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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 March 31, 2019

OR

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

For the transition period from to

Commission file number: 001-37990

LEAP THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

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

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

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class:	Trading Symbol(s)	Name of each exchange on which registered:
Common Stock, par value $0.001 per share	LPTX	Nasdaq Global Market

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

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

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

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

APPLICABLE ONLY TO CORPORATE ISSUERS

As of May 10, 2019 there were 22,949,064 shares of the registrant's common stock, par value $0.001 per share, outstanding.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

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

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

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

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

INTRODUCTORY COMMENT

References to Leap

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

Part I — FINANCIAL INFORMATION

Item 1. Financial Statements

LEAP THERAPEUTICS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share amounts)

	March 31, 2019 (Unaudited)	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 21,709	$ 16,284
Research and development incentive receivable	844	836
Prepaid expenses and other current assets	159	202
Total current assets	22,712	17,322
Property and equipment, net	74	86
Right of use asset, net	1,578	—
Research and development incentive receivable, net of current portion	74	—
Deferred tax assets	126	124
Other assets	1,519	1,542
Total assets	$ 26,083	$ 19,074
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,298	$ 3,579
Accrued expenses	4,150	2,872
Lease liability - current portion	738	—
Total current liabilities	8,186	6,451
Non current liabilities:		
Warrant liability	—	3,448
Lease liability, net of current portion	833	—
Total liabilities	9,019	9,899
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Common stock, $0.001 par value; 100,000,000 shares authorized as of March 31, 2019 and December 31, 2018, 22,260,301 and 14,703,159 shares issued and outstanding as of March 31, 2019 and December 31, 2018, respectively	22	15
Additional paid-in capital	187,635	162,393
Accumulated other comprehensive income	278	302
Accumulated deficit	(170,871)	(153,535)
Total stockholders' equity	17,064	9,175
Total liabilities and stockholders' equity	$ 26,083	$ 19,074

See notes to condensed consolidated financial statements.

LEAP THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except share and per share amounts)

(Unaudited)

	Three Months Ended March 31,	
	2019	2018
Operating expenses:		
Research and development	$ 6,790	$ 4,231
General and administrative	2,005	2,113
Total operating expenses	8,795	6,344
Loss from operations	(8,795)	(6,344)
Interest income	82	77
Interest expense	(7)	(6)
Australian research and development incentives	75	646
Foreign currency gains (loss)	42	(144)
Change in fair value of warrant liability	—	(4,851)
Net loss	(8,603)	(10,622)
Dividend attributable to down round feature of warrants	(359)	—
Net loss attributable to common stockholders	$ (8,962)	$ (10,622)
Net loss per share - basic and diluted	$ (0.47)	$ (0.85)
Weighted average common shares outstanding - basic and diluted	19,237,444	12,449,421

See notes to condensed consolidated financial statements.

LEAP THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(In thousands)

(Unaudited)

	Three Months Ended March 31,	
	2019	2018
Net loss	$ (8,603)	$ (10,622)
Other comprehensive loss:		
Foreign currency translation adjustments	(24)	110
Comprehensive loss	$ (8,627)	$ (10,512)

See notes to condensed consolidated financial statements.

LEAP THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(In thousands, except share amounts)

(Unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive 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	14,792	—	—	14,795
Foreign currency translation adjustment	—	—	—	110	—	110
Stock-based compensation	—	—	728	—	—	728
Net loss	—	—	—	—	(10,622)	(10,622)
Balances at March 31, 2018	14,500,681	15	$ 157,290	$ (158)	$ (141,019)	$ 16,128

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances at December 31, 2018	14,703,159	15	$ 162,393	$ 302	$ (153,535)	$ 9,175
Reclassification of 2017 Warrants from liability to equity upon adoption of ASU 2017-11	—	—	11,821	—	(8,374)	3,447
Issuance of common stock in connection with February 2019 Public Offering, net of issuance costs of $1,102	7,557,142	7	12,115	—	—	12,122
Record the value of the effect of the down round feature as a dividend	—	—	359	—	(359)	—
Foreign currency translation adjustment	—	—	—	(24)	—	(24)
Stock-based compensation	—	—	947	—	—	947
Net loss	—	—	—	—	(8,603)	(8,603)
Balances at March 31, 2019	22,260,301	22	$ 187,635	$ 278	$ (170,871)	$ 17,064

See notes to condensed consolidated financial statements.

