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): June 28, 2024

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 June 28, 2024, Iovance Biotherapeutics, Inc. issued a press release announcing submission of a marketing authorization application to the European Medicines Agency for lifileucel in 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 June 28, 2024.
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: June 28, 2024

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

Exhibit 99.1

Iovance Biotherapeutics Submits Marketing Authorization Application to European Medicines Agency for Lifileucel in Advanced Melanoma

First of Multiple Planned Global Submissions for Lifileucel in 2024 and 2025

Key Step in Global Expansion to Address >20,000 Patients Annually with Previously Treated Advanced Melanoma

SAN CARLOS, Calif., June 28, 2024 -- Iovance Biotherapeutics, Inc. (NASDAQ: IOVA), a commercial biotechnology company focused on innovating, developing, and delivering novel polyclonal tumor infiltrating lymphocyte (TIL) cell therapies for patients with cancer, submitted a marketing authorization application (MAA) to the European Medicines Agency (EMA) for lifileucel, a TIL cell therapy, for the treatment of adult patients with unresectable or metastatic melanoma previously treated with a PD-1 blocking antibody, and if BRAF V600 mutation positive, a BRAF inhibitor with or without a MEK inhibitor. If approved, lifileucel will be the first and only approved therapy in this treatment setting in all European Union (EU) member states.

Raj K. Puri, M.D., Ph.D., Executive Vice President, Regulatory Strategy and Translational Medicine, stated, "This EU regulatory submission is the first step toward expanding lifileucel into global markets with a high prevalence of advanced melanoma. The unmet need and strength of the clinical data will support approval of lifileucel as the first and only approved therapy for advanced melanoma patients in the EU who have progressed following standard of care therapies. Following the accelerated approval in the U.S., our global expansion strategy can more than double the number of patients with significant unmet need who may access lifileucel."

The MAA submission for lifileucel is supported by positive clinical data from the C-144-01 clinical trial in patients with advanced post-anti-PD1 melanoma. If the MAA for lifileucel is validated, which is anticipated in the third quarter of 2024, the Committee for Medicinal Products for Human Use (CHMP) is expected to issue a scientific opinion for the European Commission to adopt in 2025. Additional marketing submissions for lifileucel are on track in Canada and the United Kingdom during the second half of 2024 and in Australia in 2025. Each year, more than 20,000 people die from advanced melanoma in the U.S., EU, United Kingdom, Canada, and Australia.[1]

[1.] World Health Organization International Agency for Research on Cancer (IARC) GLOBOCAN 2022.

About Iovance Biotherapeutics, Inc.

Iovance Biotherapeutics, Inc. 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. The Iovance TIL platform has demonstrated promising clinical data across multiple solid tumors. Iovance's Amtagvi™ is the first FDA-approved T cell therapy for a solid tumor indication. 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.

Amtagvi™ and its accompanying design marks, Proleukin®, Iovance®, and IovanceCares™ are trademarks and registered trademarks of Iovance Biotherapeutics, Inc. or its subsidiaries. All other trademarks and registered trademarks are the property of their respective owners.

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"). 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," "can," "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 U.S. 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 risks related to our ability to successfully commercialize our products, including Amtagvi, for which we have obtained U.S. Food and Drug Administration ("FDA") approval, and Proleukin, for which we have obtained FDA and European Medicines Agency ("EMA") approval; the risk that the EMA or other ex-U.S. regulatory authorities may not approve or may delay approval for our marketing authorization application submission for lifileucel in metastatic melanoma; the acceptance by the market of our products, including Amtagvi and Proleukin, and their potential pricing and/or reimbursement by payors, if approved (in the case of our product candidates), in the U.S. and other international markets and whether such acceptance is sufficient to support continued commercialization or development of our products, including Amtagvi and Proleukin, or product candidates, respectively; future competitive or other market factors may adversely affect the commercial potential for Amtagvi or Proleukin; the risk regarding our ability or inability to manufacture our therapies using third party manufacturers or at our own facility, including our ability to increase manufacturing capacity at such third party manufacturers and our own facility, may adversely affect our commercial launch; the results of clinical trials with collaborators using different manufacturing processes may not be reflected in our sponsored trials; the risk regarding the successful integration of the recent Proleukin acquisition; the risk that the successful development or commercialization of our products, including Amtagvi and Proleukin, may not generate sufficient revenue from product sales, and we may not become profitable in the near term, or at all; the risks related to the timing of and our ability to successfully develop, submit, obtain, or maintain FDA, EMA, or other regulatory authority approval of, or other action with respect to, our product candidates; whether clinical trial results from our pivotal studies and cohorts, and meetings with the FDA, EMA, or other regulatory authorities may support registrational studies and subsequent approvals by the FDA, EMA, or other regulatory authorities, including the risk that the planned single arm Phase 2 IOV-LUN-202 trial may not support registration; 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 risk that 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, EMA, or other regulatory authorities; the risk that our interpretation of the results of our clinical trials or communications with the FDA, EMA, or other regulatory authorities may differ from the interpretation of such results or communications by such regulatory authorities (including from our prior meetings with the FDA regarding our non-small cell lung cancer clinical trials); the risk that clinical data from ongoing clinical trials of Amtagvi will not continue or be repeated in ongoing or planned clinical trials or may not support regulatory approval or renewal of authorization; the risk that unanticipated expenses may decrease our estimated cash balances and forecasts and increase our estimated capital requirements; the effects of the COVID-19 pandemic; and other factors, including general economic conditions and regulatory developments, not within our control.

CONTACTS

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