

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, DC 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **May 12, 2017**

Leap Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction
of incorporation)

001-37990

(Commission
File Number)

27-4412575

(IRS Employer
Identification No.)

47 Thorndike Street, Suite B1-1

Cambridge, MA

(Address of principal executive offices)

02141

(Zip Code)

Registrant's telephone number, including area code: **(617) 714-0360**

N/A

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter)

Emerging growth company

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

Introductory Comment

Throughout this Current Report on Form 8-K, the terms "Leap", "we," "us," "our" and "Company" refer to Leap Therapeutics, Inc.

Item 2.02. Results of Operations and Financial Condition.

On May 12, 2017, Leap Therapeutics, Inc. issued a press release announcing its financial results for the first quarter ended March 31, 2017 and that an investigator-initiated clinical trial of DKN-01 will be conducted in patients with advanced hepatocellular carcinoma (HCC) at the University Medical Center of the Johannes Gutenberg-University Mainz in Germany. The full text of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

In accordance with General Instruction B.2 of Form 8-K, the information in Item 2.02 of this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 7.01. Regulation FD Disclosure

The disclosure in Item 2.01 of this Current Report on Form 8-K is incorporated herein by reference.

In accordance with General Instruction B.2 of Form 8-K, the information in Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release dated May 12, 2017 issued by Leap Therapeutics, Inc.

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SIGNATURE

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 hereunto duly authorized.

Date: May 12, 2017

LEAP THERAPEUTICS, INC.
(Registrant)

By: /s/ Christopher K. Mirabelli, Ph.D.
Name: Christopher K. Mirabelli, Ph.D.
Title: Chief Executive Officer and President

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EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release dated May 12, 2017 issued by Leap Therapeutics, Inc.

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Leap Therapeutics Reports First Quarter 2017 Financial Results

Company announces investigator-sponsored study of DKN-01 in advanced hepatocellular carcinoma

Cambridge, MA — May 12, 2017 — Leap Therapeutics, Inc. (Nasdaq:LPTX), a biotechnology company developing targeted and immuno-oncology therapeutics, today reported financial results for the first quarter ended March 31, 2017. The company also announced that an investigator-sponsored clinical trial of DKN-01 will be conducted in patients with advanced hepatocellular carcinoma (HCC) at the University Medical Center of the Johannes Gutenberg-University Mainz in Germany.

“The hepatocellular carcinoma study is an important element of our plan to test DKN-01 in genetically-defined cancer populations,” commented Christopher K. Mirabelli, Ph.D, Chief Executive Officer of Leap Therapeutics. “We continue to pursue an aggressive clinical development plan for both of our programs and are highly encouraged by the positive clinical data we presented this quarter.”

“We believe that DKN-01 could be a novel therapy for patients with hepatocellular carcinoma. DKN-01 has shown activity in patients with aberrant Wnt/beta-catenin signaling, a pathway that is frequently mutated in patients with hepatocellular carcinoma. Alterations of this pathway are a driver of hepatocellular carcinoma disease progression,” observed Markus Moehler, M.D., Ph.D, Professor of Gastrointestinal Oncology and Jens Marquardt, M.D., Lichtenberg Professor for Molecular Hepatocarcinogenesis, Johannes-Gutenberg University in Mainz, principal investigators of the study. “There is a lack of effective targeted therapies to offer patients, and we look forward to conducting this clinical study of DKN-01 as a monotherapy and in combination with sorafenib, the only approved therapy in advanced stages of hepatocellular carcinoma.”

Recent Progress

- Presented DKN-01 clinical biomarker data from an esophagogastric cancer clinical study at the ASCO Gastrointestinal Cancers Symposium 2017 detailing Wnt-pathway alterations. An arm has been added to this study to explore a genetically-defined population for DKN-01 development.
- Reported top-line preliminary median progression-free survival data of 9.4 months in Leap’s clinical trial evaluating DKN-01 in combination with standard of care chemotherapy in patients with advanced biliary tract cancers. This data will be presented at the upcoming American Society for Clinical Oncology (ASCO) Annual Meeting 2017.
- Academic collaborators presented an analysis of our clinical data at the 2017 American Association for Cancer Research Annual Meeting demonstrating that TRX518, a GITR agonist monoclonal antibody, has biological activity in patient tumors and can reduce the activity of regulatory T cells, immunosuppressive cells

that prevent the immune system from attacking cancer. Leap presented DKN-01 clinical and non-clinical data at the conference.

