Iovance Biotherapeutics Reports Record Third Quarter 2026 Revenue of ~$122M, Business Achievements, and Corporate Updates

November 5, 2026

Total Revenue Increased ~80% and U.S. Amtagvi Revenue Increased ~77% Year-over-Year, and Gross Margin Increased to ~60%

24.6% Objective Response Rate (ORR) in 69 Patients with Non-Squamous Metastatic Non-Small-Cell Lung Cancer (mNSCLC)

59.1% ORR in Biomarker-Selected mNSCLC Subgroup with POSITILITY Trial Underway

55.6% ORR in Undifferentiated Pleomorphic Sarcoma (UPS) and Dedifferentiated Liposarcoma (DDLPS) with SARATOGA Registrational Trial Underway

PHILADELPHIA, Nov. 05, 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 third quarter 2026 financial results, business achievements, and corporate updates.

“Third quarter revenue reached a new record of ~$122 million with our highest gross margin ever, driven by continued U.S. Amtagvi demand,” said Frederick Vogt, Ph.D., J.D., Interim Chief Executive Officer and President. “We remain on track to achieve our full-year 2026 total revenue guidance of $410 to $420 million and recently marked the tremendous milestone of more than 1,000 commercially treated Amtagvi patients. We released our positive results for Cohorts 1 and 2 of our ongoing IOV-LUN-202 trial with a 24.6% ORR in 69 patients and excellent durability that is much greater than current standard of care. We are completing enrollment in Cohorts 1 and 2 and preparing for a supplemental Biologics License Application (sBLA) submission, while adding the new POSI*TIL*ITY and OP*TIL*ISM trials supported by a remarkable 59.1% ORR in biomarker-selected patients. We also recently presented best-in-class data for lifileucel in chemotherapy-refractory UPS and DDLPS in support of our SARATOGA registrational trial, where our confirmed ORR has now increased to 55.6% in 9 patients with strong durability.”

Third Quarter 2026 Financial Highlights
Second Consecutive Record Quarter in Revenue and High Margin Driven by Volume and Cost Discipline

- Total product revenue was ~$122 million, an increase of ~80% from ~$67 million in 3Q25 and ~22% from ~$99 million in 2Q26.
- U.S. Amtagvi revenue was ~$102 million, up ~77% from 3Q25 and ~12% from 2Q26. Global Proleukin revenue was ~$20 million in 3Q26.
- Gross margin[1] was ~60%, compared to 56% in 2Q26, reflecting higher Amtagvi sales volume and effective internal cost optimization programs spanning all of product production.
- Research and Development (R&D) expenses decreased by ~16% compared to 2Q26, driven by operational efficiencies, marking the fifth straight quarter of improvements, and allowing pipeline growth in additional indications with significant market opportunity.

Full Year 2026 Outlook
Third Quarter Performance and Demand Growth Support Guidance

- Iovance remains on track towards achieving its guidance range of $410 to $420 million in total product revenue in 2026.
- Improvements in gross margin are expected to continue, excluding occasional one-time items.

Amtagvi Commercial Business
Sustained U.S. Commercial Business Growth and Upcoming Milestones in Global Expansion

- **Authorized treatment center (ATC) network:** The network has grown to more than 100 U.S., Canadian, and Australian ATCs, with at least 110 ATCs expected to be active by the end of 2026. Community ATCs continue to represent a third of the network and are expected to increase significantly over the next several quarters.
- **Real-world experience:** Numerous real-world studies by Iovance and ATCs using commercial Amtagvi continue to highlight efficacy and safety, with objective response rates (ORRs) of 50% or greater in second-line patients, supporting earlier adoption of Amtagvi with rapid patient referrals and access. In a poster at the European Society for Medical Oncology Congress 2026 (ESMO 2026), an indirect comparison suggested that lifileucel may approximately double four-year overall survival (OS) rates compared with standard-of-care therapies in anti-PD-1-resistant advanced melanoma.

- **Manufacturing turnaround time:** Amtagvi turnaround time for the majority of lots is about 30 days or less using the only scaled, centralized commercial manufacturing process approved by the U.S. Food and Drug Administration (FDA) for TIL therapy.
- **United Kingdom (UK):** The Marketing Authorization Application (MAA) was resubmitted and is undergoing expedited review by the Medicines and Healthcare products Regulatory Agency for potential approval by 1Q27. Advanced melanoma causes more than 2,500 deaths annually in the UK.
- **Switzerland:** A potential MAA approval by Swissmedic is expected in 1Q27, and the process is moving smoothly, opening a second market opportunity in Europe with the added potential for medical tourism. Switzerland's domestic melanoma burden causes several hundred deaths annually.
- **Other markets and indications:** Iovance is planning to submit an MAA for Amtagvi in advanced melanoma to the Brazilian Health Regulatory Agency (ANVISA) in 2027. An MAA resubmission for Amtagvi to the European Medicines Agency is on track for 2027. Other regulatory submissions are planned in international markets with a high prevalence of advanced melanoma, lung cancer, and soft tissue sarcomas.

