Iovance Biotherapeutics Highlights Strong Fourth Quarter and Full Year 2025 Results, Business Achievements and Corporate Updates

February 24, 2026

~30% Quarterly Revenue Growth Driven by Amtagvi Demand

Gross Margin Increased to 50%

FY25 Revenue of $264M Achieved Annual Guidance

U.S. FDA Fast Track Designation Granted for Lifileucel in Second-Line Advanced Non-Small Cell Lung Cancer

SAN CARLOS, Calif., Feb. 24, 2026 (GLOBE NEWSWIRE) -- 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 fourth quarter and full year 2025 financial results, business achievements and corporate updates.

Frederick Vogt, Ph.D., J.D., Interim President and Chief Executive Officer of Iovance, stated, “Iovance delivered approximately 30 percent quarterly revenue growth and achieved our 2025 guidance range in the first full calendar year of launch. Growth was driven by increasing demand for Amtagvi. After ongoing improvements in our operations and gross margin, we are well positioned for future profitability. Iovance is poised to create substantial value for patients and shareholders as we increase revenue while advancing our registrational trial in non-small cell lung cancer and best-in-class TIL pipeline in solid tumors.”

Fourth Quarter and Full Year 2025 Financial Highlights
Topline Growth, Significant Margin Improvement, and Cost Optimization

- Fourth quarter 2025 total product revenue of ~$87 million with strong growth of ~30% over the prior quarter, including:
  - U.S. Amtagvi revenue of ~$65 million.
  - Global Proleukin revenue of ~$22 million.
- Fourth quarter 2025 gross margin from cost of sales was ~50%, reflecting increasing benefits from solid execution and cost optimization.
- Full year 2025 total product revenue of ~$264 million achieved the guidance range of $250 million to $300 million in the first full year of launch, including:
  - U.S. Amtagvi revenue of ~$220 million.
  - Global Proleukin revenue of ~$44 million.
- The cash position as of December 31, 2025 of ~$303 million[1] is expected to fund operations into the third quarter of 2027.
- Operational excellence initiatives, including internalization of all lifileucel manufacturing and optimization of research and development activities, are expected to drive significant additional improvements in operating expenses, cost of sales and gross margin in 2026 and 2027.

Amtagvi Commercial Launch
Strong U.S. Commercial Growth and Execution with Approvals Pending in New Global Markets

- Best-in-class Amtagvi real-world response rates are increasing adoption and strengthening referral trends toward earlier treatment.
- An oral presentation at the 2026 Tandem Meetings of the American Society for Transplantation and Cellular Therapy (ASTCT®) and the Center for International Blood and Marrow Transplant Research (CIBMTR®) reported:
  - An unprecedented overall objective response rate (ORR) of ~44%.
  - Higher ORR of 52% after two or fewer prior lines of therapy, highlighting the importance of early treatment.
- A continuously growing and maturing network of U.S. authorized treatment centers (ATCs) expanded patient access in 2025, with further acceleration anticipated in 2026.
  - Academic ATCs are contributing to growth as new centers onboard and experienced centers treat more patients.
  - The first community ATCs began treating patients in late 2025 and are expected to drive additional demand in 2026.
  - A specialty pharmacy distribution channel was introduced as another option for ATCs to purchase Amtagvi.
- Five-year analysis of the C-144-01 trial of Amtagvi demonstrated ~31% ORR, median duration of response (mDOR) of 36+ months, and ~20% five-year overall survival, highlighting the unprecedented long-term benefits of this first-in-class therapy.
- Manufacturing turnaround improved to 32 days or less from inbound to return shipment to ATCs.
- Global expansion of Amtagvi is underway in several markets outside the U.S.

- Amtagvi was approved in Canada in August 2025.
- Regulatory submissions are under review with potential approvals in the United Kingdom and Australia in the first half of 2026, and Switzerland in the first half of 2027.
- Iovance is working with the European Medicines Agency (EMA) to resubmit a marketing authorization application (MAA) in 2026.

Lifileucel in Previously Treated Advanced NSCLC: IOV-LUN-202 Registrational Trial
Clinical and Regulatory Momentum Building Towards Potential 2H27 Launch

- The U.S. FDA granted Fast Track Designation (FTD) for lifileucel for the treatment of adults with metastatic nonsquamous (NSQ) NSCLC that has progressed on or after chemo- and anti-PD-1 therapies and at least one line of FDA-approved targeted therapy, if indicated, for actionable tumor mutations excluding ALK, ROS1 and EGFR.
- Positive interim data demonstrated a potential best-in-class profile in NSQ advanced NSCLC patients.
  - The ORR was 26% and mDOR was not reached at 25+ months of follow up following one-time lifileucel monotherapy.
  - Standard of care docetaxel has shown 12.8% ORR, 5.6 months mDOR, and 12.3 months overall survival, highlighting a significant unmet medical need.[2]
- Anticipated milestones:
  - Present updated data at a major medical meeting in 2026.
  - Complete enrollment in 2026.
  - Support a supplemental Biologics License Application for U.S. accelerated approval with a potential launch in the second half of 2027.