LEAP THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Three Months Ended March 31,	
	2019	**2018**
Cash flows from operating activities:		
Net loss	$ (8,603)	$ (10,622)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	12	12
Amortization on right-of-use asset	177	—
Stock-based compensation expense	947	728
Change in fair value of warrant liability	—	4,851
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	43	(117)
Research and development incentive receivable	(75)	89
Accounts payable and accrued expenses	780	(419)
Lease liability	(149)	—
Net cash used in operating activities	(6,868)	(5,478)
Cash flows from financing activities:		
Proceeds from issuance of common stock, net of underwriter commissions and discounts	12,331	15,033
Payment of deferred offering costs	(9)	(28)
Net cash provided by financing activities	12,322	15,005
Effect of exchange rate changes on cash and cash equivalents	(29)	112
Net increase in cash and cash equivalents	5,425	9,639
Cash and cash equivalents at beginning of period	16,284	25,737
Cash and cash equivalents at end of period	$ 21,709	$ 35,376
Supplemental disclosure of non-cash financing activities:		
Reclassification of 2017 Warrants from liability to equity	$ 3,447	$ —
Dividend attributable to down round feature of warrants	$ 359	$ —
Offering costs included in accounts payable and accrued expenses	$ 213	$ 210
Right-of-use asset recorded upon adoption of ASU 2016-02	$ 1,755	—
Lease liability recorded upon adoption of ASU 2016-02	$ 1,720	—
Accrued rent reclassified upon adoption of ASU 2016-02	$ 35	—

See notes to condensed consolidated financial statements.

Leap Therapeutics, Inc.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(In thousands, except share and per share amounts)

(Unaudited)

1. Nature of Business, Basis of Presentation and Liquidity

Nature of Business

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

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

Liquidity

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

In accordance with Accounting Standards Codification ("ASC") 205-40, Going Concern, the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the condensed consolidated financial statements are issued. As of March 31, 2019, the Company had an accumulated deficit of $170,871, and during the three months ended March 31, 2019, the Company incurred a net loss of $8,603. The Company expects to continue to generate operating losses in the foreseeable future. The Company had cash and cash equivalents of $21,709 at March 31, 2019. 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, 2018 and for the three months ended March 31, 2019.

The research and development incentive receivable represents an amount due in connection with the above program. The Company has recorded a research and development incentive receivable of $918 and $836 as of March 31, 2019 and December 31, 2018, respectively, in the condensed consolidated balance sheets and other income from Australian research and development incentives of $75 and $646, respectively, for the three months ended March 31, 2019 and 2018 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, 2017 to March 31, 2019 (in thousands):

Balance at December 31, 2017	$	1,744
Australian research and development incentive income		756
Cash received for 2016 eligible overseas research and development expenses		(740)
Cash received for 2017 eligible expenses		(793)
Foreign currency translation		(131)
Balance at December 31, 2018		836
Australian research and development incentive income		75
Foreign currency translation		7
Balance at March 31, 2019	$	918

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 March 31, 2019 and December 31, 2018 included $1,344 and $1,380, respectively, of deposits made by the Company with certain service providers that are to be applied to future payments due under the service agreements or returned to the Company if not utilized. In addition, as of March 31, 2019 and December 31, 2018 other assets included $175 and $162 of deferred issuance costs, respectively.

Warrants

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

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

The Company will recognize on a prospective basis the value of the effect of the down round feature in the 2017 warrants when it is triggered (i.e., when the exercise price is adjusted downward). This value is measured as the difference between (1) the financial instrument's fair value (without the down round feature) using the pre-trigger exercise price and (2) the financial instrument's fair value (with the down round feature) using the reduced exercise price. The value of the effect of the down round feature will be treated as a dividend and a reduction to income available to common shareholders in the basic EPS calculation. In connection with the 2019 Public Offering, when the 2017 Warrants were repriced from $6.085 to $1.75 as a result of a down round, the Company recorded a dividend of $359 during the three months ended March 31, 2019.

