

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): March 12, 2018

**IOVANCE BIOTHERAPEUTICS, INC.**

(Exact Name of Registrant as Specified in Charter)

Delaware

(State of Incorporation)

001-36860

Commission File Number

75-3254381

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

999 Skyway Road, Suite 150  
San Carlos, California

(Address of Principal Executive Offices)

94070

(Zip Code)

(650) 260-7120

(Registrant's Telephone Number, Including Area Code)

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:

- 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 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 March 12, 2018, the Company issued a press release announcing its financial results for the fourth quarter and fiscal year ended December 31, 2017 and an update on recent developments. A copy of that press release is furnished as Exhibit 99.1 and is incorporated by reference herein.

The information furnished under this Item 2.02, including the accompanying Exhibit 99.1, shall not be deemed to be “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”), or otherwise subject to the liability of such section, nor shall such information be deemed to be incorporated by reference in any subsequent filing by the Company under the Securities Act of 1933 or the Exchange Act, regardless of the general incorporation language of such filing, except as specifically stated in such filing.

**Item 9.01 Financial Statements And Exhibits**

(d) Exhibits.

<b>Exhibit No.</b>	<b>Description</b>
<a href="#">99.1</a>	<a href="#">Press Release of Iovance Biotherapeutics, Inc., dated March 12, 2018.</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.

Date: March 12, 2018

**IOVANCE BIOTHERAPEUTICS, INC.**

By: /s/ MARIA FARDIS  
Maria Fardis, Chief Executive Officer



**Iovance Biotherapeutics Reports Fourth Quarter and Full-Year 2017 Financial Results  
and Provides Corporate Update**

- Company to Host Conference Call at 4:30pm ET Today -

**SAN CARLOS, CA – March 12, 2018** -- Iovance Biotherapeutics, Inc. (NASDAQ: IOVA), a biotechnology company developing novel cancer immunotherapies based on tumor-infiltrating lymphocyte (TIL) technology, today reported its fourth quarter and year-end 2017 financial results and provided a corporate update.

“We ended 2017 having completed significant accomplishments involving both manufacturing and clinical aspects of development of TIL as a viable commercial therapy. We developed a new manufacturing method, lasting 22 days and yielding a cryopreserved product, conducted a clinical study investigating the efficacy of this method, reported preliminary data showing responses from this generation 2 manufacturing method in late-line metastatic melanoma patients and subsequently selected this manufacturing method for all ongoing and future clinical trials for Iovance. We have also expanded our manufacturing capacity in the US, in commercial-ready suites, and built out our capacity in the EU. On the clinical front, we are currently running four studies to evaluate the potential breadth of utility of TIL therapy in multiple indications,” said Dr. Maria Fardis, Ph.D., MBA, president and chief executive officer of Iovance Biotherapeutics. “In early 2018, we successfully completed a common stock public offering adding approximately \$162 million in net proceeds to the cash reserves. The proceeds from this public offering, combined with the year-end cash balance, puts us in a strong position to execute on our upcoming milestones.”

**2017 Achievements and 2018 Updates**

**Manufacturing**

- Completed development of the generation 2 manufacturing method and the associated technology transfer into multiple CMOs in the US and the EU.
  - Entered into a new three-year Manufacturing Services Agreement (MSA) with PharmaCell B.V., now a subsidiary of Lonza Group Ltd., in the Netherlands to support EU manufacturing. PharmaCell is now able to receive clinical samples and manufacture TIL therapy for patients.
  - Entered into a new two-year MSA with H. Lee Moffitt Cancer Center and Research Institute (Moffitt).
  - Commenced a partnership with TrakCel Ltd. to build a scheduling and logistics software tool that automates the supply chain for the company’s TIL therapy.
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## Clinical

