

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington D.C. 20549

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended September 30, 2017

OR

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

For the transition period from      to

Commission file number: 001-37990

**LEAP THERAPEUTICS, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**

State or other jurisdiction of  
incorporation or organization

**27-4412575**

(I.R.S. Employer  
Identification No.)

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes  No

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

Large accelerated filer <input type="checkbox"/>	Accelerated filer <input type="checkbox"/>
Non-accelerated filer <input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company <input checked="" type="checkbox"/>
	Emerging growth company <input checked="" type="checkbox"/>

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

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

As of November 8, 2017 there were 9,395,920 shares of the registrant's common stock, par value \$0.001 per share, outstanding.

**TABLE OF CONTENTS**

	<u>Page</u>
<b><u>PART I — FINANCIAL INFORMATION</u></b>	
<b><u>Item 1</u></b> <b><u>Financial Statements</u></b>	5
<b><u>Item 2</u></b> <b><u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u></b>	19
<b><u>Item 3</u></b> <b><u>Quantitative and Qualitative Disclosures About Market Risk</u></b>	26
<b><u>Item 4</u></b> <b><u>Controls and Procedures</u></b>	26
<b><u>PART II — OTHER INFORMATION</u></b>	
<b><u>Item 1</u></b> <b><u>Legal Proceedings</u></b>	26

<a href="#">Item 1A</a>	<a href="#">Risk Factors</a>	26
<a href="#">Item 2</a>	<a href="#">Unregistered Sales of Equity Securities and Use of Proceeds</a>	28
<a href="#">Item 3</a>	<a href="#">Defaults Upon Senior Securities</a>	28
<a href="#">Item 4</a>	<a href="#">Mine Safety Disclosures</a>	28
<a href="#">Item 5</a>	<a href="#">Other Information</a>	28
<a href="#">Item 6</a>	<a href="#">Exhibits</a>	28

[Table of Contents](#)

**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, 2016 as filed with the Securities and Exchange Commission on March 31, 2017 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.

[Table of Contents](#)

**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.

[Table of Contents](#)

## Item 1. Financial Statements

## LEAP THERAPEUTICS, INC.

## CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share amounts)

	September 30, 2017 (Unaudited)	December 31, 2016
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 14,203	\$ 793
Research and development incentive receivable	1,894	3,053
Prepaid expenses and other current assets	404	183
Total current assets	<u>16,501</u>	<u>4,029</u>
Property and equipment, net	148	119
Deferred offering costs	—	1,402
Other assets	930	907
Total assets	<u>\$ 17,579</u>	<u>\$ 6,457</u>
<b>Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficiency)</b>		
Current liabilities:		
Accounts payable	\$ 2,598	\$ 3,225
Accrued expenses	3,396	2,658
Notes payable and accrued interest - related party	—	30,274
Total current liabilities	<u>5,994</u>	<u>36,157</u>
Commitments and contingencies		
Convertible preferred stock, 0 and 42,500,000 shares authorized as of September 30, 2017 and December 31, 2016		
Series A redeemable convertible preferred stock, \$0.001 par value; 0 and 9,000,000 shares designated as of September 30, 2017 and December 31, 2016, respectively; 0 and 9,000,000 shares issued and outstanding as of September 30, 2017 and December 31, 2016, respectively; liquidation preference of \$0 and \$11,800 as of September 30, 2017 and December 31, 2016, respectively	—	11,800
Series B convertible preferred stock, \$0.001 par value; 0 and 21,500,000 shares designated as of September 30, 2017 and December 31, 2016, respectively; 0 and 21,500,000 shares issued and outstanding as of September 30, 2017 and December 31, 2016, respectively; liquidation preference of \$0 and \$28,189 as of September 30, 2017 and December 31, 2016, respectively	—	28,189
Series C convertible preferred stock, \$0.001 par value; 0 and 12,000,000 shares designated as of September 30, 2017 and December 31, 2017, respectively; 0 and 11,781,984 shares issued and outstanding as of September 30, 2017 and December 31, 2016, respectively; liquidation preference of \$0 and \$30,542 as of September 30, 2017 and December 31, 2016, respectively	—	30,542
Stockholders' equity (deficiency):		
Common stock, \$0.001 par value; 100,000,000 and 58,500,000 shares authorized as of September 30, 2017 and December 31, 2016, respectively; 9,395,920 and 0 shares outstanding as of September 30, 2017 and December 31, 2016, respectively	9	—
Additional paid-in capital	135,649	145
Accumulated other comprehensive income (loss)	(269)	294
Accumulated deficit	(123,804)	(100,670)
Total stockholders' equity (deficiency)	<u>11,585</u>	<u>(100,231)</u>
Total liabilities, convertible preferred stock and stockholders' equity (deficiency)	<u>\$ 17,579</u>	<u>\$ 6,457</u>

See notes to condensed consolidated financial statements.

[Table of Contents](#)

## LEAP THERAPEUTICS, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except share and per share amounts)

(Unaudited)

Three Months Ended September 30,		Nine Months Ended September 30,	
2017	2016	2017	2016

Operating expenses:								
Research and development	\$	6,802	\$	5,659	\$	18,087	\$	15,870
General and administrative		1,780		1,369		7,719		3,495
Total operating expenses		<u>8,582</u>		<u>7,028</u>		<u>25,806</u>		<u>19,365</u>
Loss from operations		(8,582)		(7,028)		(25,806)		(19,365)
Interest income (expense)		19		(2)		118		2
Interest expense - related party		—		(380)		(121)		(722)
Australian research and development incentives		961		—		1,852		—
Foreign currency gains		787		133		823		184
Net loss		<u>(6,815)</u>		<u>(7,277)</u>		<u>(23,134)</u>		<u>(19,901)</u>
Accretion of preferred stock to redemption value		—		—		(244)		—
Net loss attributable to common stockholders	\$	<u>(6,815)</u>		<u>(7,277)</u>		<u>(23,378)</u>		<u>(19,901)</u>
Net loss per share - basic and diluted	\$	<u>(0.73)</u>		<u>(0.73)</u>		<u>(2.72)</u>		<u>(2.72)</u>
Weighted average common shares outstanding - basic and diluted		<u>9,395,920</u>		<u>9,395,920</u>		<u>8,584,558</u>		<u>8,584,558</u>

See notes to condensed consolidated financial statements.

6

[Table of Contents](#)

LEAP THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(In thousands)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,					
	2017	2016	2017	2016				
Net loss	\$	(6,815)	\$	(7,277)	\$	(23,134)	\$	(19,901)
Other comprehensive loss:								
Foreign currency translation adjustments		(600)		(158)		(563)		(162)
Comprehensive loss	\$	<u>(7,415)</u>	\$	<u>(7,435)</u>	\$	<u>(23,697)</u>	\$	<u>(20,063)</u>

See notes to condensed consolidated financial statements.