Fair Value of Financial Instruments

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

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

During the periods presented, the Company has not changed the manner in which it values assets and liabilities that are measured at fair value using Level 3 inputs. 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 March 31, 2019 and the year ended December 31, 2018.

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

	Total	Level 1	Level 2	Level 3
March 31, 2019				
Assets:				
Cash equivalents	$ 21,709	$ 21,709	$ —	$ —
Total assets	$ 21,709	$ 21,709	$	$ —
December 31, 2018				
Assets:				
Cash equivalents	$ 16,284	$ 16,284	$ —	$ —
Total assets	$ 16,284	$ 16,284	$ —	$ —
Liabilities:				
Warrant liability	$ 3,448	$ —	$ —	$ 3,448
Total liabilities	$ 3,448	$ —	$ —	$ 3,448

Cash equivalents of $21,709 and $16,284 as of March 31, 2019 and December 31, 2018, respectively, consisted of overnight investments and money market funds and are classified within Level 1 of the fair value hierarchy because they are valued using quoted market prices in active markets.

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

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

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

The warrant liability in the table above is composed of the fair value of warrants ("2017 Warrants") to purchase common shares that the Company issued in connection with the private placement ("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.

Leases

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

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

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

Although separation of lease and non-lease components is required, certain practical expedients are available. Entities may elect the practical expedient to not separate lease and non-lease components. Rather, they would account for each lease component and the related non-lease component together as a single component. The Company has elected to account for the lease and non-lease

components of each of its operating leases as a single lease component and allocate all of the contract consideration to the lease component only. The lease component results in an operating right-of-use asset being recorded on the consolidated balance sheets and amortized such that lease expense is recorded on a straight line basis over the term of the lease.

Net Loss per Share

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

Warrant Liability

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

On January 1, 2019, the Company adopted ASU No. 2017-11, and concluded that the 2017 Warrants qualify for equity classification. The Company applied the guidance to the 2017 Warrants by means of a cumulative-effect adjustment to its statement of financial position as of the beginning of the interim and annual period beginning January 1, 2019.

Subsequent Events

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

Recent Accounting Pronouncements

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

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

3. Accrued Expenses

Accrued expenses consist of the following:

	March 31, 2019	December 31, 2018
Clinical trials	$ 3,597	$ 1,745
Professional fees	373	219
Payroll and related expenses	180	908
Accrued expenses	$ 4,150	$ 2,872

4. Leases

In February 2016, the FASB issued ASU 2016-02, Leases, or ASU 2016-02. ASU 2016-02 requires a lessee to recognize on its balance sheet (for both finance and operating leases) a liability to make lease payments and a right-of-use asset representing its right to use the underlying asset for the lease term. ASU 2016-02 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. The Company adopted ASU 2016-02 on January 1, 2019, or the effective date, and used the effective date as its date of initial application. As such, the Company did not adjust prior period amounts. The Company also elected to adopt the practical expedients upon transition, which permit companies to not reassess lease identification, classification, and initial direct costs under ASU 2016-02 for leases that commenced prior to the effective date.

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

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

In calculating the present value of future lease payments, the Company utilized its incremental borrowing rate based on the remaining lease term at the date of adoption. The Company has elected to account for each lease component and its associated non-lease components as a single lease component and has allocated all of the contract consideration across lease components only. This will potentially result in the initial and subsequent measurement of the balances of the right-of-use asset and lease liability for leases being greater than if the policy election was not applied. The Company has existing net leases in which the non-lease components (e.g. common area maintenance, maintenance, consumables, etc.) are paid separately from rent based on actual costs incurred and therefore are not included in the right-of-use asset and lease liability and are reflected as an expense in the period incurred. On January 1, 2019, the Company recorded a right-of-use asset of $1,755 and a lease liability of $1,720 on its consolidated balance sheets and reclassified a rent liability against the right-of-use asset of $35. As of March 31, 2019, a right-of-use asset of $1,578 and lease liability of $1,571 are reflected on the consolidated balance sheets. During the three months ended March 31, 2019 and 2018, the Company recorded rent expense of $209 and $180, respectively.

