

**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 29, 2026

IOVANCE BIOTHERAPEUTICS, INC.

(Exact name of Registrant as Specified in Its Charter)

**Delaware
(State or Other Jurisdiction
of Incorporation)**

**001-36860
(Commission File Number)**

**75-3254381
(IRS Employer
Identification No.)**

**300 Rouse Blvd.
Philadelphia, Pennsylvania
(Address of Principal Executive Offices)**

**19112
(Zip Code)**

Registrant's Telephone Number, Including Area Code: 650 260-7120

**825 Industrial Road, Suite 100
San Carlos, California 94070
(Former Name or Former Address, if Changed Since Last Report)**

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))

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	IOVA	The Nasdaq Global Market

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 September 29, 2026, Iovance Biotherapeutics, Inc. issued a press release updating its full year 2026 revenue guidance. A copy of the press release is attached as Exhibit 99.1 and is 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 September 29, 2026
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.

Iovance Biotherapeutics, Inc.

Date: September 29, 2026

By: /s/ Frederick G. Vogt

Name: Frederick G. Vogt, Ph.D., J.D.

Title: Interim CEO and President, and General Counsel

Iovance Biotherapeutics Raises Full Year 2026 Revenue Guidance to \$410 to \$420 Million

New Guidance Represents an Increase of \$55 Million at the Midpoint from the Prior Range of \$350 to \$370 Million

Strong U.S. Demand for Amtagvi and Proleukin Drives Increased Outlook

PHILADELPHIA, Pennsylvania, September 29, 2026 -- 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 raised its full year 2026 total revenue guidance range to \$410 to \$420 million, driven by strong U.S. demand for Amtagvi® (lifileucel) and Proleukin. The midpoint represents an increase of \$55 million, or ~15%, over the previous guidance range of \$350 to \$370 million and implies nearly 60% annual growth in total revenue.

“Our record second quarter and sustained demand for Amtagvi and Proleukin led us to raise our full year 2026 total revenue guidance by \$55 million at the midpoint,” said Frederick Vogt, Ph.D., J.D., Interim President and Chief Executive Officer. “Increasing patient demand and our current manufacturing schedule provide strong visibility into our third and fourth quarter revenues. In addition, lifileucel continues to advance across our registrational programs in new solid tumor indications, while continued manufacturing and operating efficiencies accelerate our progress toward profitability.”

Iovance most recently reported record second quarter 2026 total product revenue of \$99.3 million, has grown its authorized treatment center (ATC) network to ~100 centers, and remains on track for expansion to at least 110 ATCs by year-end 2026.

Iovance expects to report third quarter 2026 financial results in early November 2026. This update completes the guidance review announced with the Company’s second quarter 2026 results.

About Iovance Biotherapeutics, Inc.

Iovance Biotherapeutics, Inc. is the global leader in innovating, developing, and delivering tumor infiltrating lymphocyte (TIL) cell therapies for patients with solid tumors. Amtagvi® (lifileucel) is the first FDA-approved, one-time treatment for previously treated advanced melanoma, now approved in three global markets and available at nearly 100 authorized treatment centers (ATCs). The Iovance TIL platform spans registrational trials and next-generation programs in additional solid tumors, including gene-edited and IL-12 tethered TIL therapies, next-generation IL-2, and precision immuno-oncology approaches. As the first and only company to take TIL therapy from concept to a broadly accessible commercial treatment, Iovance operates as an end-to-end cell therapy company, anchored by fully owned, centralized U.S.-based manufacturing that is scaled to serve thousands of cancer patients worldwide each year. Headquartered in Pennsylvania with offices and laboratories in California and Florida, Iovance serves patients at ATCs and clinical sites across almost the entire U.S. and in many countries around the world. 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.

Information on Iovance's broad, industry-leading patent portfolio is available on the Intellectual Property page on 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"). 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; the acceptance by the market of our products and product candidates, if approved, and their potential pricing and/or reimbursement by payors, and whether such acceptance is sufficient to support continued commercialization or development of our products or product candidates; the risk regarding our ability to manufacture our therapies at our iCTC facility, including the risk that our ability to increase manufacturing capacity at our facility may adversely affect our commercial launch; the risks related to our ability to obtain, maintain and enforce patent and other intellectual property protection for our products and product candidates; the risk that the successful development or commercialization of our products 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 regulatory authority approval of our product candidates; whether clinical trial results from our pivotal studies and cohorts, and meetings with regulatory authorities, may support registrational studies and subsequent approvals by regulatory authorities, including the risk that any of our planned registrational trials may not support approval; 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 we may be required to conduct additional clinical trials or modify ongoing or future clinical trials based on feedback from regulatory authorities; the risk that our interpretation of the results of our clinical trials or communications with regulatory authorities may differ from the interpretation of such results or communications by such regulatory authorities; 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, and other factors such as the number of ATCs, may not 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 and domestic geopolitical factors or public health events; 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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