Pipeline Updates
New Data Across Several Pipeline Programs Anticipated Throughout 2026

- Iovance announced positive early data for one-time lifileucel treatment in patients with advanced undifferentiated pleomorphic sarcoma (UPS) or dedifferentiated liposarcoma (DDLPS) who were refractory to at least one prior line of systemic therapy:
  - Among the first six evaluable patients, the confirmed RECIST v1.1 ORR was 50%.
  - Iovance plans to commence a single arm registrational trial in previously treated advanced UPS and DDLPS in the second quarter of 2026 and engage with the FDA on a path to expedited approval.
- The Phase 3 TILVANCE-301 trial of lifileucel and pembrolizumab in frontline advanced melanoma made significant progress, with enrollment accelerating across a broad and expanding global footprint. The U.S. FDA previously granted FTD in frontline advanced melanoma for lifileucel in combination with pembrolizumab. The TILVANCE-301 trial is designed with FDA and EMA input to show contribution of components for lifileucel in combination with pembrolizumab compared to pembrolizumab alone.
- Two of Iovance's Phase 2 trials, IOV-END-201 and IOV-MEL-202, are investigating lifileucel in previously treated patients with advanced endometrial cancer and melanoma, respectively.
- A Phase 1/2 trial is investigating IOV-4001, a PD-1 inactivated TIL therapy, in previously treated advanced melanoma and NSCLC.
- A Phase 1/2 trial is investigating IOV-3001, a second-generation, modified IL-2 analog for use in the TIL treatment regimen.
- An Investigational New Drug (IND) submission is planned in the first half of 2026 to begin clinical development of IOV-5001, a genetically engineered, inducible, and tethered interleukin-12 TIL therapy, in a Phase 1/2 basket trial.
- Multiple investigator-sponsored clinical trials are exploring new solid tumor indications for Iovance TIL therapies and next generation approaches.

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/5rbo34au. The live and archived webcast can be accessed in the Investors section of the Company's website, IR.Iovance.com, for one year.

1. Cash, cash equivalents, short-term investments, and restricted cash as of December 31, 2025
2. Ahn MJ et al. J Clin Onc 2024;43:260-272.

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.

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 *i*CTC facility, including the risk that our ability to increase manufacturing capacity at our facility may adversely affect our commercial launch; 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 the planned registrational trial in advanced sarcomas 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.

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

	December 31, 2025	December 31, 2024
Cash, cash equivalents, and investments	$ 296,980	$ 323,781
Restricted cash	$ 5,980	$ 6,359
Total assets	$ 913,170	$ 910,426
Stockholders' equity	$ 698,583	$ 710,405

Condensed Consolidated Statements of Operations

(in thousands, except per share information)

	For the Three Months Ended December 31,		For the Twelve Months Ended December 31,	
	2025 (unaudited)	2024 (unaudited)	2025	2024
Revenue				
Product revenue, net	$ 86,771	$ 73,694	$ 263,502	$ 164,070
Total revenue	86,711	73,694	263,502	164,070

Costs and expenses*				
Cost of sales**	$ 43,112	$ 37,789	$ 173,184	$ 93,248
Research and development**	71,202	71,007	300,270	276,228
Selling, general and administrative**	36,400	42,321	152,322	152,269
Depreciation and amortization	9,517	9,153	35,939	37,603
Restructuring charges	—	—	5,143	—
Total costs and expenses	160,231	160,270	666,858	559,348
Loss from operations	(73,460)	(86,576)	(403,356)	(395,278)
Other income				
Interest and other income, net	1,740	9,575	10,307	20,273
Net Loss before income taxes	(71,720)	(77,001)	(393,049)	(375,005)
Income tax (expense) benefit	(184)	(1,558)	2,071	2,828
Net Loss	$ (71,904)	$ (78,559)	$ (390,978)	$ (372,177)
Net Loss Per Share of Common Stock, Basic and Diluted	$ (0.18)	$ (0.26)	$ (1.09)	$ (1.28)
Weighted-Average Shares of Common Stock Outstanding, Basic and Diluted	406,966	304,890	357,345	289,877

***Non-cash stock-based compensation included in cost of sales and operating expenses:**				
Cost of sales	$ 1,309	$ 3,192	$ 7,286	$ 8,554
Research and development	5,672	13,445	26,959	49,270
Selling, general and administrative	4,836	14,336	27,330	51,799
Total stock-based compensation included in costs and expenses	$ 11,817	$ 30,973	$ 61,575	$ 109,623

**** Excludes depreciation and amortization**

CONTACTS

Investors
IR@iovance.com
650-260-7120 ext. 150

Media
PR@iovance.com
650-260-7120 ext. 150

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