

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): August 18, 2025

**IOVANCE BIOTHERAPEUTICS, INC.**  
(Exact Name of Registrant as Specified in Charter)

Delaware

(State of Incorporation)

001-36860

Commission File Number

75-3254381

(I.R.S. Employer Identification No.)

825 Industrial Road, Suite 100  
San Carlos, California

(Address of Principal Executive Offices)

94070

(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 August 18, 2025, Iovance Biotherapeutics, Inc. issued a press release announcing the approval of Amtagvi® (lifileucel) in Canada for advanced melanoma after anti-PD-1 and targeted therapy. 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.

<b>Exhibit No.</b>	<b>Description</b>
<a href="#">99.1</a>	<a href="#">Press Release of Iovance Biotherapeutics, Inc., dated August 18, 2025.</a>
104	Cover Page Interactive Data File (embedded as 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: August 19, 2025

**IOVANCE BIOTHERAPEUTICS, INC.**

By: /s/ Frederick G. Vogt

Frederick G. Vogt, Ph.D., J.D., Interim CEO and President, and General Counsel

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**Iovance's Amtagvi® (lifileucel) Receives Health Canada  
Approval for Advanced Melanoma**

*First T cell therapy for a solid tumor cancer and first treatment option approved in Canada for advanced melanoma after anti-PD-1 and targeted therapy*

**SAN CARLOS, Calif., August 18, 2025** -- Iovance Biotherapeutics, Inc. (NASDAQ: IOVA), a commercial biotechnology company focused on innovating, developing, and delivering novel polyclonal tumor infiltrating lymphocyte (TIL) therapies for patients with cancer, today announced Health Canada has issued a Notice of Compliance with Conditions (NOC/c) for Amtagvi® (lifileucel), a tumor-derived autologous T cell immunotherapy. Amtagvi is indicated for the treatment of adult patients with unresectable or metastatic melanoma that has progressed on or after at least one prior systemic therapy including a PD-1 blocking antibody, and if BRAF V600 mutation positive, a BRAF inhibitor with or without a MEK inhibitor, and who have no satisfactory alternative treatment options.

“This approval in Canada is our first marketing authorization outside the U.S. and marks a significant step forward for Iovance as we prepare to introduce Amtagvi in countries with a high prevalence of advanced melanoma and address substantial unmet needs in solid tumor cancers,” said Frederick Vogt, Ph.D., J.D., Interim Chief Executive Officer and President of Iovance. “We expect to authorize our first Canadian treatment center within the next few months, and we continue to advance our ex-U.S. strategy for Amtagvi in additional markets.”

Market authorization in Canada under the NOC/c guidance was granted based on safety and efficacy results from the global, multicenter C-144-01 trial investigating Amtagvi in patients with advanced melanoma previously treated with anti-PD-1 therapy and targeted therapy, where applicable. The market authorization is conditional, pending the results of trials to confirm its clinical benefit.

**About the C-144-01 Clinical Trial**

C-144-01 is a global, multicenter Phase 2 study in which patients received treatment with lifileucel monotherapy. The study enrolled patients with metastatic melanoma who were previously 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. Efficacy was established on the basis of objective response rate (ORR), and duration of response (DOR) by Independent Review Committee (IRC) per Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1. The detailed results of C-144-01 were published in the [Journal for ImmunoTherapy of Cancer](#) in 2022. A five-year analysis of C-144-01 was published in the [Journal of Clinical Oncology](#) in 2025.

Iovance is investigating Amtagvi in frontline advanced melanoma in the Phase 3 trial, [TILVANCE-301 \(NCT05727904\)](#), as well as in additional solid tumor types.

**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](http://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.

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## 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 risk that we may not be able to recognize revenue for our products; the risk that Proleukin revenues may not continue to serve as a leading indicator for Amtagvi revenues; the risks regarding our anticipated operating and financial performance, including our financial guidance and projections; the effects of global pandemic; the effects of global and domestic geopolitical factors; and other factors, including general economic conditions and regulatory developments, not within our control. Any financial guidance provided in this press release assumes the following: no material change in our ability to manufacture our products; no material change in payor coverage; no material change in revenue recognition policies; no new business development transactions not completed as of the period covered by this press release; and no material fluctuation in exchange rates.

## CONTACTS

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