7

[Table of Contents](#)

LEAP THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND SHAREHOLDERS' EQUITY (DEFICIT)

(In thousands, except share amounts)

(Unaudited)

	Series A Redeemable Convertible Preferred Stock,		Series B Convertible Preferred Stock,		Series C Convertible Preferred Stock,		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Deficiency
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
<b>Balances at December 31, 2016</b>	9,000,000	\$ 11,800	21,500,000	\$ 28,189	11,781,984	\$ 30,542	—	\$ —	145	294	\$ (100,670)	\$ (100,231)
Accretion to redemption value	—	37	—	90	—	117	—	—	(244)	—	—	(244)
Conversion of notes payable - related party and accrued interest into common stock	—	—	—	—	—	—	1,950,768	2	31,143	—	—	31,145
Conversion of convertible preferred stock to	(9,000,000)	(11,837)	(21,500,000)	(28,279)	(11,781,984)	(30,659)	3,174,523	3	70,772	—	—	70,775

common stock																		
Issuance of common stock, net of issuance costs of \$947	—	—	—	—	—	—	1,010,225	1	9,052	—	—	9,053						
Issuance of common stock in connection with merger with Macrocare, net of offering costs of \$1,402	—	—	—	—	—	—	3,256,898	3	19,856	—	—	19,859						
Issuance of common stock upon exercise of stock options	—	—	—	—	—	—	3,506	—	20	—	—	20						
Foreign currency translation adjustment	—	—	—	—	—	—	—	—	—	(563)	—	(563)						
Stock-based compensation	—	—	—	—	—	—	—	—	4,905	—	—	4,905						
Net loss	—	—	—	—	—	—	—	—	—	—	(23,134)	(23,134)						
Balances at September 30, 2017	—	\$	—	\$	—	\$	—	9,395,920	\$	9	\$	135,649	\$	(269)	\$	(123,804)	\$	11,585

See notes to condensed consolidated financial statements.

[Table of Contents](#)

LEAP THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	<u>Nine Months Ended September 30,</u>	
	<u>2017</u>	<u>2016</u>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (23,134)	\$ (19,901)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	35	17
Stock-based compensation expense	4,905	27
Non-cash interest expense - related party	121	722
Changes in operating assets and liabilities, net of impact of assumed net assets of Macrocare:		
Prepaid expenses and other assets	(148)	(268)
Research and development incentive receivable	1,318	—
Accounts payable and accrued expenses	1,135	1,363
Net cash used in operating activities	<u>(15,768)</u>	<u>(18,040)</u>
<b>Cash flows from investing activities:</b>		
Purchases of property and equipment	(64)	(136)
Net cash used in investing activities	<u>(64)</u>	<u>(136)</u>
<b>Cash flows from financing activities:</b>		
Proceeds from issuance of common stock in connection with merger with Macrocare	21,165	—
Proceeds from the sale of common stock	10,000	—
Proceeds from notes payable - related party	750	18,900
Proceeds from the exercise of stock options	20	—
Payment of deferred offering costs	(2,067)	—
Net cash provided by financing activities	<u>29,868</u>	<u>18,900</u>
<b>Effect of exchange rate changes on cash and cash equivalents</b>	<u>(626)</u>	<u>(164)</u>
<b>Net increase in cash and cash equivalents</b>	<u>13,410</u>	<u>560</u>
Cash and cash equivalents at beginning of period	793	405

Cash and cash equivalents at end of period	\$	14,203	\$	965
<b>Supplemental disclosure of non-cash financing activities:</b>				
Accretion of preferred stock to redemption value	\$	244	\$	3,483
Deferred offering costs included in accounts payable and accrued expenses	\$	—	\$	522
Conversion of notes payable - related party and accrued interest into common stock	\$	31,145	\$	—
Conversion of convertible preferred stock into common stock	\$	70,775	\$	—
Value of net assets acquired in connection with merger with Macrocare, excluding cash	\$	96	\$	—

See notes to condensed consolidated financial statements.

[Table of Contents](#)

**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 January 2017, the Company merged with Macrocare Ltd. (now “Leap Therapeutics Ltd.”) and its wholly-owned subsidiary Macrocare, Inc. (see Note 3).

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

*Basis of Presentation*

The accompanying condensed consolidated financial statements as of September 30, 2017 and for the three and nine months ended September 30, 2017 and 2016 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, 2016 included in the Company’s Annual Report on Form 10-K filed with the SEC on March 31, 2017.

The condensed consolidated financial statements have been prepared on the same basis as the audited consolidated financial statements. In the opinion of management, the accompanying condensed consolidated financial statements contain all adjustments which are necessary for the fair presentation of the Company’s financial position as of September 30, 2017, statements of operations and statements of comprehensive loss for the three and nine months ended September 30, 2017 and 2016 and statements of cash flows for the nine months ended September 30, 2017 and 2016. Such adjustments are of a normal and recurring nature. The results of operations for the three and nine months ended September 30, 2017 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2017.

[Table of Contents](#)

*Liquidity and going concern*

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

In accordance with ASC 205-40, Going Concern, the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company’s ability to continue as a going concern within one year after the date that the condensed consolidated financial statements are issued. As of September 30, 2017, the Company had an accumulated deficit of \$123,804. During the three months ended September 30, 2017, the Company’s second full quarter operating as a public company, the Company incurred a net loss of \$6,815 and its cash and cash equivalents decreased by \$2,968. The Company expects to continue to generate operating losses in the foreseeable future. The Company had cash and cash equivalents of \$14,203 at September 30, 2017. 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 in the 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.

---

### [Table of Contents](#)

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.

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 45% for the year ended December 31, 2016 and 43.5% for the nine months ended September 30, 2017.

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 \$1,894 and \$3,053 as of September 30, 2017 and December 31, 2016, respectively, in the condensed consolidated balance sheets and other income from Australian research and development incentives of \$961 and \$1,852, in the condensed consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2017, respectively, related to refundable research and development incentive program payments in Australia. The Company did not have other income from Australian research and development incentives for the three and nine months ended September 30, 2016.

The following table shows the change in the research and development incentive receivable from December 31, 2016 to September 30, 2017:

Balance at December 31, 2016:	\$	3,053
Australian research and development incentive income		1,852 <sup>(1)</sup>
Cash received for 2016 eligible expenses		(3,245)
Foreign currency translation		234
Balance at September 30, 2017	\$	<u>1,894</u>

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

### *Foreign Currency Translation*

The financial statements of the Company's foreign subsidiary are measured using the local currency as the functional currency. Assets and liabilities of this subsidiary are translated into U.S. dollars at exchange rates 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 (deficiency). Realized foreign currency transaction gains and losses are included in the results of operations.

