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

January 24, 2018
Date of report (Date of earliest event reported)

Iovance Biotherapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-36860**	**75-3254381**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

999 Skyway Road, Suite 150 **San Carlos, California**	**94070**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code **(650) 260-7120**

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

Check the appropriate box below if the Form 8-K 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 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.

Iovance Biotherapeutics, Inc. (the "Company") is currently in the process of finalizing its financial results for the fiscal year ended December 31, 2017. Based on information currently available, the Company estimates that as of December 31, 2017, cash and cash equivalents were approximately $145 million.

These estimates are preliminary and actual results may differ from these estimates due to the completion of the Company's closing procedures with respect to the fiscal year ended December 31, 2017, final adjustments and other developments that may arise between now and the time the financial results for the 2017 fiscal year are finalized. As such, these estimates should not be viewed as a substitute for the full audited financial statements prepared in accordance with U.S. generally accepted accounting principles. These expected results could change materially and are not necessarily indicative of the results to be achieved for the 2017 fiscal year or any future period. As a result of the foregoing considerations and the other limitations described herein, investors are cautioned not to place undue reliance on this preliminary financial information. The Company does not undertake any obligation to publicly update or revise this estimate, except as required by law.

The information in this Item 2.02 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. The information contained in this Item 2.02 shall not be incorporated by reference into any registration statement or other document filed by the Company with the Securities and Exchange Commission, whether made before or after the date of this Current Report on Form 8-K, regardless of any general incorporation language in such filing (or any reference to this Current Report on Form 8-K generally), except as shall be expressly set forth by specific reference in such filing.

Item 8.01. Other Events.

On January 24, 2018, the Company issued a press release announcing preliminary clinical results from two ongoing open-label Phase 2 studies in head and neck and cervical cancers. The Company reported preliminary data from C-145-03, a multicenter Phase 2 study to evaluate the safety and efficacy of autologous Tumor Infiltrating Lymphocytes (LN-145) for the treatment of patients with recurrent and/or metastatic squamous cell carcinoma of the head and neck. Three of the eight patients treated with LN-145 had a reduction in tumor size of at least 30% and qualified as a Partial Response ("PR") as per RECIST v1.1 criteria. The Objective Response Rate ("ORR") in the study to date is 38%. These patients had a median of 4 prior treatments for their cancer and had all received prior anti-PD-1 therapy. The most common side effects were pyrexia, chills, and hypotension. The Company will continue to enroll patients in this study to the full sample size of 47 per protocol. The Company also reported preliminary data from C-145-04, a multicenter Phase 2 study to evaluate the safety and efficacy of autologous Tumor Infiltrating Lymphocytes (LN-145) for the treatment of patients with recurrent, metastatic or persistent cervical carcinoma. Two patients are currently evaluable. One treated with LN-145 had a confirmed PR and one patient had stable disease.

The full text of the press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release dated January 24, 2018.

SIGNATURES

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

Iovance Biotherapeutics, Inc.

Dated: January 24, 2018

By: /s/ Maria Fardis
Name: Maria Fardis
Title: Chief Executive Officer

Exhibit 99.1

Iovance Biotherapeutics Announces Preliminary Phase 2 Data for TIL Treatment in Head and Neck and Cervical Cancers

- Three of Eight Evaluable Patients with Recurrent and/or Metastatic Squamous Cell Carcinoma of the Head and Neck Treated with LN-145 Experienced a Confirmed Partial Response

- One of Two Evaluable Patients with Recurrent, Metastatic or Persistent Cervical Carcinoma Treated with LN-145 Experienced a Confirmed Partial Response

SAN CARLOS, CA – January 24, 2018 – Iovance Biotherapeutics, Inc. (Nasdaq: IOVA), a biotechnology company developing novel cancer immunotherapies based on tumor-infiltrating lymphocyte (TIL) technology, today reported preliminary clinical results from two ongoing open-label Phase 2 studies in head and neck and cervical cancers.

The company reported preliminary data from C-145-03, a multicenter Phase 2 study to evaluate the safety and efficacy of autologous Tumor Infiltrating Lymphocytes (LN-145) for the treatment of patients with recurrent and/or metastatic squamous cell carcinoma of the head and neck. Three of the eight patients treated with LN-145 had a reduction in tumor size of at least 30% and qualified as a Partial Response (PR) as per RECIST 1.1 criteria. The Objective Response Rate (ORR) in the study is 38% to date. These patients had a median of 4 prior treatments for their cancer and had all received prior anti-PD-1 therapy. Two of eight had also received prior anti-CTLA-4. The most common side effects were pyrexia, chills, and hypotension. Iovance will continue to enroll patients in this study to the full sample size of 47 per protocol.

The company also reported preliminary data from C-145-04, a multicenter Phase 2 study to evaluate the safety and efficacy of autologous Tumor Infiltrating Lymphocytes (LN-145) for the treatment of patients with recurrent, metastatic or persistent cervical carcinoma. Two patients are currently evaluable. One treated with LN-145 had a confirmed PR and one patient had stable disease.

“These early data from the head and neck study show the potential safety and efficacy of TIL therapy in tumor types other than melanoma, and demonstrate the broad utility of TIL therapy in various solid tumors. Recently approved anti-PD-1 therapies have resulted in overall response rates of 13-16% in head and neck cancer patients with a median of 2 prior therapies or similar disposition. We are therefore excited by this early data and believe that LN-145 may offer patients who have failed prior therapies, including anti-PD-1 checkpoints, an important treatment alternative,” said Dr. Maria Fardis, PhD, MBA, president and chief executive officer of Iovance Biotherapeutics. “We are also encouraged by the preliminary data reported today in cervical cancer. Previously published data from the National Cancer Institute (NCI) had shown a response in three of nine cervical cancer patients treated with TIL therapy. Patients with metastatic cervical cancer have limited effective treatment options, with no transformative new systemic therapies having been approved over the last several decades.”

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 and recurrent and metastatic or persistent cervical cancer.

Forward-Looking Statements
Certain matters discussed in this press release are “forward-looking statements”. The Company 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. The forward-looking statements include risks and uncertainties, including, but not limited to, the efficacy, safety, tolerability and cost of the Gen 2 manufacturing process, the success, timing and cost of the Company’s ongoing clinical trials and anticipated clinical trials for its current product candidates, including statements regarding the timing of initiation and completion of the trials; statements with respect to the preliminary clinical results from ongoing Phase 2 studies described above, which may not be reflected in the final analyses of this trial; whether results obtained in Company’s ongoing clinical trials, such as the studies and trials referred to in this release, will be indicative of results obtained in future clinical trials the timing of and its ability to obtain and maintain U.S. Food and Drug Administration or other regulatory authority approval of, or other action with respect to, its product candidates; the strength of the 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; 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 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 circumstance.

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