- Opened a 20 patient Part B expansion phase of a multi-dose study of TRX518 monotherapy.

Selected First Quarter 2017 Financial Results

Net loss was \$9.4 million for the first quarter of 2017, compared to \$5.1 million for the same period in 2016.

Research and development expenses were \$6.4 million for the first quarter 2017, compared to \$4.1 million for the same period in 2016. This increase was primarily due to increased stock-based compensation expense and clinical development expenses of our clinical product candidates.

General and administrative expenses were \$3.8 million for the first quarter 2017, compared to \$1.1 million for the same period in 2016. This increase was primarily due to increased stock-based compensation expense and legal, finance and administrative expenses to support the company’s transition to public company operations and our transaction with MacroCure Ltd.

Net cash used in operating activities were \$6.3 million for the first quarter 2017, compared to \$4.1 million for the first quarter 2016. This increase was primarily due to increased clinical development expense for our product candidates and administrative, finance and legal expenses associated with public company operations and the transaction with MacroCure Ltd.

Cash, cash equivalents and marketable securities totaled \$23.8 million at March 31, 2017. Research and development incentive receivables totaled \$3.6 million.

About Hepatocellular Carcinoma (HCC)

Hepatocellular carcinoma (HCC), the predominant form of primary liver cancer, is one of the most common solid malignancies, and has emerged as a major cause of cancer-related death worldwide. The National Cancer Institute estimates there will be approximately 40,000 cases of liver and intrahepatic biliary tract cancer in the US this year and 30,000 deaths. To date, very few effective treatment options for hepatocellular carcinoma patients exist and the multityrosine-kinase inhibitor sorafenib is the only available systemic therapy for the management of advanced cases. The survival benefit attributed to sorafenib is only three months. Hepatocellular carcinomas are highly heterogenous and lack actionable mutations in most patients. 20-40% of patients have genetic alterations that lead to activation in Wnt/ β -catenin signaling.

About Leap Therapeutics

Leap Therapeutics' (NASDAQ:LPTX) most advanced clinical candidate, DKN-01, is a humanized monoclonal antibody targeting the Dickkopf-1 (DKK1) protein. DKN-01 is in clinical trials in patients with gastroesophageal cancer, alone and in combination with paclitaxel, and in patients with biliary tract cancer, in combination with gemcitabine and cisplatin. An investigator-initiated study of DKN-01 will be conducted in hepatocellular carcinoma patients, in combination with sorafenib. DKN-01 has demonstrated single agent activity in non-small cell lung cancer patients. Leap's second clinical candidate, TRX518, is a novel, humanized GTR agonist monoclonal antibody designed to enhance the immune system's anti-tumor response that is in two monotherapy studies. For more information about Leap Therapeutics, visit <http://www.leaptx.com> or our public filings with the SEC that are available via EDGAR at <http://www.sec.gov> or via <http://www.investors.leaptx.com/>.

FORWARD LOOKING STATEMENTS

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995, which involve risks and uncertainties. These statements include statements relating to Leap's expectations with respect to the development and advancement of DKN-01, TRX518, and other programs, including the initiation, timing and design of future studies, enrollment in future studies, business development, and other future expectations, plans and prospects. Leap has attempted to identify forward looking statements by such terminology as "believes," "estimates," "anticipates," "expects," "plans," "projects," "intends," "may," "could," "might," "will," "should," or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Although Leap believes that the expectations reflected in such forward-looking statements are reasonable as of the date made, forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from our expectations. These risks and uncertainties include, but are not limited to: the outcome, cost, and timing of our product development activities and clinical trials; the uncertain clinical development process, including the risk that clinical trials may not have an effective design or generate positive results; our ability to obtain and maintain regulatory approval of our drug product candidates; our plans to research, develop, and commercialize our drug product candidates; our ability to achieve market acceptance of our drug product candidates; unanticipated costs or delays in research, development, and commercialization efforts; the applicability of clinical study results to actual outcomes; the size and growth potential of the markets for our drug product candidates; the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for financing; our ability to continue obtaining and maintaining intellectual property protection for our drug product candidates; and other risks. Detailed information regarding factors that may cause actual results to differ materially will be included in Leap Therapeutics' periodic filings with the Securities and Exchange Commission (the "SEC"), including Leap Therapeutics' Form 10-K that Leap filed with the SEC on March 31, 2017. These statements are only predictions and involve

known and unknown risks, uncertainties, and other factors. Any forward looking statements contained in this release speak only as of its date. We undertake no obligation to update any forward-looking statements contained in this release to reflect events or circumstances occurring after its date or to reflect the occurrence of unanticipated events.