- Presented clinical data from the first cohort of the company's Phase 2 trial investigating LN-144 for the treatment of patients with metastatic melanoma, known as C-144-01, at the 2017 ASCO Annual Meeting in June.
- Began patient dosing in the second cohort of C-144-01 and reported preliminary data at the SITC Annual Meeting in November.
- Began patient dosing in C-145-03, the company's Phase 2 trial of LN-145 for the treatment of patients with recurrent and/or metastatic squamous cell carcinoma of the head and neck and reported preliminary data from this study in January 2018.
- Began patient dosing in C-145-04, the company's Phase 2 trial of LN-145 for the treatment of patients with recurrent, metastatic or persistent cervical carcinoma and provided early response data from evaluable patients in early 2018 as well.
- Entered into a new clinical grant agreement with Moffitt to provide funding for a clinical study of TIL therapy in non-small cell lung cancer (NSCLC) and Moffitt began patient enrollment in this study in patients with advanced NSCLC cancer combining TIL and nivolumab in patients who have progressed on nivolumab.
- First site was activated in the Iovance IOV-LUN-201 study to treat checkpoint naïve patients with NSCLC.
- Entered into a multi-year strategic alliance with M.D. Anderson.
- First clinical site was activated in Europe for the C-144-01 melanoma study.

## Regulatory

- Received Fast Track designation in the U.S. for LN-144 for the treatment of advanced melanoma.
- Submitted Clinical Trial Applications in multiple countries in Europe in support of the company's Phase 2 clinical trials and received multiple approvals to commence clinical trials in Europe.

## Research

- Entered into a collaboration with the Ohio State University Comprehensive Cancer Center – Arthur G. James Cancer Hospital and Richard J. Solove Research Institute to evaluate TILs, marrow infiltrating lymphocytes (MILs), and peripheral-blood associated lymphocytes in acute myeloid leukemia (AML) and chronic lymphocytic leukemia (CLL).
- Late-breaking abstract, titled *Anti-OX40 agonistic antibody enhances ex vivo CD8+ TIL expansion with increased T-cell effector function*, accepted for presentation at the American Association for Cancer Research Annual Meeting 2018. The poster will be available on April 16, 2018.

## Corporate

- Changed corporate name from Lion Biotechnologies, Inc. to Iovance Biotherapeutics, Inc. and reincorporated from a Nevada corporation to a Delaware corporation.
  - Appointed Timothy E. Morris as the company's chief financial officer in August 2017.
  - Raised approximately \$53.7 million in net proceeds, after deducting underwriting discounts and offering expenses, through a public offering that closed in September 2017.
  - In January 2018, the company closed an underwritten public offering of 15,000,000 shares of its common stock at a public offering price of \$11.50 per share, before underwriting discounts. The shares sold at closing included 1,956,521 shares issued upon the exercise in full by the underwriter of its option to purchase additional shares at the public offering price less the underwriting discount. The gross proceeds from the offering, before deducting the underwriting discounts and commissions and other estimated offering expenses payable by the company, were \$172.5 million with estimated net proceeds to the company of approximately \$161.7 million.
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## **Fourth Quarter and Full-Year 2017 Financial and Operating Results**

At December 31, 2017, the company held \$145.4 million in cash, cash equivalents and short-term investments, compared to \$166.5 million at December 31, 2016. Net cash used in operating activities was \$78.7 million during the year ended December 31, 2017.

Iovance anticipates cash, cash equivalents and investments to be between \$190 million and \$210 million at December 31, 2018.

The company is providing both GAAP and non-GAAP financial information. All non-GAAP information excludes amounts related to stock-based compensation. See "Use of Non-GAAP Financial Measures" below for a description of the company's non-GAAP Financial Measures. Reconciliation between certain GAAP and non-GAAP measures is provided at the end of this press release.

### ***GAAP and Non-GAAP Net Loss Attributable to Common Stockholders***

GAAP net loss attributable to common stockholders for the quarter ended December 31, 2017 was \$25.9 million, or \$0.36 per share, compared to GAAP net loss of \$15.7 million or \$0.25 per share for the quarter ended December 31, 2016.

Non-GAAP net loss attributable to common stockholders for the quarter ended December 31, 2017 was \$23.1 million, or \$0.32 per share, compared to \$12.6 million, or \$0.20 per share for the quarter ended December 31, 2016. The non-GAAP net loss for the quarters ended December 31, 2017 and 2016 excludes \$2.8 million and \$3.1 million of non-cash stock-based compensation, respectively.