Future lease payments under non-cancelable leases as of March 31, 2019 are detailed as follows:

Future Operating Lease Payments

2019	$ 621
2020	532
2021	434
2022	146
Total Lease Payments	**1,733**
Less: imputed interest	(162)
Total operating lease liabilities	**$ 1,571**

5. Warrants

As of March 31, 2019, outstanding warrants to purchase common stock consisted of the following:

	March 31, 2019				
Date Exercisable	Number of Shares Issuable		Exercise Price	Exercisable for	Classification
1/23/2017	54,516	$	0.01	Common Stock	Equity
11/14/2017	2,758,094	$	1.75	Common Stock	Equity
2/5/2019	7,557,142	$	1.95	Common Stock	Equity
	10,369,752				

2017 Warrants

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

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

The Company will recognize on a prospective basis the value of the effect of the down round feature in the warrant when it is triggered (i.e., when the exercise price is adjusted downward). This value is measured as the difference between (1) the financial instrument's fair value (without the down round feature) using the pre-trigger exercise price and (2) the financial instrument's fair value (with the down round feature) using the reduced exercise price. The value of the effect of the down round feature will be treated as a dividend and a reduction to income available to common shareholders in the basic EPS calculation. In connection with the public offering in February 2019, when the 2017 Warrants were repriced from $6.085 to $1.75, the Company recorded a dividend of $359 during the three months ended March 31, 2019.

2019 Warrants

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

6. Common Stock

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are entitled to receive dividends, as may be declared by the board of directors, if any, subject to the preferential dividend rights of the preferred stockholders. Through March 31, 2019 no dividends have been declared.

Public Offering of Common Stock — March 2018

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

Public Offering of Common Stock — February 2019

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

7. Equity Incentive Plans

Equity Incentive Plans

In September 2012, the Company adopted the 2012 Equity Incentive Plan, as amended (the "Plan"), which provides designated employees of the Company and its affiliates, certain consultants and advisors who perform services for the Company and its affiliates, and nonemployee members of the Board of Directors of the Company and its affiliates with the opportunity to receive grants of incentive stock options, nonqualified stock options and stock awards. 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 Macrocure. As of March 31, 2019, there were 1,379,018 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 Macrocure. 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 Macrocure 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 was increased each January 1 by an amount equal to four percent (4%) of the Company's outstanding common stock as of the end of the immediately preceding calendar year or such other amount as determined by the compensation committee of the Company's Board of Directors. As of March 31, 2019, there were 1,310,612 outstanding options issued under the 2016 Plan.

In connection with the merger with Macrocure in January 2017, the Company assumed the Macrocure 2013 Share Incentive Plan (the "2013 Plan"), the Macrocure 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 under the Equity Plan 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. As of March 31, 2019, there were 669,105 shares available for grant under the Company's Equity Incentive Plans.

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, 2018	2,761,912	$ 11.30	8.01	$ —
Granted	214,475	$ 2.00		
Exercised	—	$ —		
Forfeited	(71,053)	$ 35.10		
Outstanding at March 31, 2019	2,905,334	$ 10.03	8.10	$ —
Options exercisable at March 31, 2019	1,701,823	$ 12.44	7.59	$ —
Options vested and expected to vest at March 31, 2019	2,905,334	$ 10.03	8.10	$ —

The grant date fair value of the options granted during the year ended December 31, 2018 and the three months ended March 31, 2019, was estimated at the date of grant using the Black-Scholes option valuation model. The expected life was estimated using the "simplified" method as defined by the Securities and Exchange Commission's Staff Accounting Bulletin 107, Share-Based Payment. The expected volatility was based on the historical volatility of comparable public companies from a representative peer group selected based on industry and market capitalization data. The risk-free interest rate was based on the continuous rates provided

by the U.S. Treasury with a term approximating the expected life of the option. The expected dividend yield was 0% because the Company does not expect to pay any dividends for the foreseeable future. The Company elected the straight-line attribution method in recognizing the grant date fair value of options issued over the requisite service periods of the awards, which are generally the vesting periods.

