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): February 26, 2019

IOVANCE BIOTHERAPEUTICS, INC.

(Exact Name of Registrant as Specified in Charter)

Delaware	
(State of Incorporation)	
001-36860	**75-3254381**
Commission File Number	**(I.R.S. Employer Identification No.)**
999 Skyway Road, Suite 150 **San Carlos, California**	**94070**
(Address of Principal Executive Offices)	**(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 February 27, 2019, Iovance Biotherapeutics, Inc. (the "Company") issued a press release announcing its financial results for the fourth quarter and fiscal year ended December 31, 2018 and an update on recent developments. A copy of that press release is furnished as Exhibit 99.1.

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 8.01. Other Events.

On February 26, 2019, the Company issued a press release announcing the granting of Fast Track designation by the U.S. Food and Drug Administration for its candidate LN-145 for the treatment of patients with recurrent, metastatic or persistent cervical cancer who have progressed while on or after chemotherapy. A copy of the press release is attached hereto as Exhibit 99.2 and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release of Iovance Biotherapeutics, Inc., dated February 27, 2019.
99.2	Press Release of Iovance Biotherapeutics, Inc., dated February 26, 2019.

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: February 27, 2019

IOVANCE BIOTHERAPEUTICS, INC.

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

Exhibit 99.1

Iovance Biotherapeutics Reports Fourth Quarter and Full-Year 2018 Financial Results and Provides Corporate Update

- Patient Enrollment Commenced in the Registrational Cohort 4 in Study of Lifileucel in Advanced Melanoma -

- FDA Granted Fast Track Designation for LN-145 for Treatment of Patients with Recurrent, Metastatic or Persistent Cervical Cancer -

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

SAN CARLOS, CA, February 27, 2019 -- 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 2018 financial results and provided a corporate update.

"Over the past year, we took great strides forward in our goal of advancing TIL therapy towards approval in multiple indications and bringing this one-time treatment to patients who have progressed through existing treatment options," commented Maria Fardis, Ph.D., MBA, president and chief executive officer of Iovance Biotherapeutics. "We reported clinical results for our lead program in metastatic melanoma, received acknowledgement from the FDA on a defined path to approval with a single-arm study and have firmly established our optimized, scalable, 22-day manufacturing process. We are well financed to complete the registration-enabling study, Cohort 4, and file the Biologics License Application (BLA) in 2020 for lifileucel. The regenerative medicine advanced therapy (RMAT) designation we received this past year for lifileucel allows for close coordination with the FDA as we move forward. Now that we have demonstrated compelling data in post PD-1 melanoma patients and have received regulatory clarity, we continue our development work in additional indications, such as cervical, while preparing to build internal manufacturing capabilities. Our goals for 2019 will further propel Iovance towards registration and commercialization of TIL therapy."

2018 Highlights

Clinical

- New data from Cohort 2 of lifileucel in the treatment of metastatic melanoma study (C-144-01) was presented in poster and oral presentations at the Society for Immunotherapy of Cancer (SITC) 33rd Annual Meeting in November 2018. The presentation described results from 47 consecutively dosed, post PD-1 patients with an objective response rate (ORR) of 38%.[1] The most common treatment emergent adverse events observed in this cohort include thrombocytopenia, chills, neutropenia, febrile neutropenia and anaemia.
- In the Phase 2 study of LN-145 for cervical carcinoma (C-145-04) preliminary data was reported in October 2018 for 15 patients yielding an ORR of 27%. Patients in the study had a median of five prior therapies. The safety findings from this study remained consistent with previous reports.

Regulatory

- In May 2018, the company was granted orphan drug designation from the U.S. Food and Drug Administration (FDA) for autologous tumor infiltrating lymphocytes for the treatment of cervical cancer with a tumor size of greater than 2 cm in diameter.
- In September 2018, the company received the Regenerative Medicine Advanced Therapy (RMAT) designation from the FDA for lifileucel for the treatment of patients with metastatic melanoma.
- In September 2018, the company held an end of Phase 2 meeting with the FDA during which the agency acknowledged that a single-arm cohort as part of the C-144-01 study can be supportive of initial registration of lifileucel.

Research

- Under a collaboration with Ohio State University, Iovance has developed a product candidate called peripheral blood lymphocytes (PBL). The company anticipates filing an IND for PBL in hematological indications in 2019.

Corporate

- The company completed two underwritten public offerings in 2018 raising approximately $400 million.