Clinical and Regulatory Pipeline Updates
Progress Across a Deep Pipeline of Registrational Programs

- **IOV-LUN-202, POSI*TIL*ITY, and OP*TIL*ISM:** Iovance recently reported a 24.6% ORR in 69 patients with non-squamous mNSCLC, including two unconfirmed responses, consistent with previously reported results. IOV-LUN-202 Cohorts 1 and 2 are completing enrollment. An sBLA for lifileucel based on Cohorts 1 and 2, with a target of approximately 80 patients, is planned in 2027. Independent review committee assessments, FDA discussions, and other pre-submission activities, including confirmatory trial preparation, are ongoing.
    - Efficacy results are potentially best-in-class, with durability continuing to mature and already much greater than standard of care, including docetaxel, which offers an ORR of only 12.8%, a durability of only 5.6 months, and median overall survival of 12.3 months.[2]
    - The safety profile remains consistent with lifileucel regimen experience and was improved after switching to reduced-dose lymphodepletion.
    - The FDA awarded Fast Track Designation (FTD) on the strength of the clinical data and the high unmet medical need of mNSCLC patients.
    - A novel biomarker-enriched subgroup within IOV-LUN-202 achieved a 59.1% ORR, leading to the start of POSI*TIL*ITY, a first-in-class biomarker-enriched cohort with registrational intent, with enrollment beginning this month and a target of 80 patients.
    - Iovance plans to initiate OP*TIL*ISM, an innovative frontline trial in biomarker-enriched non-squamous mNSCLC, in 2027. The U.S. market opportunity in frontline and second-line non-squamous mNSCLC in the biomarker-selected cohort is about ten times that of advanced melanoma.
    - Translational data in a poster at ESMO 2026 showed enrichment over time of putative tumor-reactive clones in mNSCLC patients responding to lifileucel in IOV-LUN-202.
- **SARATOGA (IOV-SAR-201):** A registrational trial in UPS and DDLPS, with approximately 40 patients in each indication, is actively enrolling patients refractory to at least one prior line of anthracycline chemotherapy. Iovance has aligned with the FDA on the registrational trial design and potential accelerated approval pathway. The FDA granted FTD in both indications in 2Q26.
    - Results of lifileucel in heavily pretreated UPS and DDLPS, with 84% of patients receiving two or more prior lines of therapy, were highlighted in a Rapid Oral presentation at ESMO 2026.
    - In an updated data analysis conducted after ESMO, the confirmed ORR by RECIST v1.1 increased to 55.6% (5/9) with multiple durable responses observed, including two responses ongoing more than a year from infusion.
    - The U.S. market opportunity in UPS and DDLPS is approximately the same size as the current second-line metastatic melanoma opportunity for Amtagvi.
- **TILVANCE-301:** A Phase 3 randomized trial of lifileucel and pembrolizumab is enrolling patients with frontline advanced melanoma across a broad global footprint. The TILVANCE-301 trial includes an early interim analysis based on ORR for a potential sBLA for frontline advanced melanoma. The trial also serves as the confirmatory study for the accelerated approval of lifileucel in second-line advanced melanoma.
    - An oral presentation at ESMO 2026 reinforced the rationale for TILVANCE-301 with Phase 2 results of the combination of lifileucel and pembrolizumab as a potential best-in-class option for frontline advanced melanoma. The confirmed ORR was 62.5%, the complete response rate was 29.2%, and median OS was not reached at a median follow-up of more than four years in the IOV-COM-202 trial (n=24).
    - Enrollment momentum in TILVANCE-301 is accelerating at more than 80 sites in the U.S., Canada, Europe, and Asia-Pacific. The clinical site network is expanding into new regions, contributing to ongoing robust enrollment.
- **ENDURANCE (IOV-END-201):** Positive initial data in previously treated metastatic serous endometrial cancer using a biomarker strategy based on histology were reported in 1Q26. Enrollment of serous endometrial patients in ENDURANCE

will restart, and discussion with the FDA is planned on an expedited approval pathway to focus on this population.

Next-Generation Pipeline Updates
First-in-Class Immuno-Oncology Technologies Target New Indications

- **POTENTIL (IOV-GE1-201):** A Phase 1/2 trial is actively enrolling using IOV-5001, a second-generation IL-12 tethered TIL therapy designed to remodel the suppressive tumor microenvironment (TME) and activate immunologically "cold tumors" to support TIL responses and boost response rates.[3] Cohorts include metastatic colorectal cancer, triple-negative and estrogen receptor-low breast cancers, and other solid tumors causing more than 100,000 annual U.S. deaths.[4]
- **IOV-GM1-201:** A Phase 1/2 trial investigating IOV-4001, a PD-1 inactivated TIL therapy, is enrolling patients with previously treated metastatic melanoma and mNSCLC. IOV-4001 is engineered to resist inhibitory signals and enhance the ability of TIL therapies to fight and kill cancer in the TME.
- **IOV-IL2-101:** A Phase 1 safety cohort is advancing through multiple dose levels in the Phase 1/2 trial of IOV-3001, a second-generation modified IL-2 analog for the TIL treatment regimen. IOV-3001 selectively expands effector T cells while avoiding activation of regulatory T cells with the potential for a lower-dose IL-2 regimen with reduced adverse events. IOV-3001 is expected to be superior to Proleukin as a component of future TIL regimens.
- **Investigator-sponsored trials (ISTs):** Iovance continues to advance its broad IST portfolio in multiple new indications for lifileucel. A new IST of lifileucel in clear cell renal cell carcinoma (ccRCC) recently commenced. An ongoing IST of lifileucel in cutaneous squamous cell carcinoma (CSCC) and Merkel cell carcinoma (MCC) is accelerating. Confirmed clinical activity in both CSCC and MCC was observed, and initial results are expected in 1H27. With a lack of effective therapies after failure of checkpoint inhibitors and other frontline combinations, lifileucel could address a large CSCC, MCC, and ccRCC population suffering from thousands of annual deaths in the U.S. alone.

