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

October 11, 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** (Address of principal executive offices)	**94070** (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 8.01. Other Events.

On October 11, 2018, the Company issued a press release providing updates from the U.S. Food and Drug Administration End of Phase 2 meeting and about the Company's clinical program.

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 October 11, 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: October 11, 2018

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

Exhibit 99.1

Iovance Biotherapeutics Reports Results from FDA End of Phase 2 meeting and Provides Updates About the Company's Clinical Program

SAN CARLOS, CA – Oct 11, 2018 –

—FDA acknowledged acceptability of a single-arm cohort for registration in metastatic melanoma post PD-1 blocking antibody and, if BRAF mutation positive, a BRAF inhibitor or BRAF inhibitor with MEK inhibitor

—FDA recommended amending existing ongoing Phase 2 study C-144-01 to add a registration-enabling cohort (Cohort 4)

—Cohort 4 enrollment is expected to begin early 2019 with a BLA submission expected in the second half of 2020

—37% objective response rate (ORR) demonstrated in 46 metastatic melanoma patients previously treated with a PD-1 blocking antibody and, if BRAF mutation positive, a BRAF inhibitor, with duration of response ranging from 1.3+ to 14+ months

—31% ORR in 13 recurrent metastatic squamous cell carcinoma of the head and neck cancer patients and a 27% ORR in 15 recurrent, metastatic or persistent cervical carcinoma patients

Iovance Biotherapeutics, Inc. (NASDAQ: IOVA), a biotechnology company developing novel cancer immunotherapies based on tumor-infiltrating lymphocyte (TIL) technology, today reported results from an FDA End of Phase 2 meeting and provided a corporate update.

The company reported that an End of Phase 2 meeting with the FDA was held. FDA has acknowledged the potential acceptability of a single-arm cohort for registration. FDA has further acknowledged that conduct of a randomized Phase 3 trial may not be feasible in its intended population of advanced melanoma patients who have been treated with at least one systemic therapy including a PD-1 blocking antibody and if BRAF V600 mutation positive, a BRAF inhibitor or BRAF inhibitor with MEK inhibitor and is not required for initial registration of lifileucel. A new cohort of 80-100 patients in C-144-01 will be enrolled with a prospective definition of the primary endpoint of ORR to be read out by a Blinded Independent Review Committee (BIRC) to support registration of lifileucel. This new cohort, which the company refers to as Cohort 4, will be initiated in early 2019 and is expected to be fully enrolled by late 2019/early 2020. BLA submission to FDA is expected in the second half of 2020.

The company also reported that Iovance was granted a Regenerative Medicine Advanced Therapy (RMAT) designation for lifileucel in advanced melanoma based on data provided to the U.S. Food and Drug Administration (FDA) from the company's C-144-01 study. RMAT designation is granted for regenerative medicine drugs and allows for increased access to FDA during development. Under this designation, surrogate endpoints can be used to receive approval for a product, accelerated approval may be granted, and a rolling review of a Biologics License Application (BLA) may be possible for the Center for Biologics Evaluation and Research (CBER).

"We are very excited with the progress made at Iovance during 2018. Specifically, we are pleased to have alignment with FDA regarding acceptability of a single-arm cohort to support registration of our lead product. In addition, we have greatly optimized our manufacturing process with Gen 2, leading to a scalable, commercial manufacturing process. We now have a global footprint with our clinical sites resulting in increased clinical enrollment and have produced sufficient data to discuss our registration path with FDA. As part of the recent interactions, we have also received an RMAT designation allowing for more frequent interactions with the FDA, benefiting from the agency's guidance during development of lifileucel," said Dr. Maria Fardis, Ph.D., MBA, president and chief executive officer of Iovance Biotherapeutics.