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

	Three Months Ended March 31, 2019	Year Ended December 31, 2018
Expected volatility	66.94%	66.94%
Weighted average risk-free interest rate	2.55%	2.80%
Expected dividend yield	0.00%	0.00%
Expected term (in years)	6.84	6.95

Stock options generally vest over a three or four year period, as determined by the Compensation Committee of the Board of Directors at the time of grant. The options expire ten years from the grant date. As of March 31, 2019, there was approximately $5,007 of unrecognized compensation cost related to non-vested stock options, which is expected to be recognized over a remaining weighted-average period of approximately 2.12 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 March 31,	
	2019	2018
Research and development	$ 176	$ 117
General and administrative	771	611
Total	$ 947	$ 728

8. Net Loss Per Share

Basic and diluted net loss per share for the three months ended March 31, 2019 and 2018 was calculated as follows (in thousands except share and per share amounts):

	Three Months Ended March 31,	
	2019	2018
Numerator:		
Net loss	$ (8,603)	$ (10,622)
Dividend attributable to down round feature of warrants	(359)	—
Net loss attributable to common stockholders for basic and diluted loss per share	$ (8,962)	$ (10,622)
Denominator:		
Weighted average number of common shares outstanding - basic and diluted	19,237,444	12,449,421
Net loss per share attributable to common stockholders - basic and diluted	$ (0.47)	$ (0.85)

The Company's potentially dilutive securities include stock options and warrants. These securities were excluded from the computations of diluted net loss per share for the three months ended March 31, 2019 and 2018, as the effect would be to reduce the net loss per share. The following table includes the potential shares of common stock, presented based on amounts outstanding at each period end, that were excluded from the computation of diluted net loss per share attributable to common stockholders for the periods indicated because including them would have had an anti-dilutive effect:

	Three Months Ended March 31,	
	2019	2018
Options to purchase common stock	2,905,334	2,250,080
Warrants to purchase common stock	10,369,752	3,012,610
	13,275,086	5,262,690

9. Commitments and Contingencies

Manufacturing Agreements—The Company is party to manufacturing agreements with vendors to manufacture TRX518 and DKN-01, its lead product candidates, for use in clinical trials. As of March 31, 2019, the Company did not have any noncancelable commitments under these agreements.

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 March 31, 2019.

License Agreement—On May 28, 2015, the Company entered into a license agreement with Lonza Sales AG ("Lonza"), pursuant to which Lonza granted the Company a world-wide, non-exclusive license for certain intellectual property relating to a gene expression system for manufacturing DKN-01. As defined in the license agreement, the Company would be required to pay royalties to Lonza based on a percentage in the low single digits of net sales of DKN-01, if and when achieved. However, there can be no assurance that clinical or commercialization success will occur, and no royalties have been paid or accrued through March 31, 2019.

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

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

In 2016, a patent covering the use of the TRX518 antibody in combination with a chemotherapeutic agent for treating cancer was granted to the Company by the EPO. In March 2017, notices of opposition to this patent were filed at the EPO by ten different entities, including several major pharmaceutical companies. Oral proceedings at the EPO took place on December 4 and 5, 2018. At the conclusion of the oral proceedings, the Opposition Division decided that the patent should be revoked in its entirety on the ground that the claims as granted contained added matter. Subsequently, the Opposition Division issued an interlocutory decision restating its conclusion that the claims as granted contained added matter and revoking the patent. The Company has filed an appeal of the decision of the Opposition Division seeking to obtain a reversal of the Opposition Division's decision on added matter. A statement of our grounds of appeal is due on May 23, 2019. The EPO Board of Appeal has not yet scheduled a date for the appeal hearing.

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

10. Related Party Transactions

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

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

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

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

Company Overview

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

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

- *TRX518:* A monoclonal antibody targeting the glucocorticoid-induced tumor necrosis factor-related receptor, or GITR. GITR is a receptor found on the surface of a wide range of immune cells. GITR stimulation activates tumor fighting white blood cells and decrease the activity of potentially tumor-protective immunosuppressive cells. TRX518 has been specifically engineered to enhance the immune system's anti-tumor response by activating GITR signaling without causing the immune cells to be destroyed. 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 year ended December 31, 2018, we have continued to make strong progress with the development of our product candidates:

- ***DKN-01 in ESOPHAGOGASTRIC CANCER***: We presented clinical data from our study evaluating DKN-01 in combination with KEYTRUDA® (pembrolizumab) in patients with advanced esophagogastric cancer. The overall response rate and disease control rate has been higher in patients with higher DKK1 expression as measured by in situ hybridization RNAscope. Enrollment in this study is complete.

