2018.

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, TRX518 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, 2018 and 2017:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|--|----------------------------------|----------|---------------------------------|-----------|
| | 2018 | 2017 | 2018 | 2017 |
| | (in thousands) | | (in thousands) | |
| Direct research and development by program: | | | | |
| DKN-01 program | \$ 3,929 | \$ 4,821 | \$ 10,774 | \$ 12,413 |
| TRX518 program | 2,528 | 1,981 | 4,148 | 5,674 |
| Total research and development expenses | \$ 6,457 | \$ 6,802 | \$ 14,922 | \$ 18,087 |
| Australian research and development incentives | \$ 299 | \$ 961 | \$ 1,188 | \$ 1,852 |

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.

Interest expense—related party

Interest expense consists of interest accrued on notes payable—related party that we issued during 2017, 2016 and 2015. On January 20, 2017, prior and subject to the consummation of our merger with MacroCure, all of our notes payable and accrued interest were converted into 1,950,768 shares of common stock.

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. During the nine months ended September 30, 2018, there were no material changes to our critical accounting policies. 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 February 23, 2018 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, 2018 and 2017

The following table summarizes our results of operations for the three months ended September 30, 2018 and 2017:

| | Three Months Ended September 30, | | Change |
|--|----------------------------------|-------------------|---------------|
| | 2018 | 2017 | |
| | (in thousands) | | |
| Operating expenses: | | | |
| Research and development | \$ 6,457 | \$ 6,802 | \$ (345) |
| General and administrative | 2,142 | 1,780 | 362 |
| Total operating expenses | 8,599 | 8,582 | 17 |
| Loss from operations | (8,599) | (8,582) | (17) |
| Interest income | 128 | 40 | 88 |
| Interest expense | (4) | (21) | 17 |
| Australian research and development incentives | 299 | 961 | (662) |
| Foreign currency gains | (249) | 787 | (1,036) |
| Change in fair value of warrant liability | 1,793 | — | 1,793 |
| Net loss | <u>\$ (6,632)</u> | <u>\$ (6,815)</u> | <u>\$ 183</u> |

Research and Development Expenses

| | Three Months Ended September 30, | | Increase (Decrease) |
|---|----------------------------------|-----------------|------------------------|
| | 2018 | 2017 | |
| | (in thousands) | | |
| Direct research and development by program: | | | |
| DKN-01 program | \$ 3,929 | \$ 4,821 | \$ (892) |
| TRX518 program | 2,528 | 1,981 | 547 |
| Total research and development expenses | <u>\$ 6,457</u> | <u>\$ 6,802</u> | <u>\$ (345)</u> |

Research and development expenses were \$6.5 million for the three months ended September 30, 2018, compared to \$6.8 million for the three months ended September 30, 2017. The decrease of \$0.3 million was primarily due to a decrease of \$1.3 million in manufacturing costs related to clinical trial material due to timing of manufacturing campaigns. This decrease was partially offset by an increase of \$0.7 million in clinical trial costs due to an increase in patient enrollment and an increase of \$0.2 million in payroll and other related costs due to an increase in headcount in our research and development full time employees. There was also an increase of \$0.1 million in stock based compensation expense due to new stock options granted to employees and directors in 2018.

General and Administrative Expenses

General and administrative expenses were \$2.1 million for the three months ended September 30, 2018, compared to \$1.8 million for the three months ended September 30, 2017. The increase of \$0.3 million in general and administrative expenses was primarily due to an increase of \$0.2 million of stock based compensation expense due to new stock options granted to employees and directors during 2018 and an increase of \$0.1 million in legal, audit and consulting fees associated with corporate and business development activities.

Interest Income

We recorded interest income of \$0.1 million during the three months ended September 30, 2018. We recorded an immaterial amount of interest income during the three months ended September 30, 2017.

Australian Research and Development Incentives

We recorded R&D incentive income of \$0.3 million and \$1.0 million in the three months ended September 30, 2018 and 2017, 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.

We perform certain supporting research and development activity outside of Australia when there are no Australian facilities that support the activity (“Overseas research and development activities”). In October 2017, the Commonwealth of Australia issued us a favorable ruling on our Overseas research and development activities, considering such activities to be eligible research and development activities under the Australian Incentive Program. As such, we recorded R&D incentive income during the three months ended September 30, 2017 for our Overseas research and development activities performed during the year ended December 31, 2016 and the six months ended June 30, 2017, of \$0.3 million and \$0.4 million, respectively.

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

Foreign Currency Gains (loss)

We recorded foreign currency gains (losses) of (\$0.2) million and \$0.8 million, respectively, during the three months ended September 30, 2018 and 2017. 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. We remeasured the warrant liability as of September 30, 2018 and determined that the fair value was \$14.5 million, resulting in a gain of \$1.8 million recorded in the condensed consolidated statement of operations for the three months ended September 30, 2018.