### *Deferred Offering Costs*

The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated. After consummation of the equity financing, these costs are recorded in stockholders' equity (deficiency) as a reduction of additional paid-in capital generated as a result of the offering. As of December 31, 2016, the Company had recorded \$1,402 of deferred offering costs in contemplation of the merger with Macrocare Ltd. and in substance recapitalization of the Company. On January 23, 2017, the Company reclassified \$1,402 of deferred offering costs to additional paid-in capital as a reduction of the proceeds from the merger with Macrocare Ltd. and in substance recapitalization of the Company (see Note 3).

### *Other Assets*

Other assets as of September 30, 2017 and December 31, 2016 included \$895 and \$907, respectively, of deposits made by the Company with certain service providers that are to be applied to future payments due under the service agreements or returned to the Company if not utilized. In addition, as of September 30, 2017, other assets included a deposit of \$35 related to the operating lease for the Company's office space in Cambridge, Massachusetts.

### *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. There were no common shares outstanding during the three and nine months ended September 30, 2016, and accordingly, basic and diluted net loss per share is not presented for those periods.

#### *Reclassifications*

Certain prior period amounts have been reclassified for consistency with the current period presentation. These reclassifications had no effect on previously reported results of operations. During the three months ended March 31, 2017, the Company made a policy election to classify foreign exchange gains and losses as other income (expense), rather than general and administrative expenses, in its consolidated statement of operations on a prospective basis. The reclassification had no impact on the Company's previously reported financial position or cash flows.

---

#### [Table of Contents](#)

#### *New Accounting Pronouncements*

The Company's significant accounting policies are described in Note 2, "Summary of Significant Accounting Policies", in the Company's previously filed Annual Report on Form 10-K for the year ended December 31, 2016. Summarized below are the accounting pronouncements adopted subsequent to December 31, 2016.

Effective January 1, 2017, the Company adopted ASU 2016-09, Improvements to Employee Share-Based Payment Accounting (ASU 2016-09) which simplifies the accounting for employee share-based payment transactions, including the accounting for income taxes, forfeitures and statutory tax withholding requirements, as well as classification in the statement of cash flows. The adoption of the new guidance had no impact on the Company's condensed consolidated financial statements.

Effective January 1, 2017, the Company adopted ASU 2015-17, Balance Sheet Classification of Deferred Taxes (ASU 2015-17), which requires that all deferred tax assets and liabilities, along with any related valuation allowance, be classified as noncurrent on the balance sheet. The adoption of the new guidance had no impact on the Company's condensed consolidated financial statements.

### **3. Merger with Macrocare and Related Transactions**

#### *Merger with Macrocare Ltd.*

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

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

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

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

---

#### [Table of Contents](#)

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

#### *Recapitalization and Amendments to Certificate of Incorporation*

On January 20, 2017, in connection with and prior to the completion of the merger with Macrocare, (a) all of the Company's outstanding shares of convertible preferred stock were converted into 3,174,523 shares of common stock, (b) the outstanding note payable and accrued interest was converted into 1,950,768 shares of common stock, and (c) the Company amended and restated its certificate of incorporation and bylaws to, among other things: (i) authorize 100,000,000 shares of common stock; (ii) eliminate all references to the previously existing series of the Company's preferred stock; (iii) authorize 10,000,000 shares of undesignated



preferred stock that may be issued from time to time by the Company's board of directors and (iv) effect a one for 19.86754 reverse stock split of the Company's common stock outstanding immediately prior to the filing of the amended and restated certificate of incorporation.

#### *Subscription Agreement*

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

#### *Stock Option Grants*

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

#### *Royalty Agreement and Letter Agreement*

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

### [Table of Contents](#)

#### **4. Accrued Expenses**

Accrued expenses consist of the following:

	<u>September 30, 2017</u>	<u>December 31, 2016</u>
Clinical trials	\$ 2,593	\$ 2,545
Professional fees	120	88
Payroll and related expenses	683	25
Accrued expenses	<u>\$ 3,396</u>	<u>\$ 2,658</u>

#### **5. Notes Payable—Related Party**

During 2014, the Company entered into a convertible promissory note with a stockholder, and made multiple drawdowns under the note throughout 2014 and 2015. The note accrued interest at a rate of 8% per year until the principal of the note was either repaid or otherwise converted. During 2016, the Company made additional drawdowns under the convertible promissory note totaling \$25,900, and as of December 31, 2016, the Company owed \$29,000 aggregate principal and \$1,274 of accrued interest in connection with the promissory note. Interest expense from the related-party note was \$0 and \$380 for the three months ended September 30, 2017 and 2016, respectively, and \$121 and \$722 for the nine months ended September 30, 2017 and 2016, respectively. The accrued interest as of December 31, 2016 of \$1,274 is included in note payable and accrued interest-related party in the accompanying condensed consolidated balance sheet as of December 31, 2016.

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

#### **6. Equity Incentive Plans**

##### *Equity Incentive Plans*

In September 2012, the Company adopted the 2012 Equity Incentive Plan, as amended (the "Plan"), which provides designated employees of the Company and its affiliates, certain consultants and advisors who perform services for the Company and its affiliates, and nonemployee members of the Board of Directors of the Company and its affiliates with the opportunity to receive grants of incentive stock options, nonqualified stock options and stock awards. As of December 31, 2016, the aggregate number of shares of common stock of the Company that may be issued under the Plan was 61,483. As of December 31, 2016, 17,963 shares remained available for future grant under the Plan.

On January 20, 2017, the Company's stockholders approved the amended and restated 2012 Equity Incentive Plan (the "2012 Plan"), which amended and restated the Plan and was effective in connection with the completion of the Company's merger with Macrocare. A total of 1,387,204 shares of common stock were reserved for issuance under the 2012 Plan. As of September 30, 2017, no shares remained available for future grant under the 2012 Plan.

On January 20, 2017, the Company's stockholders approved the 2016 Equity Incentive Plan (the "2016 Plan"), which was effective in connection with the completion of the Company's merger with Macrocare. The number of shares of common stock issuable pursuant to outstanding awards granted under the 2016 Plan may not exceed the number that is equal to the sum of (i) 854,321 shares of common stock plus (ii) the number of shares of common stock (not to exceed 103,023 shares) subject to out-of-the-money options issued by Macrocare prior to the closing of the merger and assumed by the Company pursuant to the merger agreement upon consummation of the merger that expire unexercised. Beginning on January 1, 2018, the number of shares of common stock authorized for issuance pursuant to the 2016 Plan will be increased each January 1 by an amount equal to four percent (4%) of the Company's outstanding common stock as of the end of the immediately preceding calendar year or such other amount as determined by the compensation committee of the Company's Board of Directors.