- ***DKN-01 in GYNECOLOGICAL CANCERS***: At the Society for Gynecologic Oncology 50th Annual Meeting on Women's Cancer, we presented an update on our clinical study evaluating DKN-01 as a monotherapy and in combination with paclitaxel in patients with advanced gynecological cancers. DKN-01 monotherapy has generated two partial responses in patients with endometrial cancer, and DKN-01 plus paclitaxel has generated a partial response in a patient with carcinosarcoma. An additional DKN-01 monotherapy patient was initially reported by the treating investigator to have experienced a partial response; however, further follow-up identified that the patient has a tumor reduction that does not meet the threshold for a partial response and remains on treatment with ongoing clinical benefit. Eighty-seven patients have been enrolled in the study, and enrollment is ongoing.

- ***DKN-01 in PROSTATE CANCER***: The first patient has been enrolled in our investigator-initiated study of DKN-01 as a monotherapy and in combination with docetaxel in DKK1-positive metastatic prostate cancer patients.

- ***TRX518 MONOTHERAPY***: A non-virally mediated hepatocellular cancer patient, who has been treated with single agent TRX518 for two years, achieved a best response of partial response. With recent disease progression, this patient now continues on treatment for clinical benefit.

- ***TRX518 COMBINATION THERAPY***: We presented data from our clinical trial evaluating TRX518 in combination with gemcitabine chemotherapy or in combination with KEYTRUDA or OPDIVO® (nivolumab), with patients from each combination arm experiencing responses and durable stable disease. Eighteen patients have been enrolled in the TRX518/KEYTRUDA expansion cohort, and enrollment is ongoing.

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 months ended March 31, 2019 and 2018:

	Three Months Ended March 31,	
	2019	2018
	(in thousands)	
Direct research and development by program:		
DKN-01 program	$ 5,375	$ 3,193
TRX518 program	1,415	1,038
Total research and development expenses	$ 6,790	$ 4,231
Australian research and development incentives	$ 75	$ 646

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

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

- the timing and receipt of any regulatory approvals.

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

General and Administrative Expenses

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

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

Interest income

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

Research and development incentive income

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

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

- a 43.5% refundable tax offset for entities with an aggregated turnover of less than A$20 million per annum, or
- a 38.5% non-refundable tax offset for all other entities.

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

Foreign currency translation adjustment

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

Critical Accounting Policies and Estimates

Our condensed consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States, or GAAP. The preparation of our financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue, costs and expenses, and the disclosure of contingent assets and liabilities in our financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

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

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

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

Results of Operations

Comparison of the Three Months Ended March 31, 2019 and 2018

The following table summarizes our results of operations for the three months ended March 31, 2019 and 2018:

	Three Months Ended March 31,		
	2019	2018	Change
	(in thousands)		
Operating expenses:			
Research and development	$ 6,790	$ 4,231	$ 2,559
General and administrative	2,005	2,113	(108)
Total operating expenses	8,795	6,344	2,451
Loss from operations	(8,795)	(6,344)	(2,451)
Interest income	82	77	5
Interest expense	(7)	(6)	(1)
Australian research and development incentives	75	646	(571)
Foreign currency gains	42	(144)	186
Loss on change in fair value of warrant liability	—	(4,851)	4,851
Net loss	$ (8,603)	$ (10,622)	$ 2,019

Research and Development Expenses

	Three Months Ended March 31,		Increase (Decrease)
	2019	2018	
	(in thousands)		
Direct research and development by program:			
DKN-01 program	$ 5,375	$ 3,193	$ 2,182
TRX518 program	1,415	1,038	377
Total research and development expenses	$ 6,790	$ 4,231	$ 2,559

Research and development expenses were $6.8 million for the three months ended March 31, 2019, compared to $4.2 million for the three months ended March 31, 2018. The increase of $2.6 million was primarily due to an increase of $2.4 million in clinical trial costs due to an increase in patient enrollment, a $0.5 million increase in consulting fees associated with research and development activities and an increase of $0.2 million in payroll and other related expenses due to an increase in headcount in our research and development full time employees. These increases were partially offset by a decrease of $0.5 million in manufacturing costs related to clinical trial material due to timing of manufacturing campaigns.

