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): May 18, 2021

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. ☐

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value $0.000041666 per share	IOVA	The Nasdaq Stock Market, LLC

Item 8.01. Other Events.

On May 18, 2021, Iovance Biotherapeutics, Inc. (the "Company") issued a press release providing a regulatory update for its lifileucel potency assays. The full text of the press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

On May 19, 2021, the Company issued a press release announcing clinical data updates for lifileucel in advanced melanoma at the upcoming American Society of Clinical Oncology 2021 Annual Meeting. The full text of the press release is attached hereto as Exhibit 99.2 and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release of Iovance Biotherapeutics, Inc., dated May 18, 2021.
99.2	Press Release of Iovance Biotherapeutics, Inc., dated May 19, 2021.
104	Cover Page Interactive Data File - the cover page interactive date file does not appear in the Interactive Date File because its XBRL tags are embedded within the Inline XBRL document.

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: May 20, 2021

IOVANCE BIOTHERAPEUTICS, INC.

By: /s/ Frederick G. Vogt
Frederick G. Vogt, General Counsel

Exhibit 99.1

Iovance Biotherapeutics Provides Regulatory Update for Lifileucel Potency Assays

SAN CARLOS, Calif., May 18, 2021 -- Iovance Biotherapeutics, Inc. (NASDAQ: IOVA), a late-stage biotechnology company developing novel T cell-based cancer immunotherapies, today announced receipt of regulatory feedback from the U.S. Food and Drug Administration (FDA) regarding its potency assays for lifileucel. Previously, the company reported the submission of assay data to the FDA and recently the FDA provided comments regarding the data package.

Following FDA feedback, Iovance will continue its ongoing work developing and validating its potency assays and plans to submit additional assay data and to meet with the FDA in the second half of 2021. The company's biologics license application (BLA) submission for lifileucel is now expected to occur during the first half of 2022.

“TIL is a first-in-class, one-time administration cell therapy and the first potential BLA for a cell therapy in solid tumors,” stated Maria Fardis, Ph.D., MBA, Iovance President and Chief Executive Officer. “As such, TIL product is complex by nature and alignment with FDA on a potency assay is an important step toward BLA submission. With a regenerative medicines advanced therapy (RMAT) designation for lifileucel, FDA recognizes the unmet need for patients with metastatic melanoma who progress after anti-PD1 therapy.”

About Iovance Biotherapeutics, Inc.