GAAP net loss attributable to common stockholders for the year ended December 31, 2017 was \$92.1 million, or \$1.41 per share, compared to \$102.3 million or \$1.85 per share for the year ended December 31, 2016. The 2016 GAAP net loss attributable to common stockholders included a one-time deemed dividend related to a charge of \$49.5 million incurred because of the conversion feature of the Series B convertible preferred stock. Non-GAAP net loss for the year ended December 31, 2017 was \$80.1 million, or \$1.23 per share, compared to non-GAAP net loss of \$34.0 million or \$0.62 per share for the year ended December 31, 2016. The non-GAAP net loss for the years ended December 31, 2017 and 2016 excludes \$12.0 million and \$18.9 million of non-cash stock-based compensation, respectively. The 2016 non-GAAP net loss also excludes the one-time charge of \$49.5 million related to the deemed dividend.

### ***GAAP and Non-GAAP Expenses***

GAAP research and development (R&D) expenses were \$20.7 million for the quarter ended December 31, 2017, an increase of \$10.6 million compared to \$10.1 million for the quarter ended December 31, 2016. The increase in R&D expenses is due to increased spending on clinical activities and manufacturing. R&D associated stock-based compensation expense was \$0.9 million for the three months ended December 31, 2017 and \$1.5 million for the three months ended December 31, 2016. Non-GAAP R&D expenses were \$19.8 million for the quarter ended December 31, 2017, an increase of \$11.1 million, compared to \$8.7 million for the quarter ended December 31, 2016.

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GAAP general and administrative (G&A) expenses were \$5.4 million for the quarter ended December 31, 2017, a decrease of \$0.5 million compared to \$5.8 million for the quarter ended December 31, 2016. G&A associated stock-based compensation expense was \$1.8 million for the three months ended December 31, 2017 and \$1.7 million for the three months ended December 31, 2016. Non-GAAP G&A expenses were \$3.5 million for the quarter ended December 31, 2017, a decrease of \$0.6 million, compared to \$4.1 million for the quarter ended December 31, 2016.

### **Use of Non-GAAP Financial Measures**

This press release contains non-GAAP financial measures, including expenses adjusted to exclude certain non-cash expenses. These measures are not in accordance with, or an alternative to, generally accepted accounting principles (GAAP), and may be different from non-GAAP financial measures used by other companies. The items included in GAAP presentations but excluded for purposes of determining non-GAAP financial measures for the periods presented in this press release are: (i) the non-cash stock-based compensation expense which may fluctuate from period-to-period based on factors including the timing and accounting of grants for stock options and changes in the company's stock price which impacts the fair value of options granted, and (ii) the one-time non-cash deemed dividend related to the conversion feature of the Series B Preferred Stock. The company believes the presentation of non-GAAP financial measures provides useful information to management and investors regarding various financial and business trends relating to the company's financial condition and results of operations. When GAAP financial measures are viewed in conjunction with non-GAAP financial measures, investors are provided with a more meaningful understanding of Iovance's ongoing operating performance. In addition, these non-GAAP financial measures are among those indicators the company uses as a basis for evaluating operational performance, allocating resources and planning and forecasting future periods. Non-GAAP financial measures are not intended to be considered in isolation or as a substitute for GAAP financial measures. To the extent this release contains historical or future non-GAAP financial measures, the company has also provided corresponding GAAP financial measures for comparative purposes. Reconciliation between certain GAAP and non-GAAP measures is provided at the end of this press release. Beginning in 2018, Iovance will no longer report non-GAAP expenses or non-GAAP net loss per share.

### **Webcast and Conference Call**

Iovance will host a conference call today at 4:30 p.m. ET to discuss these fourth quarter and full-year 2017 results and provide a corporate update. The conference call dial-in numbers are: 1-844-646-4465 (domestic) or 1-615-247-0257 (international). The conference ID access number for the call is 1497629. The live webcast can be accessed under "News & Events" in the "Investors" section of the company's website at <http://www.iovance.com/> or you may use the link: <https://edge.media-server.com/m6/p/qiinketi>.