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

[Table of Contents](#)

The Company could also make awards of restricted stock under the 2012 Plan and the 2016 Plan (together, the “Equity Plans”). Restricted stock may be issued under the Equity Plans for such consideration, in cash, other property or services, or any combination thereof, as is determined by the Board of Directors. During the restriction period applicable to the shares of restricted stock, such shares shall be subject to limitations on transferability, subject to forfeiture or repurchase by the Company and/or subject to other terms and conditions. Upon lapse of such restrictions, the stock certificates representing shares of common stock shall be delivered to the grantee.

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

	Options	Weighted Average Exercise Price Per Share	Weighted Average Remaining Life in Years	Aggregate Intrinsic Value
Outstanding at December 31, 2016	53,228	\$4.93	7.00	
Granted	1,825,858	\$13.81		
Exercised	(3,506)	\$5.55		
Forfeited	(12,959)	\$5.78		
Outstanding at September 30, 2017	<u>1,862,621</u>	<u>\$13.63</u>	8.65	\$36
Options exercisable at September 30, 2017	692,103	\$20.01	7.53	\$35
Options vested and expected to vest at September 30, 2017	1,862,621	\$13.63	8.65	\$36

The Company did not grant any stock options during the nine months ended September 30, 2016. The grant date fair value of the options granted during the nine months ended September 30, 2017 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.

Stock options generally vest over a three or four year period, as determined by the Compensation Committee of the Board of Directors at the time of grant. The options expire ten years from the grant date. As of September 30, 2017, there was approximately \$5,844 of unrecognized compensation cost related to non-vested stock options, which is expected to be recognized over a remaining weighted-average period of approximately 2.4 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:

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2017</u>	<u>2016</u>	<u>2017</u>	<u>2016</u>
Research and development	\$ 42	\$ 7	\$ 1,758	\$ 21
General and administrative	607	2	3,147	6
Total	<u>\$ 649</u>	<u>\$ 9</u>	<u>\$ 4,905</u>	<u>\$ 27</u>

**7. Net Loss Per Share**

There were no common shares outstanding during the three and nine months ended September 30, 2016, and accordingly, the Company has not presented basic and diluted net loss per share for those periods. Basic and diluted net loss per share for the three and nine months ended September 30, 2017 was calculated as follows:

[Table of Contents](#)

	<u>Three Months Ended September 30, 2017</u>	<u>Nine Months Ended September 30, 2017</u>
Numerator:		
Net loss	\$ (6,815)	\$ (23,134)
Accretion of preferred stock to redemption value	—	(244)
Net loss attributable to common stockholders	<u>\$ (6,815)</u>	<u>\$ (23,378)</u>
Denominator:		
Weighted average number of common shares outstanding - basic and diluted	<u>9,395,920</u>	<u>8,584,558</u>
Net loss per share attributable to common stockholders - basic and diluted	<u>\$ (0.73)</u>	<u>\$ (2.72)</u>

The Company’s potentially dilutive securities include stock options and convertible preferred stock. These securities were excluded from the computations of diluted net loss per share for the three and nine months ended September 30, 2017 and would have been excluded from the computations for the three and nine months ended September 30, 2016, as the effect would be to reduce the net loss per share. The following table includes the potential common shares, presented

based on amounts outstanding at each period end, that were excluded from the computation of diluted net loss per share attributable to common stockholders for the periods indicated because including them would have had an anti-dilutive effect:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Options to purchase common stock	1,862,621	53,228	1,862,621	53,228
Warrants assumed from MacroCure	54,516	—	54,516	—
Convertible preferred stock and accrued dividends (as converted to common stock)	—	3,491,291	—	3,491,291
	1,917,137	3,544,519	1,917,137	3,544,519

In addition to the potentially dilutive securities noted above, as of September 30, 2016, the Company had outstanding notes payable—related party for which principal and unpaid accrued interest due under the notes will automatically be converted into the class of the Company’s stock issued in the Company’s next qualified financing, as defined, based on a conversion price equal to the price per share paid by the investors in the financing. Because the necessary conditions for conversion of the notes had not been met during the three and nine months ended September 30, 2016, these notes were excluded from the table above. On January 20, 2017, in connection with and prior to the completion of the merger with MacroCure, the Company’s Charter and Bylaws were amended to reflect the conversion of all outstanding shares of the Company’s convertible preferred stock into 3,174,523 shares of common stock, and to reflect the conversion of the outstanding note payable and accrued interest into 1,950,768 shares of common stock.

## 8. Commitments and Contingencies

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

**Manufacturing Agreements**—The Company is party to manufacturing agreements with vendors to manufacture TRX518 and DKN-01, our lead product candidates, for use in clinical trials. As of September 30, 2017, noncancelable commitments under these agreements totaled \$3,267.

**License and Service Agreement**—On January 3, 2011, the Company entered into a license agreement with Eli Lilly and Company (“Lilly”) to grant a license to the Company for certain intellectual property rights relating to pharmaceutically active compounds that may be useful in the treatment of bone healing, cancer and, potentially, other medical conditions. The Company previously issued 9,000,000 shares of Series A Stock to Lilly in consideration for the grant of the license. As defined in the license agreement, the Company would be required to pay royalties to Lilly based upon a percentage in the low single digits of net sales of developed products, if and when achieved. However, there can be no assurance that clinical or commercialization success of developed products will occur, and no royalties have been paid or accrued through September 30, 2017.

**License Agreement**—On May 28, 2015, the Company entered into a license agreement with Lonza Sales AG (“Lonza”), pursuant to which Lonza granted the Company a world-wide, non-exclusive license for certain intellectual property relating to a gene expression system for manufacturing DKN-01. As defined in the license agreement, the Company would be required to pay royalties to Lonza based on a percentage in the low single digits of net sales of DKN-01, if and when achieved. However, there can be no assurance that clinical or commercialization success will occur, and no royalties have been paid or accrued through September 30, 2017.

## [Table of Contents](#)

**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 TRX518 and its uses was granted to the Company by the European Patent Office. Three notices of opposition to this patent were filed by two major pharmaceutical companies and an individual, possibly on behalf of a major pharmaceutical company. At the conclusion of the opposition proceedings in 2016, the Opposition Division of the European Patent Office that heard the case issued an interlocutory decision indicating that the Company’s patent should be maintained with modified claims that differ from the claims as originally granted. These claims cover the TRX518 antibody and uses of TRX518 in a method of enhancing an immune response in a subject. In July 2016, the Company 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 Board of Appeal has not scheduled a date for the appeal hearing. The Company is appealing the decision of the Opposition Division of the European Patent Office.

In 2016, a patent covering the use of TRX518 in combination with a chemotherapeutic agent for treating cancer was granted to the Company by the European patent office. In March 2017, notices of opposition to this patent were filed by ten different entities, including several major pharmaceutical companies. The Company intends to defend the patent as granted through opposition proceedings.