General and Administrative Expenses

General and administrative expenses were $2.0 million for the three months ended March 31, 2019, compared to $2.1 million for the three months ended March 31, 2018. The decrease of $0.1 million in general and administrative expenses was primarily due to a decrease of $0.3 million in payroll and other related expenses due to a decrease in bonus expense in the three months ending March 31, 2019 as compared to the same period in 2018, partially offset by an increase of $0.2 million of stock based compensation expense due to new stock options granted to employees and directors during the three months ended March 31, 2019.

Interest Income

We recorded interest income of $0.1 million and $0.1 million in the three months ended March 31, 2019 and 2018, respectively.

Australian Research and Development Incentives

We recorded R&D incentive income of $0.1 million and $0.6 million in the three months ended March 31, 2019 and 2018, respectively, based upon the applicable percentage of eligible research and development activities under the Australian Incentive Program, which expenses included the cost of manufacturing clinical trial material.

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.

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 ($0.1) million during the three months ended March 31, 2018. We recorded an immaterial amount of foreign currency gains during the three months ended March 31, 2019. 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 loss on the change in fair value of the warrant liability during the three months ended March 31, 2018 of $4.9 million. As of January 1, 2019, we adopted ASU No. 2017-11, *Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480), and Derivatives and Hedging (Topic 815)* ("ASU 2017-11"), which changes the classification analysis of certain equity-linked financial instruments (or embedded features) with down round features. The amendments require entities that present earnings per share ("EPS") in accordance with Topic 260 to recognize the effect of the down round feature when triggered with the effect treated as a dividend and as a reduction of income available to common shareholders in basic EPS.

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

Financial Position, Liquidity and Capital Resources

Since our inception, we have 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, 2018, we reported a net loss of $23.1 million, and had an accumulated deficit of $153.5 million at December 31,

2018. For the three months ended March 31, 2019, we reported a net loss of $8.6 million, and had an accumulated deficit of $170.9 million at March 31, 2019.

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 March 31, 2019, we had cash and cash equivalents of $21.7 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:

	Three Months Ended March 31,	
	2019	2018
	(in thousands)	
Cash used in operating activities	$ (6,868)	$ (5,478)
Cash provided by financing activities	12,322	15,005
Effect of exchange rate changes on cash and cash equivalents	(29)	112
Net increase in cash and cash equivalents	$ 5,425	$ 9,639

Operating activities. Net cash used in operating activities for the three months ended March 31, 2019 was primarily related to our net loss from the operation of our business of $8.6 million and net changes in working capital, including a decrease of $0.1 million in lease liabilities due to rent payments and an increase in research and development receivable of $0.1 million. These changes were partially offset by an increase of $0.8 million in accounts payable and accrued expenses and noncash stock based compensation expense and amortization on right-of-use assets of $0.9 million and $0.2 million, respectively.

Net cash used in operating activities for the three months ended March 31, 2018 was primarily related to our net loss from the operation of our business of $10.6 million and net changes in working capital, including a decrease of $0.4 million in accounts payable and accrued expenses, partially offset by a noncash change in the fair value of the warrant liability of $4.9 million and noncash stock based compensation expense of $0.7 million. The decrease in accounts payable and accrued expenses was due to timing of vendor payments.

Investing Activities. There were no investing activities during the three months ended March 31, 2019 and 2018.

Financing Activities. Net cash provided by financing activities for the three months ended March 31, 2019 consisted of $12.3 million in proceeds from the issuance of common stock in connection with the 2019 Public Offering, net of underwriter commissions and discounts.

Net cash provided by financing activities for the three months ended March 31, 2018 consisted of $15.0 million in proceeds from the issuance of common stock in connection with the March 2018 public offering, net of underwriter commissions and discounts.

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 March 31, 2019, our management, with the participation of our principal executive officer and principal financial and accounting officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities and Exchange Act of 1934) using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control—Integrated Framework (2013 Framework). Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our principal executive officer and principal financial and accounting officer have concluded based upon the evaluation described above that, as of March 31, 2019, our disclosure controls and procedures were effective to ensure that information required to be disclosed by it in reports the Company files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC, and that such material information is accumulated and communicated to the Company's management, including its Principal Executive Officer and Principal Financial Officer, to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

During the three months ended March 31, 2019, there were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) that materially affected, or are reasonably likely to affect, internal control over financial reporting.

