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): September 15, 2023

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.)**
825 Industrial Road, Suite 400 **San Carlos, CA**	**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 value	IOVA	The Nasdaq Stock Market, LLC

Item 8.01. Other Events.

On September 14, 2023, Iovance Biotherapeutics, Inc. issued a press release announcing that the U.S. Food and Drug Administration has updated the Prescription Drug User Fee Act (PDUFA) target action date for lifileucel for the treatment of advanced melanoma.

A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release dated September 14, 2023.
104	Cover Page Interactive Data File, formatted in Inline XBRL and included as Exhibit 101

SIGNATURES

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

Iovance Biotherapeutics, Inc.

Dated: September 15, 2023

By: /s/ Frederick G. Vogt
Name: Frederick G. Vogt, Ph.D., J.D.
Title: Interim CEO and General Counsel

Exhibit 99.1

U.S. Food and Drug Administration Updates
Prescription Drug User Fee Act (PDUFA) Action Date for Lifileucel for the Treatment of Advanced Melanoma

Priority Review Continues with Successful Facility Inspections Completed,
no Major Review Issues

FDA Extends PDUFA Date to February 24, 2024 on Resource Constraints and Agrees to Work with Iovance to Expedite Remaining Review

SAN CARLOS, Calif., September 14, 2023 -- Iovance Biotherapeutics, Inc. (NASDAQ: IOVA), a biotechnology company focused on innovating, developing, and delivering novel polyclonal tumor infiltrating lymphocyte (TIL) therapies for patients with cancer, today announced the U.S. Food and Drug Administration (FDA), because of resource constraints, requires additional time to complete the Priority Review of Iovance's Biologics License Application (BLA) for lifileucel. The BLA is seeking accelerated approval of lifileucel for patients with advanced melanoma. The FDA extended the new target action date for a decision under the Prescription Drug User Fee Act (PDUFA) to February 24, 2024, but agreed to work with Iovance to expedite the remaining review for a potentially earlier approval date.

The FDA recently notified Iovance that they had insufficient resources to review a recent response to an information request for the ongoing BLA review prior to the planned late-cycle review meeting scheduled for September 11, 2023. In a meeting with the FDA held on September 14, 2023, the FDA acknowledged the resource constraints and agreed to work closely with Iovance to expedite the remaining review.

The overall BLA process continues under Priority Review with several recent positive status updates. The FDA reiterated there are no major review issues, and there are no plans to hold an advisory committee meeting. In addition, all pre-approval inspections of clinical sites. internal and external manufacturing and testing facilities have been successfully completed. The FDA is also engaged and has expressed no concerns on the status of the TILVANCE-301 confirmatory trial in frontline advanced melanoma, which remains on track to be well underway by the PDUFA date.

Frederick Vogt, Ph.D., J.D., Interim President and Chief Executive Officer of Iovance, stated, "While the resource constraints at FDA have extended our PDUFA date, Iovance and FDA remain engaged to complete the review process as quickly as possible. We appreciate FDA management's efforts to expedite the remaining review so that we can bring lifileucel to critically ill patients with no other FDA approved options after current standard of care. We are confident in the potential for lifileucel to redefine the treatment paradigm for these patients. With the strength of our clinical data, manufacturing capabilities, and commercial readiness efforts, Iovance is well positioned to rapidly serve the U.S. melanoma community immediately following an approval."

Lifileucel, if approved, will be the first and only TIL therapy for patients with advanced melanoma, as well as the first one-time cell therapy for a solid tumor cancer. Lifileucel is an individualized therapy intended for patients with advanced melanoma who progressed on or after prior anti-PD-1/L1 therapy and targeted therapy, where applicable. There are no FDA approved therapies in this treatment setting.

The FDA accepted the BLA for lifileucel in May 2023 under Priority Review and previously granted a Regenerative Medicine Advanced Therapy (RMAT) designation for lifileucel in advanced melanoma. The extension of the PDUFA date does not impact the Priority Review status or RMAT designation.

The BLA submission for lifileucel is supported by positive data from the C-144-01 clinical trial in patients with advanced melanoma who progressed on or after prior anti-PD-1/L1 therapy and targeted therapy, where applicable. If lifileucel receives accelerated approval, the randomized Phase 3 TILVANCE-301 trial in frontline advanced melanoma can serve as the confirmatory study to support full approval. TILVANCE-301 is expected to be well underway at the time of approval.

About Iovance Biotherapeutics, Inc.

Iovance Biotherapeutics aims to be the global leader in innovating, developing and delivering tumor infiltrating lymphocyte (TIL) therapies for patients with cancer. We are pioneering a transformational approach to cure cancer by harnessing the human immune system's ability to recognize and destroy diverse cancer cells in each patient. Our lead late-stage TIL product candidate, lifileucel for metastatic melanoma, has the potential to become the first approved one-time cell therapy for a solid tumor cancer. The Iovance TIL platform has demonstrated promising clinical data across multiple solid tumors. We are committed to continuous innovation in cell therapy, including gene-edited cell therapy, that may extend and improve life for patients with 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") 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; whether clinical trial results from our pivotal studies and cohorts, and meetings with the FDA, may support registrational studies and subsequent approvals by the FDA; preliminary and interim clinical results, which may include efficacy and safety results, from ongoing clinical trials or cohorts may not be reflected in the final analyses of our ongoing clinical trials or subgroups within these trials or in other prior trials or cohorts; 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 changing landscape of care for cervical cancer patients may impact our clinical trials in this indication; 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 (including from the prior pre-BLA meeting with the FDA); the risk that the FDA may not approve or may delay approval for our BLA submission for lifileucel in metastatic melanoma; 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 forecasts 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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