Corporate Update

Regulatory

- Iovance held an End of Phase 2 meeting with FDA during which the agency acknowledged that a single-arm cohort as part of C-144-01 could be supportive of initial registration and conduct of a randomized Phase 3 trial in the patient population being enrolled may not be feasible.
- Iovance was granted an RMAT designation for advanced melanoma.
- Iovance intends to continue consultation with FDA under the RMAT designation and enroll a new cohort of patients to support registration of lifileucel. The new cohort will have a prospective definition of the primary endpoint of ORR by BIRC and release criteria for lifileucel.

Clinical

- The Company also reported that data from 46 patients of Cohort 2 of trial C-144-01 will be provided at SITC 2018. For these 46 patients, an objective response rate (ORR) of 37% has been observed in the cohort, with duration of response (DOR) ranging from 1.3+ to 14+ months depending on time of enrollment. The ORR includes one (1) complete response and 16 partial responses, six (6) of which are unconfirmed and pending patient's upcoming second assessments.
- Enrollment in the global Phase 2 metastatic melanoma study, C-144-01, has reached the predefined sample size. Enrollment into the existing Cohort 2 will be closed and a new Cohort 4 will be initiated in early 2019. The company plans on initiating enrollment into Cohort 4 in early 2019 and expects to fully enroll the necessary patients into Cohort 4 by late 2019/early 2020.
- BLA submission is expected in the second half of 2020.
- Enrollment continues in other Iovance studies. Patient dosing in EU was initiated in the C-145-04 study of cervical carcinoma. The study design is based on Simon's two-stage design. Stage one has now been completed and enrollment in the study continues. To date, preliminary data for 15 patients yields an ORR of 27% with an early look at the DOR ranging from 2.4 to 2.5+ months. In the C-145-03 study of head and neck cancer, to date, preliminary data for 13 patients yields an ORR of 31% with a DOR ranging from 2.8 to 7.6 months. The safety findings from these studies remain consistent with previous reports.
- Data referenced above is from a data cut as of October 4, 2018.

Manufacturing

- In support of the ongoing studies in EU, in addition to Lonza, Netherlands, a second European manufacturing collaboration was initiated.

IP

- Two U.S. patent applications covering therapeutic methods based upon Generation 2 manufacturing, developed at Iovance, have been recently allowed.

About Iovance Biotherapeutics, Inc.
Iovance Biotherapeutics, Inc. (the Company) 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 http://www.iovance.com.

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 trends and potential future results, including those relating to its financial condition, its clinical programs and product pipeline, its clinical data, its regulatory plans, and the timing and costs of these trends and results, are examples of such forward-looking statements. The forward-looking statements include, but are 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 both Company-sponsored and collaborator-sponsored trials (for example, the FDA strongly recommended that the Company validate a potency assay prior to starting its Cohort 4 of the C-144-01 study for metastatic melanoma, and if there is a delay in such validation, then the timing of our clinical trial may be delayed); 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 these trials; whether results obtained in the 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 or supportive of product approval; the timing of and the Company’s ability to obtain or maintain FDA or other regulatory authority approval of, or other action with respect to, its product candidates (specifically, our FDA interactions are subject to FDA’s interpretation and authority to request new and additional information), such as 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, safety (the safety findings from the Company’s studies remain consistent with previous reports for advanced cancer patients, including two grade 5 treatment adverse events to date), manufacturing, or control requirements by FDA for additional cohorts of our clinical trials, as well as the Company’s ability to utilize accelerated FDA review designations, such as the Regenerative Medicine Advanced Therapy designation, to address regulatory requirements for approval of its products; the strength of the Company’s product pipeline; the successful implementation of the Company’s research and development programs and collaborations; statements regarding the approval of lifileucel and that a Phase 3 trial may not be required; statements regarding the timing for BLA submission; the success of the Company’s manufacturing, license or development agreements; the ability of the Company to obtain and maintain intellectual property rights relating to its product pipeline; the acceptance by the market of the Company’s product candidates and their potential reimbursement by payors, if approved; the Company’s cash guidance; and other factors, including general economic conditions and regulatory developments, and adequate capital resources to meet the projected timelines (for example, the start of the Company’s Cohort 4 and the included timeline will depend on the Company’s ability to raise additional capital), 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 circumstances.

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