Part II — OTHER INFORMATION

Item 1. Legal Proceedings

None.

Item 1A. Risk Factors

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

Risks Related to Leap's Financial Position and Capital Needs

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

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

As a result, we are not profitable and have incurred losses in every reporting period since our inception in 2011. For the year ended December 31, 2018, we reported a net loss of $23.1 million, and had an accumulated deficit of $153.5 million at December 31, 2018. For the three months ended March 31, 2019, we reported a net loss of $8.6 million, and had an accumulated deficit of $170.9 million at March 31, 2019.

We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate these losses to increase as we continue the research and development of, and seek regulatory approvals for DKN-01 and 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 March 31, 2019 has concluded that due to our need for additional capital, and the uncertainties surrounding our ability to raise such funding, substantial doubt exists as to our ability to continue as a going concern.

Our financial statements for the quarter ended March 31, 2019 were prepared assuming that we will continue as a going concern. The going concern basis of presentation assumes that we will continue in operation for the foreseeable future and will be able to realize our assets and discharge our liabilities and commitments in the normal course of business and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from our inability to continue as a going concern. Our management concluded as of March 31, 2019 that due to our need for additional capital and the uncertainties surrounding our ability to raise such funding, substantial doubt exists as to our ability to continue as a going concern for a period from one year after our financial statements have been issued.

We have based these estimates on assumptions that may prove to be wrong, and we could exhaust our available financial resources sooner than we currently anticipate. We 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 March 31, 2019, we had cash and cash equivalents of $21.7 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

1.1	Underwriting Agreement, dated as of February 1, 2019, by and among the Registrant, Raymond James & Associates, Inc. and Ladenburg Thalmann & Co. Inc., as representatives of the underwriters named therein (incorporated by reference to Exhibit 1.1 to the Registrant's current report on Form 8-K (File No. 001-37990) as filed on February 1, 2019).
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).
4.1	Form of Warrant, dated as of February 5, 2019 by and between Leap Therapeutics, Inc. and each of the purchasers in the Registrant's 2019 Public Offering (incorporated by reference to Exhibit 4.1 to the Registrant's current report on Form 8-K (File No. 001-37990) as filed on February 1, 2019).
31.1 ±	Certification of Principal Executive Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.
31.2 ±	Certification of Principal Financial Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.
32.1 ±**	Principal Executive Officer Certification and Principal Financial Officer Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101 ±	The following materials from Leap Therapeutics, Inc.'s Quarterly Report on Form 10-Q for the quarter ended March 31, 2019, formatted in XBRL (Extensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets at March 31, 2019 and December 31, 2018, (ii) Condensed Consolidated Statements of Operations for the three months ended March 31, 2019 and March 31, 2018, (iii) Condensed Consolidated Statements of Comprehensive Loss for the three months ended March 31, 2019 and March 31, 2018, (iv) Condensed Consolidated Statements of Shareholders' Equity at March 31, 2019 and December 31, 2018 (v) Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2019 and March 31, 2018, and (vi) Notes to Condensed Consolidated Financial Statements, tagged as blocks of text.

± Filed herewith.

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

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: May 15, 2019

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: May 15, 2019

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

(Principal Financial Officer and Principal Accounting Officer)

Exhibit 31.1

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

I, Christopher K. Mirabelli, 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.

May 15, 2019	/s/ CHRISTOPHER K. MIRABELLI, PH.D.
Date	Christopher K. Mirabelli, Ph.D. Chief Executive Officer, President and Chairman of the Board (Principal Executive Officer)

Exhibit 31.2

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

I, Douglas E. Onsi, certify that:

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

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

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

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

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

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

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

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

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's Board of Directors (or persons performing the equivalent functions):

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

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

May 15, 2019	/s/ DOUGLAS E. ONSI
Date	Douglas E. Onsi Chief Financial Officer, General Counsel, Treasurer and Secretary (Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.1

CERTIFICATIONS PURSUANT TO

18 U.S.C. SECTION 1350,

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Leap Therapeutics, Inc. (the "Corporation") on Form 10-Q for the quarter ended March 31, 2019, 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: May 15, 2019

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: May 15, 2019

By: /s/ DOUGLAS E. ONSI

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

(Principal Financial Officer and Principal Accounting Officer)

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