A replay of the call will be available from March 12, 2018 at 7:30 p.m. ET to April 18, 2018 at 8:30 p.m. ET. To access the replay, please dial 1-855-859-2056 (domestic) or 1-404-537-3406 (international). The conference ID number for the replay is 1497629. The archived webcast will be available for thirty days in the Investors section of Iovance Biotherapeutics' website at <http://www.iovance.com>.

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**About Iovance Biotherapeutics, Inc.**

Iovance Biotherapeutics, Inc. is a clinical-stage biotechnology company focused on the development of cancer immunotherapy products for the treatment of various cancers. The company's lead product candidate is an adoptive cell therapy using tumor-infiltrating lymphocyte (TIL) technology being investigated for the treatment of patients with metastatic melanoma, recurrent and/or metastatic squamous cell carcinoma of the head and neck, recurrent, metastatic or persistent cervical cancer, and locally advanced or metastatic non-small cell lung cancer. For more information, please visit <http://www.iovance.com>.

**Forward-Looking Statements**

Certain matters discussed in this press release are "forward-looking statements". We may, in some cases, use terms such as "predicts," "believes," "potential," "continue," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. In particular, the company's statements regarding trends and potential future results are examples of such forward-looking statements. These forward-looking statements include, but are not limited to, the success, timing and cost of our ongoing clinical trials and anticipated clinical trials for our current product candidates, including statements regarding the timing of initiation and completion of the trials; the timing of and our ability to obtain and maintain U.S. Food and Drug Administration or other regulatory authority approval of, or other action with respect to, our product candidates; the strength of company's product pipeline; the successful implementation of the company's research and development programs and collaborations; the success of the company's license or development agreements; the acceptance by the market of the company's product candidates, if approved; the future amount of the company's cash, cash equivalents and investments; and other factors, including general economic conditions and regulatory developments, not within the company's control. The factors discussed herein could cause actual results and developments to be materially different from those expressed in or implied by such statements. A further list and description of the company's risks, uncertainties and other factors can be found in the company's most recent Annual Report on Form 10-K and the company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at [www.sec.gov](http://www.sec.gov) or [www.iovance.com](http://www.iovance.com). The forward-looking statements are made only as of the date of this press release and the company undertakes no obligation to publicly update such forward-looking statements to reflect subsequent events or circumstance.

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**Iovance Biotherapeutics, Inc.**  
**Selected Consolidated Balance Sheet Data**  
(unaudited; in thousands)

	<i>December 31,</i> <i>2017</i>		<i>December 31,</i> <i>2016</i>	
Cash, cash equivalents and short-term investments	\$	145,373	\$	166,470
Total assets	\$	155,373	\$	171,886
Stockholders' equity	\$	145,481	\$	166,918

**Condensed Consolidated Statements of Operations**  
(unaudited; in thousands, except per share data)

	<b>For the Three Months Ended</b> <b>December 31,</b>		<b>Year Ended</b> <b>December 31,</b>	
	<b>2017</b>	<b>2016</b>	<b>2017</b>	<b>2016</b>
<b>Revenues</b>	\$ -	\$ -	\$ -	\$ -
<b>Costs and expenses*</b>				
Research and development	20,696	10,119	71,615	26,941
General and administrative	5,375	5,804	21,262	26,698
Total costs and expenses	<u>26,071</u>	<u>15,923</u>	<u>92,877</u>	<u>53,639</u>
<b>Loss from operations</b>	(26,071)	(15,923)	(92,877)	(53,639)
<b>Other income</b>				
Interest income	217	234	813	745
<b>Net Loss</b>	<u>\$ (25,854)</u>	<u>\$ (15,689)</u>	<u>\$ (92,064)</u>	<u>\$ (52,894)</u>
Deemed dividend related to beneficial conversion feature of convertible preferred stock	-	-	-	(49,454)
<b>Net Loss Attributable to Common Stockholders</b>	<u>(25,854)</u>	<u>(15,689)</u>	<u>(92,064)</u>	<u>(102,348)</u>
<b>Net Loss Per Common Share, Basic and Diluted</b>	<u>\$ (0.36)</u>	<u>\$ (0.25)</u>	<u>(1.41)</u>	<u>\$ (1.85)</u>
<b>Weighted-Average Common Shares Outstanding, Basic and Diluted</b>	<u>72,794</u>	<u>62,130</u>	<u>65,242</u>	<u>55,268</u>
<b>* Includes stock-based compensation as follows</b>				
Research and development	\$ 934	\$ 1,449	5,270	\$ 3,267
General and administrative	1,826	1,674	6,698	15,637
	<u>\$ 2,760</u>	<u>\$ 3,123</u>	<u>11,968</u>	<u>\$ 18,904</u>

