

**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): **March 31, 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))

**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 March 31, 2017, Leap Therapeutics, Inc. issued a press release announcing its financial results for the year ended December 31, 2016 and progression-free survival data in advanced biliary tract cancer. The full text of the press release is attached 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 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 March 31, 2017 issued by Leap Therapeutics, Inc.

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: March 31, 2017

**LEAP THERAPEUTICS, INC.**

(Registrant)

By: /s/ Christopher Mirabelli, Ph.D.

Name: Christopher Mirabelli, Ph.D.

Title: Chief Executive Officer

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**EXHIBIT INDEX**

<b>Exhibit No.</b>	<b>Description</b>
99.1	Press release dated March 31, 2017 issued by Leap Therapeutics, Inc.

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## **Leap Therapeutics Reports Full Year 2016 Financial Results and Progression-Free Survival Data in Advanced Biliary Tract Cancers**

**Cambridge, MA — March 31, 2017** — Leap Therapeutics, Inc. (Nasdaq: LPTX), a biotechnology company developing targeted and immuno-oncology therapeutics, today reported financial results for the year ended December 31, 2016 and top-line progression-free survival (PFS) data.

Preliminary median progression-free survival was 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. The median PFS for standard of care chemotherapy has been reported to be six to eight months. Data from the study has been submitted for presentation at an upcoming medical conference.

“2016 was an important year for Leap. We became a public company and we generated exciting clinical data from our multiple ongoing clinical studies of two innovative cancer therapeutics,” said Christopher K. Mirabelli, Ph.D, Chief Executive Officer of Leap. “We are especially pleased with the PFS observed in patients with biliary cancers and the clinical data from our industry-leading GITR agonist program.”

### About the DKN-01 P103 Clinical Trial

The open-label, dose-escalation study enrolled 27 patients with treatment-naïve advanced biliary tract cancer. Patients received two dose levels of DKN-01 in combination with gemcitabine and cisplatin. The primary objective of this study is to evaluate the safety, pharmacokinetics, and efficacy of DKN-01 in combination with gemcitabine and cisplatin. The study has recently been expanded to enroll an additional 20 patients to enhance biomarker collection and analysis.

### 2016 Accomplishments

- Presented proof of concept clinical data of DKN-01 in advanced biliary tract and esophagogastric cancers with encouraging overall response and disease control rates at meetings of the European Society for Medical Oncology (ESMO), American Society for Clinical Oncology (ASCO), and the Cholangiocarcinoma Foundation.
- Identified Wnt-pathway alterations as a potential genetically-defined population for DKN-01 development
- Developed and presented first observed cases of human pharmacodynamic activity of GITR agonist TRX518 on immunosuppressive T cells.

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- Initiated two repeat-dose TRX518 studies in patients with refractory solid tumors.
  - Commenced trading on the Nasdaq Global Market in January 2017.

### Selected Year-End 2016 Financial Results

Net loss was \$25.6 million for the year ended December 31, 2016, compared to \$12.1 million for the year ended December 31, 2015.

Research and development expenses were \$23.3 million for the full year 2016, compared to \$10.4 million for the same period in 2015. This increase was primarily due to clinical development expenses and manufacturing costs of our clinical product candidates.

General and administrative expenses were \$4.2 million for the full year 2016, compared to \$1.5 million for the same period in 2015. This increase was primarily due to increased personnel and legal expenses to support the company’s expanding operations, including our acquisition of Macrocare Ltd.

The financial results presented for 2016 represent Leap Therapeutics as a private company, as the merger with Macrocare was completed on January 23, 2017. The financial results presented also include an unaudited pro-forma calculation of Leap Therapeutics’ balance sheet to present the merger with Macrocare and the related transactions as if they had closed on December 31, 2016. The financial statements for the first quarter 2017 will reflect the actual transaction closing date and subsequent financial results as a public company.

### 2017 Objectives and Upcoming Presentations

#### DKN-01 Program Objectives

- Extend biomarker clinical studies to include genetically-identified populations in gastric, liver, ovarian, and uterine cancers
- Initiate immunotherapy combination study with PD-1 inhibitor
- Present DKN-01 non-clinical and clinical biomarker data at the 2017 American Association for Cancer Research Annual Meeting
- Present clinical data of DKN-01 in advanced biliary tract and esophagogastric cancers

#### TRX518 Program Objectives

- Complete enrollment of TRX518-003 repeat-dose monotherapy study in patients with refractory solid tumors
- Present TRX518 clinical biomarker data at the 2017 American Association for Cancer Research Annual Meeting

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 in combination with paclitaxel and in patients with biliary tract cancers in combination with gemcitabine and cisplatin. 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. 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.

## CONTACT:

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## Leap Therapeutics, Inc. Condensed Statement of Operations

	(Amount in thousands)	
	2016	2015
Operating expenses:		
Research and development	\$ 23,292	\$ 10,411
General and administrative	4,229	1,511
Total operating expenses	27,521	11,922
Loss from operations	(27,521)	(11,922)
Interest income	2	1
Interest expense - related party	(1,233)	(129)
Other income (expense), net	3,120	—
Net loss	(25,632)	(12,050)
Other comprehensive loss:		
Foreign currency translation adjustments	295	(1)

Comprehensive loss	\$	(25,337)	\$	(12,051)
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Leap Therapeutics, Inc.  
Condensed Balance Sheet

(Amount in thousands)  
December 31,

2016 2015

**Assets**

Current assets:

Cash and cash equivalents	\$	793	\$	405
Research and development incentive receivable		3,053		—
Prepaid expenses and other current assets		183		89
Total current assets		4,029		494

Property and equipment, net		119		—
Deferred offering costs		1,402		—
Other assets		907		766
Total assets	\$	6,457	\$	1,260

**Liabilities, Convertible Preferred Stock and Stockholders' Deficiency**

Current liabilities:

Accounts payable	\$	3,225	\$	2,048
Accrued expenses		2,658		479
Notes payable and accrued interest - related party		30,274		3,141
Total current liabilities		36,157		5,668

Total stockholders' equity		(29,700)		(4,408)
Total liabilities and stockholders' equity	\$	6,457	\$	1,260

Leap Therapeutics, Inc.  
Condensed Statement of Cash Flows

(Amount in thousands)  
Year Ended December 31,

2016 2015

Cash flows from operating activities:		(25,337)		(8,102)
Cash flows from investing activities:		(144)		—
Cash flows from financing activities:		25,618		8,270
Effect of exchange rate changes on cash and cash equivalents		251		(1)
Net increase (decrease) in cash and cash equivalents		388		167
Cash and cash equivalents at beginning of period		405		238
Cash and cash equivalents at end of period	\$	793	\$	405