Comparison of the Nine Months Ended September 30, 2018 and 2017

The following table summarizes our results of operations for the nine months ended September 30, 2018 and 2017:

| | <u>Nine Months Ended September 30,</u> | | <u>Change</u> |
|--|--|--------------------|-------------------|
| | <u>2018</u> | <u>2017</u> | |
| | (in thousands) | | |
| Operating expenses: | | | |
| Research and development | \$ 14,922 | \$ 18,087 | \$ (3,165) |
| General and administrative | 6,858 | 7,719 | (861) |
| Total operating expenses | <u>21,780</u> | <u>25,806</u> | <u>(4,026)</u> |
| Loss from operations | (21,780) | (25,806) | 4,026 |
| Interest income | 327 | 130 | 197 |
| Interest expense | (18) | (12) | (6) |
| Interest expense - related party | — | (121) | 121 |
| Australian research and development incentives | 1,188 | 1,852 | (664) |
| Foreign currency gains | (615) | 823 | (1,438) |
| Change in fair value of warrant liability | (3,720) | — | (3,720) |
| Net loss | <u>\$ (24,618)</u> | <u>\$ (23,134)</u> | <u>\$ (1,484)</u> |

Research and Development Expenses

| | <u>Nine Months Ended September 30,</u> | | <u>Increase (Decrease)</u> |
|---|--|------------------|--------------------------------|
| | <u>2018</u> | <u>2017</u> | |
| | (in thousands) | | |
| Direct research and development by program: | | | |
| DKN-01 program | \$ 10,774 | \$ 12,413 | \$ (1,639) |
| TRX518 program | <u>4,148</u> | <u>5,674</u> | <u>(1,526)</u> |
| Total research and development expenses | <u>\$ 14,922</u> | <u>\$ 18,087</u> | <u>\$ (3,165)</u> |

Research and development expenses were \$14.9 million for the nine months ended September 30, 2018, compared to \$18.1 million for the nine months ended September 30, 2017. The decrease of \$3.2 million was primarily due to a decrease of \$2.0 million in manufacturing costs related to clinical trial material due to timing of manufacturing campaigns and a decrease of \$1.3 million in stock based compensation expense due to an increased number of stock options granted during the nine months ended September 30, 2017 in connection with the merger with Macrocare. There was also a decrease of \$0.5 million in consulting fees associated with research and development activities. These decreases were partially offset by a \$0.3 million increase in payroll and other related expenses due to an increase in headcount in our research and development full time employees and a \$0.3 million increase in clinical trial costs due to an increase in patient enrollment.

General and Administrative Expenses

General and administrative expenses were \$6.9 million for the nine months ended September 30, 2018, compared to \$7.7 million for the nine months ended September 30, 2017. The decrease of \$0.8 million in general and administrative expenses was primarily due to a decrease of \$1.0 million of stock based compensation expense due to an increased number of stock options granted during the nine months ended September 30, 2017 in connection with the merger with Macrocare and charges associated with the acceleration of vesting of all unvested Macrocare equity awards, partially offset by an increase of \$0.2 million in legal, audit and consulting fees associated with corporate and business development activities.

Interest Income

We recorded interest income of \$0.3 million and \$0.1 million during the nine months ended September 30, 2018 and 2017, respectively.

Interest Expense—Related Party

We recorded interest expense—related party of \$0 and \$0.1 million, respectively, for the nine months ended September 30, 2018 and 2017 related to borrowings under our note payable—related party. On January 20, 2017, in connection with and prior to the completion of the merger with Macrocare, the outstanding note payable and accrued interest was converted into 1,950,768 shares of common stock.

Australian Research and Development Incentives

We recorded R&D incentive income of \$1.2 million and \$1.9 million in the nine months ended September 30, 2018 and 2017, 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.

We perform certain supporting research and development activity outside of Australia when there are no Australian facilities that support the activity (“Overseas research and development activities”). In October 2017, the Commonwealth of Australia issued us a favorable ruling on our Overseas research and development activities, considering such activities to be eligible research and development activities under the Australian Incentive Program. As such, we recorded R&D incentive income during the three months ended September 30, 2017 for our Overseas research and development activities performed during the year ended December 31, 2016 and the six months ended June 30, 2017, of \$0.3 million and \$0.4 million, respectively.

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

During the nine months ended September 30, 2018, we received \$0.7 million of research and development tax incentive payments from the Commonwealth of Australia as a result of the research and development activities of our Australian subsidiary, HCP Australia.

Foreign Currency Gains (loss)

We recorded foreign currency gains (losses) of (\$0.6) million and \$0.8 million during the nine months ended September 30, 2018 and 2017, respectively. 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. We remeasured the warrant liability as of September 30, 2018 and determined that the fair value was \$14.5 million, resulting in a loss of \$3.7 million recorded in the condensed consolidated statement of operations for the nine months ended September 30, 2018.

Financial Position, Liquidity and Capital Resources

Since our inception, we have incurred significant operating losses. We have not yet commercialized any of our product candidates, which are in various phases of clinical trials, and we do not expect to generate revenue from sales of any product for several years, if at all. We have funded our operations to date with proceeds from the sale of common stock and preferred stock and notes payable—related party.