Corporate Updates

- Iovance currently owns or licenses more than 400 granted or allowed U.S. and international patents and patent rights for Amtagvi and other TIL-related technologies, including patent rights directed to its biomarker-directed strategy, and has filed more than 1,000 additional patent applications worldwide. This broad patent portfolio is expected to provide patent exclusivity through at least 2042 and beyond.
- Iovance entered into a contract research agreement with Cell and Gene Therapy Catapult, a UK independent innovation and technology organization advancing cell and gene therapies, with an option to license a next-generation smart manufacturing platform.
- As of September 30, 2026, Iovance's cash position [5] was ~$382 million, and current cash is expected to fund operations well into 2029.

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/j9pwh6ke. The live and archived webcast can be accessed in the Investors section of the Company's website, iovance.com, for one year.

1. Excludes depreciation and amortization.
2. Ahn MJ, Tanaka K, et al., J Clin Oncol 2025;43:260–272.
3. Zhang L, Rosenberg SA, et al., Clin Cancer Res 2015;21(10):2278–2288.
4. Surveillance, Epidemiology, and End Results Program Cancer Stat Facts (accessed November 2026).
5. Cash, cash equivalents, short-term investments, and restricted cash as of September 30, 2026.

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 more than 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.

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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 ATC network expansion and new markets; the size of the addressable patient populations for, and 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 supply or clinical supply; the risks related to our ability to obtain, maintain, and enforce patent and other intellectual property protection for our products and product candidates, including our biomarker-directed strategy; 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 clinical studies and cohorts, and meetings with regulatory authorities, may support registrational studies, including biomarker-selected studies, and subsequent approvals by regulatory authorities, and the risk that our clinical trials, including registrational and investigator-sponsored trials, may experience delays in site activation, enrollment, or data readouts, may not meet their primary endpoints, or may not support approval; clinical results, whether preliminary, interim, or final, which may include efficacy and safety results, from clinical trials or cohorts may not be confirmed or reflected in independent review assessments or the final analyses of our ongoing clinical trials or subgroups within these trials or in other prior or future 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, including comparisons to other therapies, or communications with regulatory authorities may differ from the interpretation of such results or communications by such regulatory authorities or others; 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)

	September 30, 2026	December 31, 2025
	(unaudited)	
Cash, cash equivalents, and investments	$ 376,320	$ 296,980
Restricted cash	$ 6,018	$ 5,980
Total assets	$ 991,214	$ 913,170
Stockholders' equity	$ 812,662	$ 698,583

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,	
	2026	2025	2026	2025
Revenue				
Product revenue, net	$ 121,469	$ 67,455	$ 292,212	$ 176,731
Total revenue	121,469	67,455	292,212	176,731

Costs and expenses*				
Cost of sales**	$ 48,028	$ 38,477	$ 134,121	$ 130,073
Research and development**	49,337	75,174	170,675	229,067
Selling, general, and administrative**	38,575	34,555	116,796	115,922
Depreciation and amortization	9,497	9,007	27,536	26,422
Restructuring charges	-	5,143	-	5,143
Total costs and expenses	145,437	162,356	449,128	506,627
Loss from operations	(23,968)	(94,901)	(156,916)	(329,896)
Other income				
Interest and other income, net	2,311	1,243	6,861	8,567
Net Loss before income taxes	$ (21,657)	$ (93,658)	$ (150,055)	$ (321,329)
Income tax benefit (expense)	(614)	2,405	1,424	2,255
Net Loss	$ (22,271)	$ (91,253)	$ (148,631)	$ (319,074)
Net Loss Per Share of Common Stock, Basic and Diluted	$ (0.05)	$ (0.25)	$ (0.34)	$ (0.94)
Weighted Average Shares of Common Stock Outstanding, Basic and Diluted	455,919	364,037	442,683	340,623

***Non-cash stock-based compensation included in cost of sales and operating expenses**				
Cost of sales	$ 1,721	$ 1,408	$ 4,276	$ 5,977
Research and development	4,771	5,011	14,966	21,287
Selling, general, and administrative	5,341	5,481	15,593	22,494
	$ 11,833	$ 11,900	$ 34,835	$ 49,758

**** Excludes depreciation and amortization**

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