Iovance Biotherapeutics Reports Record Second Quarter 2026 Revenue of ~$99M, Business Achievements, and Corporate Updates

August 6, 2026

U.S. Amtagvi Revenue Reaches ~$91M and Total Revenue Increased 66% Year-over-Year

Gross Margin Increased to 56%

Fast Track Designation (FTD) Granted by the FDA for Lifileucel in Soft Tissue Sarcomas

SAN CARLOS, Calif., Aug. 06, 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 second quarter 2026 financial results, business achievements, and corporate updates.

"Second-quarter revenue reached a record $99.3 million with gross margin of 56%, driven by continued U.S. Amtagvi demand," said Frederick Vogt, Ph.D., J.D., Interim President and Chief Executive Officer. "Based on our second-quarter performance and strong demand trends, we are reviewing our previously issued 2026 revenue guidance of $350 million to $370 million and will provide an update during the third quarter. Additionally, we continue to be excited by our clinical pipeline as lifileucel advances across other solid tumor indications including metastatic non-squamous non-small-cell lung cancer (NSCLC), the new registrational SARATOGA trial in undifferentiated pleomorphic sarcoma (UPS) and dedifferentiated liposarcoma (DDLPS), and metastatic serous endometrial cancer. Continued manufacturing and operating efficiencies support our sustainable growth, accelerate progress toward profitability, and advance our clinical pipeline with first-in-class, novel products in new solid tumor indications."

Second Quarter 2026 Financial Highlights
Record Revenue and Improving Margin Supported by Cost Discipline

- Total product revenue was ~$99 million, an increase of 66% from ~$60 million in 2Q25 and 39% from ~$71 million in 1Q26.
- U.S. Amtagvi revenue was ~$91 million, up 40% from 4Q25. Global Proleukin revenue was ~$9 million and is expected to grow during the remainder of 2026.
- Gross margin was 56%[1], reflecting higher Amtagvi sales volume, continued cost optimization, and maturing internal manufacturing efficiencies.
- Research and Development (R&D) expenses decreased by ~6% compared to 1Q26, driven by continued operational efficiencies during the fourth straight quarter of improvements.

Full Year 2026 Outlook
Second Quarter Performance and Demand Growth

- Based on strong second-quarter sales and current demand trends, Iovance is reviewing its FY26 total revenue guidance of $350 million to $370 million. An update will be provided during the third quarter.
- Improvements in gross margin are expected to continue, excluding occasional one-time items.

Amtagvi Commercial Business
Significant U.S. Commercial Business Growth and Progress in Global Expansion

- **Demand and awareness:** Record Amtagvi demand, catalyzed by a new marketing campaign and an expanded sales team, is driving increased adoption across a growing ATC network and referrals toward earlier treatment. Unaided physician awareness of Amtagvi has nearly tripled during the last year.
- **Authorized treatment center (ATC) network:** The network has grown to more than 95 U.S., Canadian, and Australian ATCs, with at least 110 ATCs expected to be active by the end of 2026. Community ATCs now represent a third of the network and are expected to increase significantly over the next several quarters.
- **Real-world experience:** Multiple real-world studies by Iovance and ATCs using commercial Amtagvi continue to advance, supporting broader adoption of Amtagvi and earlier patient referrals and access. These studies highlight objective response rates (ORRs) of 50% or greater and address identification of tumor harvest sites, accelerated institutional workflows, and improved patient care.
- **Manufacturing turnaround time:** Amtagvi turnaround time is 31 days or less using the only scaled, centralized commercial manufacturing process approved by FDA for TIL therapy.