Iovance Biotherapeutics aims to improve patient care by making T cell-based immunotherapies broadly accessible for the treatment of patients with solid tumors and blood cancers. Tumor infiltrating lymphocyte (TIL) therapy uses a patient’s own immune cells to attack cancer. TIL cells are extracted from a patient’s own tumor tissue, expanded through a proprietary process, and infused back into the patient. Upon infusion, TIL reach tumor tissue, where they attack cancer cells. The company has completed dosing in pivotal programs in patients with metastatic melanoma and cervical cancer. In addition, the company’s TIL therapy is being investigated in a registration-supporting study for the treatment of patients with locally advanced, recurrent or metastatic non-small cell lung cancer (NSCLC). Clinical studies are also underway to evaluate TIL in earlier stage cancers in combination with currently approved treatments, and to investigate Iovance peripheral blood lymphocyte (PBL) T cell therapy for blood cancers. 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”) within the meaning of the Private Securities Litigation Reform Act of 1995 (the “PSLRA”). All such written or oral statements made in this press release, other than statements of historical fact, are forward-looking statements and are intended to be covered by the safe harbor for forward-looking statements provided by the PSLRA. Without limiting the foregoing, we may, in some cases, use terms such as “predicts,” “believes,” “potential,” “continue,” “estimates,” “anticipates,” “expects,” “plans,” “intends,” “forecast,” “guidance,” “outlook,” “may,” “could,” “might,” “will,” “should” or other words that convey uncertainty of future events or outcomes and are intended to identify forward-looking statements. Forward-looking statements are based on assumptions and assessments made in light of management’s experience and perception of historical trends, current conditions, expected future developments and other factors believed to be appropriate. Forward-looking statements in this press release are made as of the date of this press release, and we undertake no duty to update or revise any such statements, whether as a result of new information, future events or otherwise. Forward-looking statements are not guarantees of future performance and are subject to risks, uncertainties and other factors, many of which are outside of our control, that may cause actual results, levels of activity, performance, achievements and developments to be materially different from those expressed in or implied by these forward-looking statements. Important factors that could cause actual results, developments and business decisions to differ materially from forward-looking statements are described in the sections titled "Risk Factors" in our filings with the Securities and Exchange Commission, including our most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q, and include, but are not limited to, the following substantial known and unknown risks and uncertainties inherent in our business: the effects of the COVID-19 pandemic; risks related to the timing of and our ability to successfully develop, submit, obtain and maintain U.S. Food and Drug Administration (“FDA”) or other regulatory authority approval of, or other action with respect to, our product candidates, and our ability to successfully commercialize any product candidates for which we obtain FDA approval; preliminary and interim clinical results, which may include efficacy and safety results, from ongoing clinical trials may not be reflected in the final analyses of our ongoing clinical trials or subgroups within these trials; the risk that enrollment may need to be adjusted for our trials and cohorts within those trials based on FDA and other regulatory agency input; the new version of the protocol which further defines the patient population to include more advanced patients in our cervical cancer trial may have an adverse effect on the results reported to date; the risk that we may be required to conduct additional clinical trials or modify ongoing or future clinical trials based on feedback from the FDA or other regulatory authorities; the risk that our interpretation of the results of our clinical trials or communications with the FDA may differ from the interpretation of such results or communications by the FDA; the acceptance by the market of our product candidates and their potential reimbursement by payors, if approved; our ability or inability to manufacture our therapies using third party manufacturers or our own facility may adversely affect our potential commercial launch; the results of clinical trials with collaborators using different manufacturing processes may not be reflected in our sponsored trials; the risk that unanticipated expenses may decrease our estimated cash balances and increase our estimated capital requirements; and other factors, including general economic conditions and regulatory developments, not within our control.

CONTACTS

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Exhibit 99.2

Iovance Biotherapeutics Announces Clinical Data Updates for Lifileucel in Advanced Melanoma at Upcoming ASCO 2021 Annual Meeting

86% Overall Response Rate (ORR) for Lifileucel in Combination with Pembrolizumab in Immune Checkpoint Inhibitor (ICI) Naïve Advanced Melanoma Patients in IOV-COM-202 Clinical Study

At Median of 28-Month Study Follow up, Median Duration of Response (DOR) not reached in Cohort 2 in post-PD1 Advanced Melanoma in C-144-01 Study; Data Support Use of Lifileucel Following Earlier Detection of Progression on Anti-PD-1 Therapy

Additional Data Updates at ASCO 2021 Meeting

SAN CARLOS, Calif., May 19, 2021 -- Iovance Biotherapeutics, Inc. (NASDAQ: IOVA), a late-stage biotechnology company developing novel T cell-based cancer immunotherapies, today announced additional clinical data for lifileucel alone and in combination with pembrolizumab in patients with advanced melanoma. The data are available in two ASCO abstracts, with additional updates to be provided at the upcoming ASCO 2021 Annual Meeting, to be held June 4-8, 2021.

Maria Fardis, Ph.D., President and Chief Executive Officer of Iovance Biotherapeutics, stated, “We are very excited that our latest clinical datasets demonstrate the broad potential for lifileucel in advanced melanoma. For the first time we are reporting results for lifileucel as an earlier treatment for advanced melanoma in combination with pembrolizumab, demonstrating an overall response rate (ORR) of 86% in patients who are naïve to anti-PD-1 therapy. We are impressed with the results for this combination regimen, particularly since pembrolizumab alone demonstrated a 33% ORR in a comparable patient population. In addition, in a post-PD1 advanced melanoma patient population in Cohort 2 in the C-144-01 study, shorter duration of prior anti-PD-1 therapy maximizes Duration of Response (DOR) to lifileucel treatment.”