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, 2017, we reported a net loss of \$29.7 million, and had an accumulated deficit of \$130.4 million at December 31, 2017. For the nine months ended September 30, 2018, we reported a net loss of \$24.6 million, and had an accumulated deficit of \$155.0 million at September 30, 2018.

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance the preclinical activities and clinical trials of our product candidates in development. In addition, we expect to incur additional costs associated with operating as a public company.

Our expenses will also increase as we:

- pursue the clinical development of our most advanced product candidates, DKN-01 and TRX518;
- seek to identify and develop additional product candidates;
- maintain, expand and protect our intellectual property portfolio;
- expand our operational, financial and management systems and increase personnel, including personnel to support our clinical development, manufacturing and commercialization efforts and our operations as a public company; and
- increase our product liability and clinical trial insurance coverage as we initiate our clinical trials and commercialization efforts.

Additional funding may not be available at the time needed on commercially reasonable terms, if at all. As of September 30, 2018, we had cash and cash equivalents of \$23.2 million. The foregoing matters give rise to a substantial doubt about our ability to continue as a going concern for one year after our financial statements have been issued. 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, | |
|--|---------------------------------|-------------|
| | 2018 | 2017 |
| | (in thousands) | |
| Cash used in operating activities | \$ (18,983) | \$ (15,768) |
| Cash used in investing activities | — | (64) |
| Cash provided by financing activities | 15,946 | 29,868 |
| Effect of exchange rate changes on cash and cash equivalents | 549 | (626) |
| Net increase (decrease) in cash and cash equivalents | \$ (2,488) | \$ 13,410 |

Operating activities. 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.

Net cash used in operating activities for the nine months ended September 30, 2017 was primarily related to our net loss from the operation of our business of \$23.1 million and net changes in working capital, partially offset by noncash stock-based compensation expense of \$4.9 million and noncash interest expense — related party of \$0.1 million.

Investing Activities. Net cash used in investing activities during the nine months ended September 30, 2017 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, 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.

Net cash provided by financing activities for the nine months ended September 30, 2017 consisted of \$21.2 million in proceeds from the issuance of common stock in connection with the merger with Macrocare, \$10.0 million in proceeds from the issuance of common stock to existing shareholders and \$0.8 million in proceeds from notes payable—related party, partially offset by payments of \$2.1 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, 2018, 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, 2018, 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, 2018, 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, 2017 as filed with the SEC on February 23, 2018, 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, 2017, we reported a net loss of \$29.7 million, and had an accumulated deficit of \$130.4 million at December 31, 2017. For the nine months ended September 30, 2018, we reported a net loss of \$24.6 million, and had an accumulated deficit of \$155.0 million at September 30, 2018.

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 TRX518, and we potentially begin to commercialize DKN-01 and TRX518, if they receive 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 either or both of DKN-01 or TRX518 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, 2018 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, 2018 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, 2018 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 may be forced to reduce 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 or TRX518 or acquire other products.

Our operations have consumed substantial amounts of cash since inception. As of September 30, 2018, we had cash and cash equivalents of \$23.2 million. We expect to continue to spend substantial amounts to advance the clinical development of DKN-01 and

TRX518. 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.

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, TRX518, 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.

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

| | |
|----------|---|
| 2.1 | Agreement and Plan of Merger, dated as of August 29, 2016, among the Registrant, Merger Sub and MacroCure (filed as Exhibit 2.1 to the Registrant’s registration statement on Form S-4 (File No. 333-213794), as filed on September 26, 2016 and attached as Annex A to the prospectus which forms part of such registration statement). |
| 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, 2018, formatted in XBRL (Extensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets at September 30, 2018 and December 31, 2017, (ii) Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2018 and September 30, 2017, (iii) Condensed Consolidated Statements of Comprehensive Loss for the three and nine months ended September 30, 2018 and September 30, 2017, (iv) Condensed Consolidated Statements of Shareholders’ Equity at September 30, 2018 and December 31, 2017 (v) Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2018 and September 30, 2017, 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.

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 9, 2018

By: /s/ Christopher K. Mirabelli, Ph.D.
Christopher K. Mirabelli, Ph.D.
President, Chief Executive Officer and Chairman of the
Board of Directors

(Principal Executive Officer)

Date: November 9, 2018

By: /s/ Douglas E. Onsi
Douglas E. Onsi
Chief Financial Officer, General Counsel, Treasurer and
Secretary

(Principal Financial Officer and Principal Accounting
Officer)

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

I, Christopher K. Mirabelli, Ph.D., 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 9, 2018

/s/ CHRISTOPHER K. MIRABELLI, PH.D.

Date

Christopher K. Mirabelli, Ph.D.
Chief Executive Officer, President and Chairman of the Board
(Principal Executive Officer)

**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 9, 2018

/s/ DOUGLAS E. ONSI

Date

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

(Principal Financial Officer and Principal Accounting Officer)

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, 2018, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Christopher K. Mirabelli, Ph.D., 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 9, 2018

By: /s/ CHRISTOPHER K. MIRABELLI, PH.D.

Christopher K. Mirabelli, Ph.D.
Chief Executive Officer, President and Chairman of the Board
(Principal Executive Officer)

Date: November 9, 2018

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.