**Indemnification Agreements**—In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company is not aware of any claims under indemnification arrangements, and it has not accrued any liabilities related to such obligations in its condensed consolidated financial statements as of September 30, 2017 or December 31, 2016.

## 9. Related Party Transactions

During the three and nine months ended September 30, 2016, the Company reimbursed an entity related to one of its stockholders for shared office space and office related expenses. The total amount charged to the Company was approximately \$86 and \$213 in the three and nine months ended September 30, 2016, respectively. Effective January 1, 2017, the Company entered into an assignment agreement to assume the operating lease for its office space in Cambridge, Massachusetts, and accordingly, the Company was not required to reimburse the related party during the three and nine months ended September 30, 2017.

During the three and nine months ended September 30, 2016 and the nine months ended September 30, 2017, the Company executed promissory notes with stockholders (See Note 5).

The Company has a license agreement with a stockholder (See Note 8).

---

[Table of Contents](#)

**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, 2016, which was filed with the Securities and Exchange Commission, or the SEC, on March 31, 2017. 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 acquiring and developing novel therapeutics at the leading edge of cancer biology. Our approach is designed to target compelling tumor-promoting and immuno-oncology pathways to generate durable clinical benefit and enhanced outcomes for patients. Our 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. Our two clinical stage programs are:

- **DKN-01**: A monoclonal antibody targeting Dickkopf-related protein 1, or DKK1. DKK1 is a protein that regulates the Wnt signaling pathways, and has an important role in tumor cell signaling and in mediating an immuno-suppressive tumor microenvironment. DKN-01 has been engineered to bind to DKK1 and to generate an anti-tumor effect through altering the Wnt signaling pathways and the immune tumor microenvironment. We are testing DKN-01 in ongoing clinical trials in patients with esophagogastric cancer and biliary tract cancer. We have studied DKN-01 as a monotherapy in patients with non-small cell lung cancer. Based on the patient responses and clinical benefit in these trials, we are also studying or planning to study DKN-01 in patients with Wnt pathway alterations with gastric cancer, hepatocellular carcinoma, or endometrial cancer, and in combination with immune checkpoint inhibitors, such as Merck’s KEYTRUDA® (pembrolizumab) or Roche’s TECENTRIQ® (atezolizumab).
- **TRX518**: A monoclonal antibody targeting the glucocorticoid-induced tumor necrosis factor-related receptor, or GITR, a receptor found on the surface of a wide range of immune cells. TRX518 has been specifically engineered to enhance the immune system’s anti-tumor response by activating GITR signaling, or GITR agonism, to activate tumor fighting white blood cells, or T effector cells, and decrease the activity of potentially tumor-protective white blood cells, or T regulatory cells, without causing the immune cells to be destroyed. We believe GITR is an ideal immune system agonist target through this two-pronged approach of stimulating an anti-tumor response and reducing immune suppression. We are conducting two clinical trials of TRX518 in patients with advanced solid tumors and have evidence of biomarker modulation and clinical activity. Based on the results seen in these trials, we are planning to evaluate the combination of TRX518 with a chemotherapy, gemcitabine, and in combination with immune checkpoint inhibitors in patients with advanced solid tumors.

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**

During the three month period ended September 30, 2017, we made progress with the clinical development of our product candidates:

**DKN-01:**

- Announced updated clinical efficacy data from the P102 clinical trial evaluating DKN-01 in combination with paclitaxel in patients with advanced relapsed or refractory esophagogastric cancer. The recent data indicated that 26% of patients on combination therapy had a partial response. When analyzed by prior taxane experience, patients had a response rate of 40.9% and 12.5%, a disease control rate of 72.7% and 45.8%, and a median progression-free survival of 17.0 and 9.7 weeks, in taxane-naïve patients and taxane-experienced patients, respectively. A patient on DKN-01 monotherapy achieved a partial response by central imaging analysis and has been on therapy for over 1 year. Enrollment in the study continues.
- Announced a collaborative-group sponsored study with the European Organisation for Research and Treatment of Cancer (EORTC) and Roche to evaluate DKN-01 in combination with TECENTRIQ® (atezolizumab), a PD-L1 antagonist, ± paclitaxel in patients with advanced esophagogastric cancer or biliary tract cancer.
- Filed an IND application with the FDA to initiate a clinical trial of DKN-01 in patients with gynecological malignancies, a population known to have a high frequency of Wnt pathway mutations.

---

[Table of Contents](#)

**TRX518:**

- Announced clinical data from the 003 repeat-dose clinical trial evaluating TRX518 monotherapy in patients with advanced solid tumors. The Part B expansion cohort has been fully enrolled and as of August 31 2017, 50% of patients experienced a best response of stable disease, 25% had progressive disease, and 25% were non-evaluable for response. Patient follow-up, biopsy, and biomarker analysis are ongoing. Signs of pharmacodynamic activity including CD8+ T cell activation have been observed.

- Announced the first combination study evaluating TRX518 in combination with a chemotherapy, gemcitabine, or in combination with immune checkpoint inhibitors in patients with advanced solid tumors.

## Financial Overview

### Research and Development Expenses

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

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

We plan to increase our research and development expenses for the foreseeable future as we continue the development of DKN-01, TRX518 and any other product candidates, subject to the availability of additional funding.

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

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

The table below summarizes our research and development expenses incurred by development program and the R&D Incentive income for the three and nine months ended September 30, 2017 and 2016:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
	(in thousands)			
Direct research and development by program:				
DKN-01 program	\$ 4,821	\$ 1,994	\$ 12,413	\$ 10,159
TRX518 program	1,981	3,665	5,674	5,711
Total research and development expenses	\$ 6,802	\$ 5,659	\$ 18,087	\$ 15,870
Australian research and development incentives	\$ 961	\$ —	\$ 1,852	\$ —

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

## [Table of Contents](#)

- 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. Our interest income has not been significant due to nominal cash and investment balances prior to the Macrocore merger and low interest earned on invested balances.

#### **Interest expense—related party**

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

#### **Research and development incentive income**

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

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

- a 45% refundable tax offset for entities with an aggregated turnover of less than A\$20 million per annum, (the legislative rate for the tax year commencing July 1, 2016 will be reduced to 43.5%), or
- a 40% non-refundable tax offset for all other entities (the legislative rate for the tax year commencing July 1, 2016 will be reduced to 38.5%).

We recognize as income the amount we expect to be reimbursed for qualified expenses. We commenced recognizing expected reimbursements as income during the three months ended December 31, 2016, based upon the applicable percentage of eligible research and development activities under the Australian Incentive Program.