Lifileucel in Combination with Pembrolizumab in Advanced Melanoma (IOV-COM-202 Study)
Early data suggest the response rate of lifileucel plus pembrolizumab may be additive in patients with immune checkpoint inhibitor (ICI)-naïve advanced melanoma. Cohort 1A in the IOV-COM-202 study is evaluating lifileucel in combination with pembrolizumab in up to 12 patients who are naïve to ICI, or anti-PD-1, therapy. Six of the initial seven patients had a confirmed objective response, representing an 86% ORR (1 Complete Response (CR) and 5 Partial Responses (PR), with one best response of stable disease (abstract data extraction: February 2021). The longest duration of response was 16.8 months.

The Treatment-Emergent Adverse Event (TEAE) profile was consistent with the underlying disease and known Adverse Event (AE) profiles of pembrolizumab, NMA-LD and IL-2. These encouraging data confirm the potential feasibility and activity of lifileucel in combination with pembrolizumab in early-line treatment of patients with advanced melanoma. Updated results for the initial seven patients will be available in the upcoming ASCO poster.

Lifileucel Following anti-PD-1 therapy in Advanced Melanoma (C-144-01 clinical study)
As previously reported, the long-term follow-up data for Cohort 2 in the C-144-01 clinical study continue to demonstrate durability and depth of lifileucel TIL therapy response. DOR was not reached at 28.1 months of median study follow up and ORR remained at 36.4 percent.

New data in the ASCO abstract suggest that DOR was positively associated with shorter cumulative duration of prior anti-PD-1 therapy. In responders, the median cumulative duration and median prior lines of anti-PD-1 therapy was 4.4 months (range: 1.4-22.5 months) and 1.5 lines (range: 1-4). These results support earlier use of lifileucel following anti-PD-1 therapy instead of retreatment with anti-PD-1 based - regimens.

All patients in Cohort 2 had high baseline disease burden and were heavily pretreated (3.3 mean prior therapies), including anti-PD1 and BRAF/MEK inhibitors if BRAFV600 mutation positive. The adverse event profile was consistent with the underlying advanced disease, lymphodepletion and IL-2 regimens, with no new adverse events emerging over time. Updated results for Cohort 2 with longer duration of follow up will be part of the oral presentation during ASCO 2021.

Iovance Presentation and Poster at ASCO 2021

Title: Lifileucel (LN-144), a cryopreserved autologous tumor infiltrating lymphocyte (TIL) therapy in patients with advanced melanoma: Evaluation of impact of prior anti-PD-1 therapy.
Authors: James M. G. Larkin, *et al.*
Session Title: Melanoma/Skin Cancers
Session Type: Oral Abstract Session
Abstract Number: 9505
Location: ASCO Meeting Library at https://meetinglibrary.asco.org/ and https://www.iovance.com/our-science/publications/
Session Date and Time: Sunday, June 6, 2021 from 8:00 – 11:00 a.m. ET

Title: Safety and efficacy of lifileucel (LN-144), an autologous, tumor infiltrating lymphocyte cell therapy in combination with pembrolizumab for immune checkpoint inhibitor naïve patients with advanced melanoma.
Authors: Sajeve Samuel Thomas, *et al.*
Session Title: Melanoma/Skin Cancers
Session Type: ePoster Session
Abstract Number: 9537
Location: ASCO Meeting Library at https://meetinglibrary.asco.org/ and https://www.iovance.com/our-science/publications/
ePoster Viewing: on demand beginning Friday, June 4, 2021 at 9:00 a.m. ET

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CONTACTS

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