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): November 6, 2025

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 100 **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 2.02. Results of Operations and Financial Condition.

On November 6, 2025, Iovance Biotherapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 2025, and an update on recent developments. A copy of that press release is furnished as Exhibit 99.1.

The information furnished under this Item 2.02, including the accompanying Exhibit 99.1, shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of such section, nor shall such information be deemed to be incorporated by reference in any subsequent filing by the Company under the Securities Act of 1933, as amended, or the Exchange Act, regardless of the general incorporation language of such filing, except as specifically stated in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release of Iovance Biotherapeutics, Inc., dated November 6, 2025.
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.

Dated: November 6, 2025

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 Highlights Business Achievements,
Pipeline Milestones, and Third Quarter 2025 Results

Quarterly Revenue Growth of 13% to ~$68 Million

Gross Margin Increased to 43% on Improved Execution and Operational Efficiency

Best-in-Class Clinical Profile for Lifileucel in Previously Treated Advanced Non-Small Cell Lung Cancer (NSCLC) with Median Duration of Response Not Reached after 25+ Months Follow Up

SAN CARLOS, Calif., November 6, 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 reported third quarter and year-to-date 2025 financial results, business achievements, pipeline progress, and corporate updates.

Frederick Vogt, Ph.D., J.D., Interim President and Chief Executive Officer of Iovance, stated, "We continued to see revenue growth with significant gross margin improvement in the third quarter of 2025. Amtagvi demand is increasing as we integrate our community treatment centers to drive earlier treatment and better outcomes for patients. We are building a successful commercial business, while advancing our high value development programs to address significant unmet medical needs in patients with solid tumor cancers."

Third Quarter Financial Highlights

Topline Growth, Significant Margin Improvement, and Initial Benefits of Cost Optimization

- Total product revenue grew 13% over the prior quarter to ~$68 million, including U.S. Amtagvi revenue of ~$58 million and global Proleukin revenue of ~$10 million.
- Gross margin of 43% from cost of sales of ~$39 million reflected improved execution and the initial benefits of cost optimization. Additional operational excellence initiatives are underway to drive further near- and long-term improvements.
- Cash and cash equivalents, investments, and restricted cash totaled ~$307 million as of September 30, 2025. The current cash position, bolstered by expense reductions, is expected to fund operations into the second quarter of 2027.
- Full-year 2025 revenue guidance is reaffirmed within the range of $250 to $300 million in the first full calendar year of Amtagvi sales.
- Centralizing manufacturing at the Iovance Cell Therapy Center (*i*CTC) in early 2026 will reduce external manufacturing expenses and continue to improve gross margins.

Amtagvi U.S. Launch

Strong Commercial Execution Across Growing Academic and Community Treatment Networks

- More than 80 U.S. authorized treatment centers (ATCs) have been activated across nearly 40 states, providing a broad network within a two-hour drive for ~95% of Amtagvi patients.
- Community ATCs have treated their first Amtagvi patients, with growth acceleration expected in future quarters.
- More community ATCs are being opened, which is expected to further drive demand.
- Increased awareness of treatment benefits from real-world evidence data is driving earlier Amtagvi adoption and improved referral trends among medical oncologists.
- A number of initiatives are underway to broaden patient access to Amtagvi, including a specialty pharmacy agreement with InspiroGene by McKesson.
- Manufacturing turnaround time continues to improve with a current average of 32 days from inbound to return shipment to ATCs.

Amtagvi Global Expansion

Opportunity to Address up to 30,000 Patients Globally with Previously Treated Advanced Melanoma[1]

- In August 2025, Health Canada granted the first Amtagvi approval outside the U.S. for patients with previously treated advanced melanoma.
- Potential approvals of Amtagvi are anticipated in the United Kingdom and Australia in the first half of 2026 and Switzerland in 2027.
- Iovance is finalizing a strategy with the European Medicines Agency (EMA) to support EU marketing authorization for Amtagvi.