#### **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.

### [Table of Contents](#)

#### **Critical Accounting Policies and Estimates**

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

Our actual results may differ from these estimates under different assumptions or conditions. During the nine months ended September 30, 2017, there were no material changes to our critical accounting policies. Our critical accounting policies are described under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations— Critical Accounting Policies and Significant Judgments and Estimates” in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on March 31, 2017 and the notes to the condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q. We believe that of our critical accounting policies, the following accounting policies involve the most judgment and complexity:

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

#### **Results of Operations**

##### **Comparison of the Three Months Ended September 30, 2017 and 2016**

The following table summarizes our results of operations for the three months ended September 30, 2017 and 2016:

	<b>Three Months Ended September 30,</b>		<b>Change</b>
	<b>2017</b>	<b>2016</b>	
	(in thousands)		
Operating expenses:			
Research and development	\$ 6,802	\$ 5,659	\$ 1,143
General and administrative	1,780	1,369	411
Total operating expenses	8,582	7,028	1,554
Loss from operations	(8,582)	(7,028)	(1,554)
Interest income (expense)	19	(2)	21
Interest expense - related party	—	(380)	380
Australian research and development incentives	961	—	961
Foreign currency gains	787	133	654
Net loss	\$ (6,815)	\$ (7,277)	\$ 462

#### *Research and Development Expenses*

	2017	2016	(Decrease)
	(in thousands)		
<b>Direct research and development by program:</b>			
DKN-01 program	\$ 4,821	\$ 1,994	\$ 2,827
TRX518 program	1,981	3,665	(1,684)
Total research and development expenses	\$ 6,802	\$ 5,659	\$ 1,143
Australian research and development incentives	\$ 961	—	\$ 961

Research and development expenses were \$6.8 million for the three months ended September 30, 2017, compared to \$5.7 million for the three months ended September 30, 2016. The increase of \$1.1 million was primarily due to an increase of \$1.1 million in clinical trial costs, an increase of \$0.2 million in consulting fees associated with research and development activities and an increase in rent expense of \$0.1 million due to our use of a research laboratory. These increases were partially offset by a decrease of \$0.3 million in manufacturing costs related to clinical trial material.

[Table of Contents](#)

*General and Administrative Expenses*

General and administrative expenses were \$1.8 million for the three months ended September 30, 2017, compared to \$1.4 million for the three months ended September 30, 2016. The increase of \$0.4 million in general and administrative expenses was primarily due to an increase of \$0.6 million of stock based compensation expense and an increase of \$0.3 million in payroll and other related expenses due to an increase in headcount related to general and administrative full time employees for the three months ended September 30, 2017 as compared to the same period in 2016. These increases were partially offset by a \$0.5 million decrease in legal, audit and consulting fees associated with corporate and business development activities.

*Interest Income*

We recorded an immaterial amount of interest income for both the three months ended September 30, 2017 and 2016.

*Interest Expense—Related Party*

We recorded interest expense—related party of \$0 for the three months ended September 30, 2017 compared to \$0.4 million for the three months ended September 30, 2016 related to borrowings under our note payable—related party. On January 20, 2017, in connection with and prior to the completion of the merger with Macrocare, the outstanding note payable and accrued interest was converted into 1,950,768 shares of common stock.

*Australian Research and Development Incentives*

We recorded R&D incentive income of \$1.0 million in the three months ended September 30, 2017, 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 did not record any R&D incentive income during the three months ended September 30, 2016.

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

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

During the three months ended September 30, 2017, we received \$3.2 million of research and development tax incentive payments from the Commonwealth of Australia as a result of the 2016 research and development activities of our Australian subsidiary, HCP Australia.

**Comparison of the Nine Months Ended September 30, 2017 and 2016**

The following table summarizes our results of operations for the nine months ended September 30, 2017 and 2016:

	Nine Months Ended September 30,		Change
	2017	2016	
	(in thousands)		
<b>Operating expenses:</b>			
Research and development	\$ 18,087	\$ 15,870	\$ 2,217
General and administrative	7,719	3,495	4,224
Total operating expenses	25,806	19,365	6,441
Loss from operations	(25,806)	(19,365)	(6,441)
Interest income	118	2	116
Interest expense - related party	(121)	(722)	601
Australian research and development incentives	1,852	—	1,852
Foreign currency gains	823	184	639
Net loss	\$ (23,134)	\$ (19,901)	\$ (3,233)

[Table of Contents](#)

*Research and Development Expenses*

	Nine Months Ended September 30,		Increase (Decrease)
	2017	2016	

(in thousands)			
<b>Direct research and development by program:</b>			
DKN-01 program	\$ 12,413	\$ 10,159	\$ 2,254
TRX518 program	5,674	5,711	(37)
Total research and development expenses	<u>\$ 18,087</u>	<u>\$ 15,870</u>	<u>\$ 2,217</u>
Australian research and development incentives	<u>\$ 1,852</u>	<u>\$ —</u>	<u>\$ 1,852</u>

Research and development expenses were \$18.1 million for the nine months ended September 30, 2017, compared to \$15.9 million for the nine months ended September 30, 2016. The increase of \$2.2 million was primarily due to an increase of \$1.8 million in stock based compensation expense and an increase of \$2.2 million in clinical trial costs. Additionally, rent expense increased \$0.4 million due to our use of a research laboratory. These increases were partially offset by a decrease of \$1.6 million in manufacturing costs related to clinical trial material, a decrease of \$0.3 million in consulting fees associated with research and development activities and a decrease of \$0.3 million in payroll and other related costs due to a decrease in headcount in our research and development full time employees.

#### *General and Administrative Expenses*

General and administrative expenses were \$7.7 million for the nine months ended September 30, 2017, compared to \$3.5 million for the nine months ended September 30, 2016. The increase of \$4.2 million in general and administrative expenses was primarily due to an increase of \$3.1 million of stock based compensation expense, an increase of \$1.0 million in payroll and other related expenses due to an increase in headcount related to general and administrative full time employees for the nine months ended September 30, 2017 as compared to the same period in 2016 and an increase in rent expense of \$0.1 million.

#### *Interest Income*

We recorded interest income of \$0.1 million for the nine months ended September 30, 2017 compared to an immaterial amount for the nine months ended September 30, 2016. Interest income consists of interest earned on cash equivalents held during the nine months ended September 30, 2017.

#### *Interest Expense—Related Party*

We recorded interest expense—related party of \$0.1 million for the nine months ended September 30, 2017 compared to \$0.7 million for the nine months ended September 30, 2016, respectively, related to borrowings under our note payable—related party. The decrease was due to the conversion of our outstanding note payable and accrued interest into 1,950,768 shares of common stock in connection with our merger with MacroCure in January 2017.

#### *Australian Research and Development Incentives*

We recorded R&D incentive income of \$1.9 million for the nine months ended September 30, 2017, 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 did not record any R&D incentive income for the nine months ended September 30, 2016.