**Iovance Biotherapeutics, Inc. <sup>(1)</sup>**  
**Reconciliation of Selected GAAP Measures to Non-GAAP**  
(unaudited; in thousands, except per share data)

	Three Months Ended December 31,		Year Ended December 31,	
	2017	2016	2017	2016
<b>Reconciliation of GAAP to non-GAAP Research and development</b>				
GAAP Research and development	\$ 20,696	\$ 10,119	\$ 71,615	\$ 26,941
Less:				
Non-cash stock-based compensation <sup>(2)</sup>	(934)	(1,449)	(5,270)	(3,267)
Non-GAAP Research and development	<u>\$ 19,762</u>	<u>\$ 8,670</u>	<u>\$ 66,345</u>	<u>\$ 23,674</u>
<b>Reconciliation of GAAP to non-GAAP General and administrative</b>				
GAAP General and administrative	\$ 5,375	\$ 5,804	\$ 21,262	\$ 26,698
Less:				
Non-cash stock-based compensation <sup>(2)</sup>	(1,826)	(1,674)	(6,698)	(15,637)
Non-GAAP General and administrative	<u>\$ 3,549</u>	<u>\$ 4,130</u>	<u>\$ 14,564</u>	<u>\$ 11,061</u>
<b>Non-GAAP Net loss attributable to common stockholders reconciliation</b>				
GAAP Net loss attributable to common stockholders	\$ (25,854)	\$ (15,689)	\$ (92,064)	\$ (102,348)
Add back:				
Non-cash stock-based compensation <sup>(2)</sup>	2,760	3,123	11,968	18,904
Non-cash Deemed dividend related to beneficial conversion feature of convertible preferred stock <sup>(3)</sup>	-	-	-	49,454
Non-GAAP Net loss attributable to common stockholders	<u>\$ (23,094)</u>	<u>\$ (12,566)</u>	<u>\$ (80,096)</u>	<u>\$ (33,990)</u>
<b>Non-GAAP net loss per share reconciliation</b>				
GAAP net loss per common share, basic and diluted:	\$ (0.36)	\$ (0.25)	\$ (1.41)	\$ (1.85)
Add back:				
Non-cash stock-based compensation <sup>(2)</sup>	0.04	0.05	0.18	0.34
Non-cash Deemed dividend related to beneficial conversion feature of convertible preferred stock <sup>(3)</sup>	-	-	-	0.89
Non-GAAP net loss per common share, basic and diluted	<u>\$ (0.32)</u>	<u>\$ (0.20)</u>	<u>\$ (1.23)</u>	<u>\$ (0.62)</u>
<b>Weighted-Average Common Shares Outstanding, Basic and Diluted</b>	<u>72,794</u>	<u>62,130</u>	<u>65,242</u>	<u>55,268</u>

(1) This presentation includes non-GAAP measures. The company's non-GAAP measures are not meant to be considered in isolation or as a substitute for comparable GAAP measures and should be read only in conjunction with its financial statements prepared in accordance with GAAP.

(2) All stock-based compensation was excluded for the non-GAAP analysis.

(3) The deemed dividend related to the conversion feature of the Series B Preferred Stock was excluded for non-GAAP analysis.

