

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 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): **November 13, 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.

**Item 2.02. Results of Operations and Financial Condition**

On November 13, 2017, Leap Therapeutics, Inc. (the "Company") announced its financial results for the quarter ended September 30, 2017. The full text of the press release issued by the Company in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained herein and in the accompanying exhibit shall not be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing, unless expressly incorporated by specific reference to such filing. The information in this Current Report on Form 8-K, including the information set forth under this Item 2.02 and the exhibit hereto, shall not be

deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended.

**Item 9.01. Financial Statements and Exhibits.**

**(d) Exhibits.**

Exhibit Number	Description
99.1	<a href="#">Press Release of Leap Therapeutics, Inc. dated November 13, 2017.</a>

**SIGNATURES**

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

**LEAP THERAPEUTICS, INC.**

Dated: November 13, 2017

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



## Leap Therapeutics Reports Third Quarter 2017 Financial Results and Announces First Patient Dosed with DKN-01 and KEYTRUDA® (pembrolizumab) in Esophagogastric Cancer Trial

**Cambridge, MA — November 13, 2017** — Leap Therapeutics, Inc. (Nasdaq:LPTX), a biotechnology company developing targeted and immuno-oncology therapeutics, today reported financial results for the third quarter ended September 30, 2017. Leap additionally announced that the first patient has been dosed in a Phase 1/2 clinical trial evaluating Leap's DKK1 antagonist, DKN-01, in combination with Merck's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab), in patients with relapsed or refractory advanced esophagogastric adenocarcinoma.

"The use of checkpoint inhibitors has generated exciting responses in a minority of patients with advanced relapsed or recurrent esophagogastric cancer. We are hopeful that the addition of DKN-01 to pembrolizumab will expand the clinical benefit without added toxicity," commented Dr. Samuel Klempner, Director of Precision Medicine at The Angeles Clinic and Research Institute and an investigator on the study.

"We have continued to advance development of both of our pipeline assets as we aim to build a world-class immuno-oncology company. This quarter we reported promising clinical activity for both assets and have begun the process to launch clinical studies exploring novel therapeutic combinations in targeted patient populations," commented Christopher K. Mirabelli, Ph.D, President and Chief Executive Officer of Leap Therapeutics. "The combination study of DKN-01 with pembrolizumab in esophagogastric cancer is the first example of this strategy. We are eager to explore the complementary mechanism of action of DKN-01 and checkpoint inhibitors to enhance anti-tumor immune responses."

The P102 esophagogastric cancer study is a multipart study evaluating DKN-01 as a monotherapy and in combination with paclitaxel or pembrolizumab in patients with advanced relapsed or refractory esophagogastric cancer. The combination arm evaluating DKN-01 with pembrolizumab includes both dose escalation and dose confirmation cohorts and is designed to evaluate the safety, pharmacokinetics and efficacy of the combination in patients with esophagogastric adenocarcinoma. The DKN-01+pembrolizumab study will enroll up to approximately 67 patients. The dose confirmation cohort (n=55) will include patients that are naïve (n=40) or refractory (n=15) to PD-1/ PD-L1 antagonists.

### Recent Highlights

#### DKN-01:

- Announced updated clinical efficacy data from the P102 clinical trial evaluating

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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 one 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.

#### 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, 26% had progressive disease, and 24% 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.

### Selected Third Quarter 2017 Financial Results

Net loss was \$6.8 million for the third quarter of 2017, compared to \$7.3 million for the same period in 2016.

Research and development expenses were \$6.8 million for the third quarter 2017, compared to \$5.7 million for the same period in 2016. This increase was primarily due to increased clinical trial expenses.

General and administrative expenses were \$1.8 million for the third quarter 2017, compared to \$1.4 million for the same period in 2016. This increase was primarily due to an increase in stock based compensation expense and increased headcount needed to support public company operations.

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Cash, cash equivalents and marketable securities totaled \$14.2 million at September 30, 2017. Research and development incentive receivables totaled \$1.9 million.

## About Leap Therapeutics

Leap Therapeutics (Nasdaq:LPTX) is developing targeted and immuno-oncology therapeutics. Leap's most advanced clinical candidate, DKN-01, is a humanized monoclonal antibody targeting the Dickkopf-1 (DKK1) protein, a Wnt pathway modulator. DKN-01 is in clinical trials in patients with esophagogastric cancer and biliary tract cancer, with an emerging focus on patients with defined mutations of the Wnt pathway and in combinations with immune checkpoint inhibitors. 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 accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for financing; the ability to complete a financing or form business development relationships to fund our expenses; 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;

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.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA.

TECENTRIQ® (atezolizumab) is a registered trademark of Genentech, a member of the Roche Group.

## CONTACT:

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## Leap Therapeutics, Inc

### Condensed Consolidated Statement of Operations (unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
	(in thousands)		(in thousands)	
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	8,582	7,028	25,806	19,365
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	(6,815)	<u>\$ (7,277)</u>	(23,134)	<u>\$ (19,901)</u>
Accretion of preferred stock to redemption value	—		(244)	
Net loss attributable to common stockholders	<u>\$ (6,815)</u>		<u>\$ (23,378)</u>	
Net loss per share - basic and diluted	<u>\$ (0.73)</u>		<u>\$ (2.72)</u>	
Weighted average common shares outstanding - basic and diluted	<u>9,395,920</u>		<u>8,584,558</u>	

Leap Therapeutics, Inc

Condensed Consolidated Balance Sheet

	September 30, 2017 (unaudited)	December 31, 2016
	(in thousands)	
<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, 2016, 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>

Leap Therapeutics, Inc

Condensed Consolidated Statement of Cash Flows

(unaudited)

	<u>Nine Months Ended September 30,</u>	
	<u>2017</u>	<u>2016</u>
	<u>(in thousands)</u>	
<b>Cash used in operating activities</b>	\$ (15,768)	\$ (18,040)
<b>Cash used in investing activities</b>	(64)	(136)
<b>Cash provided by financing activities</b>	29,868	18,900
<b>Effect of exchange rate changes on cash and cash equivalents</b>	(626)	(164)
<b>Net increase in cash and cash equivalents</b>	<u>13,410</u>	<u>560</u>
Cash and cash equivalents at beginning of period	<u>793</u>	<u>405</u>
Cash and cash equivalents at end of period	<u>\$ 14,203</u>	<u>\$ 965</u>

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