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

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

During the nine months ended September 30, 2017, we received \$3.2 million of research and development tax incentive payments from the Commonwealth of Australia as a result of the 2016 research and development activities of our Australian subsidiary, HCP Australia.

## [Table of Contents](#)

### **Financial Position, Liquidity and Capital Resources**

We are a clinical-stage biopharmaceutical company with two clinical-stage product candidates, DKN-01 and TRX518, 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. We have funded our operations to date with proceeds from the sale of preferred stock, common 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, 2016, we reported a net loss of \$25.6 million, and had an accumulated deficit of \$100.7 million at December 31, 2016. For the nine months ended September 30, 2017, we reported a net loss of \$23.1 million, and had an accumulated deficit of \$123.8 million at September 30, 2017.

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

Our expenses will also increase as we:

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



- increase our product liability and clinical trial insurance coverage as we initiate our clinical trials and commercialization efforts.

Additional funding may not be available at the time needed on commercially reasonable terms, if at all. As of September 30, 2017, we had cash and cash equivalents of \$14.2 million. The foregoing matters give rise to a substantial doubt about our ability to continue as a going concern for one year after our financial statements have been issued. We will seek additional funding through public or private equity financings or government programs and will seek funding or development program cost-sharing through collaboration agreements or licenses with larger pharmaceutical or biotechnology companies. If we do not obtain additional funding or development program cost-sharing, we will be forced to delay, reduce or eliminate certain clinical trials or research and development programs, reduce or eliminate discretionary operating expenses, and delay company and pipeline expansion, which would adversely affect our business prospects. The inability to obtain funding, as and when needed, would have a negative impact on our financial condition and ability to pursue our business strategies.

### Cash Flows

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

	Nine Months Ended September 30,	
	2017	2016
	(in thousands)	
Cash used in operating activities	\$ (15,768)	\$ (18,040)
Cash used in investing activities	(64)	(136)
Cash provided by financing activities	29,868	18,900
Effect of exchange rate changes on cash and cash equivalents	(626)	(164)
Net increase in cash and cash equivalents	<u>\$ 13,410</u>	<u>\$ 560</u>

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

Net cash used in operating activities for the nine months ended September 30, 2016 was primarily related to our net loss from the operation of our business of \$19.9 million including expenses incurred for the development of DKN-01 and TRX518, partially offset by changes in working capital, partially offset by noncash charges and noncash expenses of \$0.8 million, including \$0.7 million of noncash interest — related party.

*Investing Activities.* Net cash used in investing activities during the nine months ended September 30, 2017 and 2016 was related to purchases of equipment.

*Financing Activities.* Net cash provided by financing activities for the nine months ended September 30, 2017 consisted of \$21.2 million in proceeds from the issuance of common stock in connection with the merger with Macrocare, \$10.0 million in proceeds from the issuance of common stock to existing shareholders and \$0.8 million in proceeds from notes payable—related party, partially offset by payments of \$2.1 million for deferred offering costs.

Net cash provided by financing activities for the nine months ended September 30, 2016 consisted of \$18.9 million from the issuance of notes payable—related party.

## [Table of Contents](#)

### Off-Balance Sheet Arrangements

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

### Item 3. Quantitative and Qualitative Disclosures about Market Risk

Not Applicable.

### Item 4. Controls and Procedures

#### *Evaluation of Disclosure Controls and Procedures*

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

As of September 30, 2017, 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. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our principal executive officer and principal financial and accounting officer have concluded based upon the evaluation described above that, as of September 30, 2017, our disclosure controls and procedures were effective to ensure that information required to be disclosed by it in reports the Company files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC, and that such material information is accumulated and communicated to the Company's management, including its Principal Executive Officer and Principal Financial Officer, to allow timely decisions regarding required disclosure.

#### *Changes in Internal Control over Financial Reporting*

During the three and nine months ended September 30, 2017, 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.

## 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

26

---

### [Table of Contents](#)

Report on Form 10-K for the year ended December 13, 2016 as filed with the SEC on March 31, 2017, 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, 2016, we reported a net loss of \$25.6 million, and had an accumulated deficit of \$100.7 million at December 31, 2016. For the nine months ended September 30, 2017, we reported a net loss of \$23.1 million, and had an accumulated deficit of \$123.8 million at September 30, 2017.

We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate these losses to increase as we continue the research and development of, and seek regulatory approvals for DKN-01 and TRX518, and we potentially begin to commercialize DKN-01 and TRX518, if they receive regulatory approval. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues. If either or both of DKN-01 or TRX518 fails in clinical trials or does not gain regulatory approval, or if approved, fails to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods.

***Our management as of September 30, 2017 has concluded that due to our need for additional capital, and the uncertainties surrounding our ability to raise such funding, substantial doubt exists as to our ability to continue as a going concern.***

Our financial statements for the quarter ended September 30, 2017 were prepared assuming that we will continue as a going concern. The going concern basis of presentation assumes that we will continue in operation for the foreseeable future and will be able to realize our assets and discharge our liabilities and commitments in the normal course of business and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from our inability to continue as a going concern. Our management concluded as of September 30, 2017 that due to our need for additional capital and the uncertainties surrounding our ability to raise such funding, substantial doubt exists as to our ability to continue as a going concern for a period from one year after our financial statements have been issued.

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

***We will require additional capital to fund our operations and if we fail to obtain necessary financing, we may be unable to complete the development and potential commercialization of DKN-01 or TRX518 or acquire other products.***

Our operations have consumed substantial amounts of cash since inception. As of September 30, 2017, we had cash and cash equivalents of \$14.2 million. We expect to continue to spend substantial amounts to advance the clinical development of DKN-01 and TRX518. We will require additional capital for the further development. If we are unable to raise capital when needed or at all, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

27

---

### [Table of Contents](#)

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.

## [Table of Contents](#)

### **EXHIBIT INDEX**

2.1	<a href="#">Agreement and Plan of Merger, dated as of August 29, 2016, among the Registrant, Merger Sub and Macrocore (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).</a>
3.1	<a href="#">Third Amended and Restated Certificate of Incorporation of the Registrant (filed as Exhibit 3.1 to the Registrant's current report on Form 8-K (File No. 001-37990) as filed on January 26, 2017).</a>
3.2	<a href="#">Amended and Restated By-laws of the Registrant (filed as Exhibit 3.4 to the Registrant's registration statement on Form S-4 (File No. 333-213794) as filed on September 26, 2016 and attached as Annex D to the prospectus which forms part of such registration statement).</a>
4.1	<a href="#">Form of Common Stock Certificate of the Registrant (filed as Exhibit 4.1 to Amendment No. 2 to the Registrant's registration statement on Form S-4 (File No. 333-213794) as filed on November 16, 2016).</a>
4.2	<a href="#">Amended and Restated Stockholders' Agreement, between the Registrant and its stockholders, effective as of December 10, 2015 (filed as Exhibit 4.2 to the Registrant's registration statement on Form S-4 (File No. 333-213794) as filed on September 26, 2016).</a>
4.3	<a href="#">Registration Rights Agreement, by and among the Registrant and certain stockholders, dated as of January 23, 2017 (filed as Exhibit 3.1 to the Registrant's current report on Form 8-K (File No. 001-37990) as filed on January 26, 2017).</a>
4.4	<a href="#">Amendment No. 2 to Warrant, by and among Macrocore, the Registrant and certain warrant holders, dated as of January 23, 2017 (filed as Exhibit 4.4 to the Registrant's Annual Report on Form 10-K (File No. 001-37990) as filed on March 31, 2017).</a>
10.1 †	<a href="#">Amended and Restated 2012 Equity Incentive Plan of the Registrant (filed as Exhibit 10.1 to the Registrant's registration statement on Form S-8 (File No. 333-215787) as filed on January 27, 2017).</a>