2019 Updates

Clinical

- The protocol for the metastatic melanoma study (C-144-01) was amended based on FDA feedback. The trial sites are in process of re-activation for Cohort 4, which is expected to enroll 75 patients. Patient enrollment has commenced.
- The last patient was enrolled in Cohort 2 of the metastatic melanoma study in the fourth quarter of 2018. The company anticipates providing an update on the full cohort of patients at a medical meeting in 2019.
- The protocol for the cervical carcinoma study has been amended to limit the number of prior therapies to no more than three and to exclude patients who have been treated with prior immunotherapy. The company anticipates providing an update on this study at an upcoming medical meeting in 2019.
- The company has dosed over 100 patients with the Gen 2 manufacturing product across multiple studies.

Regulatory

- In February 2019, the company was granted Fast Track designation from the FDA for treatment of patients with recurrent, metastatic, or persistent cervical cancer patients who have progressed while on or after chemotherapy.

Research

- An abstract titled “Persistence of cryopreserved tumor-infiltrating lymphocyte product lifileucel (LN-144) in C-144-01 study of advanced metastatic melanoma” was accepted for presentation at the upcoming American Association for Cancer Research (AACR) meeting March 29-April 3, 2019.

Fourth Quarter 2018 Financial Results

Net loss for the fourth quarter 2018 was $32.6 million, or $0.27 per share, compared to net loss of $25.9 million or $0.36 per share for the fourth quarter 2017.

Research and Development expenses were $27.4 million for the fourth quarter 2018, an increase of $6.7 million compared to $20.7 million for the quarter ended December 31, 2017. The increase in Research and Development expenses is attributable to; an increase in Research and Development staff and the related compensation expense, an increase in clinical trial and manufacturing costs due to the initiation of clinical trials in 2018 for new indications and increased number of patients enrolled across all the studies.

General and administrative expenses were $7.5 million for the fourth quarter 2018, an increase of $2.1 million compared to $5.4 million for the fourth quarter ended 2017. The increase in General and Administrative expenses was primarily attributable to an increase in General and Administrative headcount and related compensation expenses and an increase in external professional service fees.

Full Year 2018 Financial Results

Net loss for the year ended December 31, 2018 was $123.6 million, or $1.27 per share, compared to $92.1 million or $1.41 per share for the year ended December 31, 2017.

Research and Development expenses were $99.8 million for the year ended December 31, 2018, an increase of $28.2 million compared to $71.6 million for 2017. The increase was primarily attributable to an increase in payroll and related expenses, including stock-based compensation expenses, due to a higher number of full-time employees and dedicated consultants as we expanded our internal research efforts and clinical development programs. Further, clinical trial costs increased due to; higher patient enrollment and an increase in the number of clinical sites for lifileucel and LN-145.

General and Administrative expenses were $28.4 million for the year ended December 31, 2018, an increase of $7.1 million compared to $21.3 million for 2017. The increase was primarily attributable to an increase in payroll and related expenses, including stock-based compensation expenses, driven by a higher number of full-time employees and higher stock prices during 2018, and an increase in external professional service fees including preparation and filing of patents.

Cash, Cash Equivalents and Short-term Investments

At December 31, 2018, the company held $468.5 million in cash, cash equivalents and short-term investments, compared to $145.4 million at December 31, 2017. Net cash used in operating activities was $101.2 million during the year ended December 31, 2018.

Iovance anticipates cash, cash equivalents and investments to be between $310 million and $320 million at December 31, 2019.

Webcast and Conference Call

Iovance will host a conference call and live audio webcast to discuss financial results and provide a corporate update today at 4:30 p.m. ET.

To participate in the conference call, please dial 1-844-646-4465 (domestic) or 1-615-247-0257 (international) and reference the access code 7055329. The live webcast can be accessed under "News & Events" in the Investors section of the Company's website at www.iovance.com, or you may use the link: https://edge.media-server.com/m6/p/hijrs8as.

A replay of the call will be available from February 27, 2019 at 7:00 p.m. ET to March 6, 2019 at 6:30 p.m. ET. To access the replay, please dial 1-855-859-2056 (domestic) or 1-404-537-3406 (international) and reference the access code 7055329. The archived webcast will be available for thirty days in the Investors section at www.iovance.com.

[1] The ORR included one complete response and 17 partial responses, one of which was unconfirmed and pending patient's subsequent clinical assessment.

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 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 www.iovance.com.