Pipeline Progress and Anticipated Milestones by Program

Lifileucel in Solid Tumors

- Positive interim data from the IOV-LUN-202 clinical trial demonstrated a potentially best-in-class clinical profile for lifileucel in previously treated advanced nonsquamous NSCLC patients.
    - The objective response rate (ORR) was 26% and the median duration of response (mDOR) was not reached at more than 25 months of follow up. Updated data will be presented at a medical meeting in 2026.
    - The U.S. Food and Drug Administration (FDA) previously provided positive regulatory feedback on the IOV-LUN-202 trial design and the proposed potency assay matrix to support registration.
    - Iovance expects the IOV-LUN-202 trial to complete enrollment in 2026 and support a supplemental Biologics License Application for lifileucel in nonsquamous NSCLC, with a potential launch in 2027.
- Initial results from the IOV-END-201 clinical trial of lifileucel in previously treated advanced endometrial cancer are on track for early 2026.
- The TILVANCE-301 clinical trial is active at more than 75 clinical sites and continues to accrue patients to investigate lifileucel in combination with pembrolizumab in frontline advanced melanoma. The trial is designed with FDA and EMA input to show contribution of components compared to pembrolizumab alone.
- A new potentially registrational clinical trial, designated IOV-MEL 202, will investigate lifileucel in advanced melanoma patients previously treated with anti-PD-1 therapy, primarily outside the U.S. The trial includes outpatient use of Amtagvi in the community setting and will enroll a subgroup of true second-line BRAF mutation positive patients without prior BRAF inhibitor therapy.

Next Generation Programs

- Clinical results for IOV-4001, a PD-1 inactivated TIL cell therapy, in previously treated advanced melanoma patients are anticipated in the first quarter of 2026. Other potential indications for IOV-4001 are also in development.
- Dose escalation is continuing for IOV-3001, a second-generation, modified IL-2 analog for use in the TIL therapy treatment regimen. Preclinical studies of IOV-3001 demonstrated the potential for improved safety, convenience of less frequent dosing and strong effector T cell expansion. Advancement into Phase 2 development is expected in 2026.
- An Investigational New Drug (IND) submission is planned in early 2026 for IOV-5001, a genetically engineered, inducible, and tethered interleukin-12 TIL therapy, in solid tumor cancers with large patient populations and urgent unmet medical.

Webcast and Conference Call

Management will host a conference call and live audio webcast to discuss these results and provide a corporate update today at 8:30 a.m. ET. To listen to the live or archived audio webcast, please register at https://edge.media-server.com/mmc/p/pg9qgz86. The live and archived webcast can be accessed in the Investors section of the Company's website, IR.Iovance.com, for one year.

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.

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, 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 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 our restructuring plan and workforce reduction will not result in the intended benefits or savings; 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.

IOVANCE BIOTHERAPEUTICS, INC.
Selected Condensed Consolidated Balance Sheets
(in thousands)

	September 30, 2025 (unaudited)	December 31, 2024
Cash, cash equivalents, and investments	$ 300,803	$ 323,781
Restricted cash	$ 5,965	$ 6,359
Total assets	$ 904,948	$ 910,426
Stockholders' equity	$ 702,287	$ 710,405

Condensed Consolidated Statements of Operations

(unaudited, in thousands, except per share information)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2025	2024	2025	2024
Revenue				
Product revenue	$ 67,455	$ 58,555	$ 176,731	$ 90,376
Total revenue	67,455	58,555	176,731	90,376
Costs and expenses*				
Cost of sales**	$ 38,477	$ 31,518	$ 130,073	$ 55,459
Research and development**	75,174	67,036	229,067	205,221
Selling, general and administrative**	34,555	39,336	115,922	109,948
Depreciation and amortization	9,007	9,731	26,422	28,450
Restructuring charges	5,143	—	5,143	—
Total costs and expenses	162,356	147,621	506,627	399,078
Loss from operations	(94,901)	(89,066)	(329,896)	(308,702)
Other income				
Interest and other income, net	1,243	4,005	8,567	10,698
Net Loss before income taxes	$ (93,658)	$ (85,061)	$ (321,329)	$ (298,004)
Income tax (expense) benefit	2,405	1,520	2,255	4,386
Net Loss	$ (91,253)	$ (83,541)	$ (319,074)	$ (293,618)
Net Loss Per Share of Common Stock, Basic and Diluted	$ (0.25)	$ (0.28)	$ (0.94)	$ (1.03)
Weighted-Average Shares of Common Stock Outstanding, Basic and Diluted	364,037	303,269	340,623	284,836
***Non-cash stock-based compensation included in cost of sales and operating expenses:**				
Cost of sales	$ 1,408	$ 3,065	$ 5,977	$ 5,362
Research and development	5,011	13,803	21,287	35,825
Selling, general and administrative	5,481	14,138	22,494	37,463
Total stock-based compensation included in costs and expenses	$ 11,900	$ 31,006	$ 49,758	$ 78,650

**** Excludes depreciation and amortization**

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