10.2	<a href="#">Form of Stock Option Grant Notice and Stock Option Agreement under the Registrant's Amended and Restated 2012 Equity Incentive Plan, as amended (filed as Exhibit 10.2 to the Registrant's annual report on Form 10-K (File No. 001-37990) as filed on March 31, 2017).</a>
10.3 †	<a href="#">2016 Equity Incentive Plan of the Registrant (filed as Exhibit 10.2 to the Registrant's registration statement on Form S-8 (File No. 333-215787) as filed on January 27, 2017).</a>

---

[Table of Contents](#)

10.4	<a href="#">Form of Stock Option Grant Notice and Stock Option Agreement under the Registrant's 2016 Equity Incentive Plan, as amended (filed as Exhibit 10.3 to Amendment No. 1 to the Registrant's registration statement on Form S-4 (File No. 333-213794) as filed on November 2, 2016).</a>
10.5	<a href="#">Summary Translation of Macrocare 2008 Stock Option Plan stockholders (filed as Exhibit 10.3 to the Registrant's registration statement on Form S-8 (File No. 333-215787) as filed on January 27, 2017).</a>
10.6	<a href="#">Macrocare 2013 Share Incentive Plan (filed as Exhibit 10.4 to the Registrant's registration statement on Form S-8 (File No. 333-215787) as filed on January 27, 2017).</a>
10.7	<a href="#">Amendment No. 1 to Macrocare 2013 Share Incentive Plan (filed as Exhibit 10.5 to the Registrant's registration statement on Form S-8 (File No. 333-215787) as filed on January 27, 2017).</a>
10.8	<a href="#">Royalty Agreement, between the Registrant and Leap Shareholder Royalty Vehicle, Inc. (filed as Exhibit 10.1 to the Registrant's current report on Form 8-K (File No. 001-37990) as filed on January 26, 2017).</a>
10.9	<a href="#">Letter Agreement, between Leap Shareholder Royalty Vehicle, Inc. and certain of the Registrant's stockholders (filed as Exhibit 10.2 to the Registrant's current report on Form 8-K (File No. 001-37990) as filed on January 26, 2017).</a>
10.10	<a href="#">Subscription Agreement, between the Registrant and HealthCare Ventures IX, L.P., dated as of January 23, 2017 (filed as Exhibit 10.4 to the Registrant's current report on Form 8-K (File No. 001-37990) as filed on January 26, 2017).</a>
10.11	<a href="#">Lease by and between Bulfinch Square Limited Partnership and Healthcare Ventures LLC, dated as of March 31, 2012 amended (filed as Exhibit 10.26 to the Registrant's annual report on Form 10-K (File No. 001-37990) as filed on March 31, 2017)</a>
10.12	<a href="#">Amendment to Lease by and between Bulfinch Square Limited Partnership and Healthcare Ventures LLC, dated as of June 30, 2015 amended (filed as Exhibit 10.27 to the Registrant's annual report on Form 10-K (File No. 001-37990) as filed on March 31, 2017)</a>
10.13	<a href="#">First Amendment to Lease by and between Bulfinch Square Limited Partnership and Healthcare Ventures LLC, dated as of January 4, 2016 amended (filed as Exhibit 10.287 to the Registrant's annual report on Form 10-K (File No. 001-37990) as filed on March 31, 2017)</a>
10.14	<a href="#">Consent to Assignment and Assumption of Lease, by and between Bulfinch Square Limited Partnership, Healthcare Ventures LLC, and Leap Therapeutics, Inc., dated as of December 19, 2016 and Assignment and Assumption Agreement by and between Healthcare Ventures LLC and Leap Therapeutics, Inc., dated as of December 19, 2016 amended (filed as Exhibit 10.29 to the Registrant's annual report on Form 10-K (File No. 001-37990) as filed on March 31, 2017).</a>
31.1 ±	<a href="#">Certification of Principal Executive Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.</a>
31.2 ±	<a href="#">Certification of Principal Financial Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.</a>
32.1 ±**	<a href="#">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.</a>
101 ±	The following materials from Leap Therapeutics, Inc.'s Quarterly Report on Form 10-Q for the quarter ended September 30, 2017, formatted in XBRL (Extensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets at September 30, 2017 and December 31, 2016, (ii) Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2017 and September 30, 2016, (iii) Condensed Consolidated Statements of Comprehensive Loss for the three and nine months ended September 30, 2017 and September 30, 2016, (iv) Condensed Consolidated Statements of Redeemable Convertible Preferred Stock and Shareholders' Equity (Deficit) at September 30, 2017 and December 31, 2016 (v) Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2017 and September 30, 2016, and (v) Notes to Condensed Consolidated Financial Statements, tagged as blocks of text.

† Indicates a management compensatory plan

± 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.

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

LEAP THERAPEUTICS, INC.

Date: November 13, 2017

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

Date: November 13, 2017

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

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

I, Christopher K. Mirabelli, Ph.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Leap Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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) (Paragraph omitted pursuant to SEC release Nos. 33-8238/34-47986 and 33-8392/34-49133);
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's Board of Directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

November 13, 2017

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

Date

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

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

I, Douglas E. Onsi, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Leap Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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) (Paragraph omitted pursuant to SEC release Nos. 33-8238/34-47986 and 33-8392/34-49133);
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's Board of Directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

November 13, 2017

/s/ DOUGLAS E. ONSI

Date

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

---

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

In connection with the Quarterly Report of Leap Therapeutics, Inc. (the "Corporation") on Form 10-Q for the fiscal quarter ended September 30, 2017, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Christopher K. Mirabelli, Ph.D., the President and Chief Executive Officer of the Corporation, and 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 their knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Corporation.

Date: November 13, 2017

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

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

Date: November 13, 2017

By: /s/ DOUGLAS E. ONSI

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

---