Forward-Looking Statements

Certain matters discussed in this press release are "forward-looking statements" of Iovance Biotherapeutics, Inc. (hereinafter referred to as the "Company," "we," "us," or "our"). 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. The forward-looking statements include, but are not limited to, risks and uncertainties relating to the success, timing, projected enrollment, manufacturing capabilities, and cost of our ongoing clinical trials and anticipated clinical trials for our current product candidates (including both Company-sponsored and collaborator-sponsored trials in both the U.S. and Europe), such as statements regarding the timing of initiation and completion of these 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 manufacturing, license or development agreements; the acceptance by the market of the Company's product candidates, if approved; 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. Actual results may differ from those set forth in this press release due to the risks and uncertainties inherent in the Company's business, including, without limitation: the FDA may not agree with the Company's interpretation of the results of its clinical trials; later developments with the FDA that may be inconsistent with already completed FDA meetings; the preliminary clinical results, including efficacy and safety results, from ongoing Phase 2 studies may not be reflected in the final analyses of these trials, including new cohorts within these trials, and may not be supportive of product approval; the FDA or other regulatory authorities may potentially delay the timing of their approval of, or other action with respect to, the Company's product candidates (specifically, the Company's description of FDA interactions are subject to FDA's interpretation, as well as FDA's authority to request new or additional information); the Company's ability to address FDA or other regulatory authority requirements relating to its clinical programs and registrational plans, such requirements including, but not limited to, clinical and safety requirements as well as manufacturing and control requirements; risks related to the Company's accelerated FDA review designations; and the ability of the Company to manufacture its therapies using third party manufacturers. 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 or 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 circumstances.

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IOVANCE BIOTECHNOLOGIES, INC.
Selected Consolidated Balance Sheet Data
(In thousands)

	December 31, 2018	December 31, 2017
Cash, cash equivalents, and short-term investments	$ 468,523	$ 145,373
Total assets	$ 480,821	$ 155,373
Stockholders' equity	$ 466,193	$ 145,481

IOVANCE BIOTECHNOLOGIES, INC.
Condensed Consolidated Statements of Operations
(In thousands, except per share information)

	For the Three Months Ended December 31,		For the Years Ended December 31,	
	2018	2017	2018	2017
Revenues	$ -	$ -	$ -	$ -
Costs and expenses*				
Research and development	27,418	20,696	99,828	71,615
General and administrative	7,525	5,375	28,430	21,262
Total costs and expenses	34,943	26,071	128,258	92,877
Loss from operations	(34,943)	(26,071)	(128,258)	(92,877)
Other income				
Interest income, net	2,368	217	4,678	813
Net Loss	$ (32,575)	$ (25,854)	$ (123,580)	$ (92,064)
Net Loss Per Common Share, Basic and Diluted	$ (0.27)	$ (0.36)	$ (1.27)	$ (1.41)
Weighted-Average Common Shares Outstanding, Basic and Diluted	119,085	72,794	97,277	65,242
*** Includes stock-based compensation as follows**				
Research and development	$ 2,669	$ 1,397	$ 9,305	$ 5,270
General and administrative	2,516	1,363	10,722	6,698
	$ 5,185	$ 2,760	$ 20,027	$ 11,968

Exhibit 99.2

Iovance Biotherapeutics was Granted Fast Track Designation for LN-145 for Cervical Cancer

SAN CARLOS, CA, February 26, 2019 -- Iovance Biotherapeutics, Inc. (NASDAQ: IOVA), a biotechnology company developing novel cancer immunotherapies based on tumor-infiltrating lymphocyte (TIL) technology, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for LN-145 for the treatment of patients with recurrent, metastatic or persistent cervical cancer who have progressed while on or after chemotherapy. LN-145 is the Company's adoptive cell therapy produced using its proprietary TIL manufacturing technology.

"We are quite pleased to have received the Fast Track Designation for LN-145 for the treatment of cervical cancer patients who have failed chemotherapy treatments," commented Maria Fardis, Ph.D., MBA, president and chief executive officer of Iovance Biotherapeutics. "The designation is an important positive step for the development of LN-145 in a serious and unmet medical need patient population. We are excited about the clinical data for LN-145 in the cervical cancer patients and look forward to a closer collaboration with the FDA as we advance the clinical development of LN-145 for the treatment of cervical cancer patients."

The Fast Track designation from the FDA is designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need. Filling an unmet medical need includes providing a therapy which may be potentially better than available therapy. With the Fast Track designation for LN-145, Iovance is expected to have more frequent meetings and communications with the FDA and is eligible, if relevant criteria are met upon submission, for a Rolling Review of the Biologic License Application (BLA) and potentially Accelerated Approval.[1]

The Company had previously reported preliminary data from the Phase 2 study of LN-145 for cervical cancer (C-145-04) in October 2018 for 15 patients yielding an overall response rate (ORR) of 27%. Patients in the study had a median of five prior therapies. The most common treatment-related adverse events included chills, pyrexia and anaemia. The protocol for the cervical cancer study has been amended to limit the number of prior therapies to no more than three and to exclude patients who have been treated with prior immunotherapy. The study is actively recruiting patients at 32 clinical sites in the United States and Europe. The company anticipates providing an update on this study at an upcoming medical meeting in 2019.

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1. https://www.fda.gov/forpatients/approvals/fast/ucm405399.htm