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Leap Therapeutics, Inc. Condensed Statement of Operations

	Three Months Ended March 31,	
	2017	2016
	(in thousands)	
Operating expenses:		
Research and development	\$ 6,404	\$ 4,087
General and administrative	3,804	1,056
Total operating expenses	10,208	5,143
Loss from operations	(10,208)	(5,143)
Interest income	50	—
Interest expense - related party	(121)	(113)
Australian research and development incentives	397	—
Foreign currency gains	468	109

Net loss	(9,414)	<u>\$ (5,147)</u>
Accretion of preferred stock to redemption value	(244)	
Net loss attributable to common stockholders	<u>\$ (9,658)</u>	
Net loss per share - basic and diluted	<u>\$ (1.39)</u>	
Weighted average common shares outstanding - basic and diluted	<u>6,945,623</u>	

Leap Therapeutics, Inc.
Condensed Balance Sheet

	March 31, 2017	December 31, 2016
	(in thousands)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 23,800	\$ 793
Research and development incentive receivable	3,167	3,053
Prepaid expenses and other current assets	319	183
Total current assets	<u>27,286</u>	<u>4,029</u>
Property and equipment, net	159	119
Research and development incentive receivable, net of current portion	397	—
Deferred offering costs	—	1,402
Other assets	937	907
Total assets	<u>\$ 28,779</u>	<u>\$ 6,457</u>
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficiency)		
Current liabilities:		
Accounts payable	\$ 2,793	\$ 3,225
Accrued expenses	1,819	2,658
Notes payable and accrued interest - related party	—	30,274
Total current liabilities	<u>4,612</u>	<u>36,157</u>
Commitments and contingencies		
Convertible preferred stock, 0 and 42,500,000 shares authorized as of March 31, 2017 and December 31, 2016		
Series A redeemable convertible preferred stock, \$0.001 par value; 0 and 9,000,000 shares designated as of March 31, 2017 and December 31, 2016, respectively; 0 and 9,000,000 shares issued and outstanding as of March 31, 2017 and December 31, 2016, respectively; liquidation preference of \$0 and \$11,800 as of March 31, 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 March 31, 2017 and December 31, 2016, respectively; 0 and 21,500,000 shares issued and outstanding as of March 31, 2017 and December 31, 2016, respectively; liquidation preference of \$0 and \$28,189 as of March 31, 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 March 31, 2017 and December 31, 2017, respectively; 0 and 11,781,984 shares issued and outstanding as of March 31, 2017 and December 31, 2016, respectively; liquidation preference of \$0 and \$30,542 as of March 31, 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 March 31, 2017 and December 31, 2016, respectively; 9,392,414 and 0 shares outstanding as of March 31, 2017 and December 31, 2016, respectively	9	—
Additional paid-in capital	134,347	145
Accumulated other comprehensive income (loss)	(105)	294
Accumulated deficit	(110,084)	(100,670)
Total stockholders' equity (deficiency)	<u>24,167</u>	<u>(100,231)</u>
Total liabilities, convertible preferred stock and stockholders' equity (deficiency)	<u>\$ 28,779</u>	<u>\$ 6,457</u>

Leap Therapeutics, Inc.
Condensed Statement of Cash Flows

	Three Months Ended March 31,	
	2017	2016
	(in thousands)	
Cash used in operating activities	\$ (6,349)	\$ (4,133)
Cash used in investing activities	(65)	(30)
Cash provided by financing activities	29,848	6,900
Effect of exchange rate changes on cash and cash equivalents	(427)	(11)
Net increase in cash and cash equivalents	<u>23,007</u>	<u>2,726</u>
Cash and cash equivalents at beginning of period	793	405

Cash and cash equivalents at end of period

\$ 23,800

\$ 3,131