- **Australia**: The marketing authorization application (MAA) for Amtagvi in Australia was approved by the Therapeutic Goods Administration (TGA), marking the third approval of Amtagvi by global health authorities to date. A high incidence of advanced melanoma in Australia causes more than 1,500 annual deaths. Australian ATCs are currently progressing through the authorization process in parallel with discussions for national reimbursement.
- **United Kingdom (UK):** The MAA for Amtagvi in the UK was resubmitted in early July and is undergoing expedited review by the Medicines and Healthcare products Regulatory Agency (MHRA) for potential approval later in 2026. Advanced melanoma causes more than 2,500 deaths annually in the UK.
- **Switzerland:** Potential approval of the MAA in Switzerland is expected in 1H27, opening a second market opportunity in Europe with the potential for medical tourism. Switzerland's domestic melanoma burden causes several hundred deaths annually.
- **Other markets and indications:** An MAA resubmission for Amtagvi in advanced melanoma 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, NSCLC, and soft tissue sarcomas.

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

- **IOV-LUN-202:** Initial results in previously treated metastatic non-squamous NSCLC supported FDA FTD. Enrollment is nearly complete in the pivotal cohorts and program updates are expected in 4Q26. A supplemental Biologics License Application (sBLA) submission is planned in 2027. The U.S. market opportunity in metastatic non-squamous NSCLC is about seven times that of advanced melanoma.
- **SARATOGA (IOV-SAR-201):** The registrational trial in UPS and DDLPS is underway, driven by positive early data with an ORR by RECIST v1.1 of 50% in the first six evaluable patients. Based on the strength of this early data, FDA granted FTD for UPS and DDLPS. Results will be highlighted in an oral presentation (abstract #3725RO) at the European Society for Medical Oncology (ESMO) meeting in Madrid, Spain, from October 23–27, 2026.
- **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. Results supporting the combination of lifileucel and pembrolizumab as a potential best-in-class option for frontline advanced melanoma were accepted (abstract #2072O) for an oral presentation at the ESMO annual meeting.
- **IOV-END-201:** Positive initial data in previously treated metastatic serous endometrial cancer using a biomarker strategy based on histology were recently reported. A protocol amendment is being submitted and engagement with FDA is underway on an expedited approval pathway to focus on this population.

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

- **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 NSCLC. IOV-4001 is engineered to resist inhibitory signals and enhance the ability of TIL therapies to fight and kill cancer in the tumor microenvironment (TME).
- **IOV-GE1-201:** A Phase 1/2 trial is underway using IOV-5001, a second-generation IL-12 tethered TIL therapy designed to remodel the suppressive TME and activate immunologically "cold tumors" to support TIL responses and boost response rates.[2] 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.[3]
- **IOV-IL2-101:** A Phase 1 safety cohort is advancing through multiple dose levels in the Phase 1/2 trial of IOV-3001, our 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 is advancing several lifileucel ISTs in new indications. Multiple patients have been treated for cutaneous squamous cell carcinoma (CSCC) and Merkel cell carcinoma (MCC) with initial data expected in 1H27. To date, early clinical activity has been reported. With no approved therapies after failure of checkpoint inhibitors, lifileucel could address a large CSCC and MCC market with several thousand annual deaths in the U.S.

Corporate Updates

- Iovance is deploying and advancing artificial intelligence (AI) tools to drive significant future cost efficiencies and new product pipeline insights.
- 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 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.

- As of June 30, 2026, Iovance's cash position was ~$304 million[4] and current cash is expected to fund operations into 2H28.

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/3f4w9ts7/. The live and archived webcast can be accessed in the Investors section of the Company's website, IR.Iovance.com, for one year.

1. Excludes depreciation and amortization
2. Zhang L, Rosenberg SA, et al., Clin Cancer Res 2015;21(10):2278–2288.
3. Surveillance, Epidemiology, and End Results Program Cancer Stat Facts (accessed April 2026).
4. Cash, cash equivalents, short-term investments, and restricted cash as of June 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 95 authorized treatment centers. 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. 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; 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 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 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)

	June 30, 2026 (unaudited)	December 31, 2025
Cash, cash equivalents, and investments	$ 297,674	$ 296,980
Restricted cash	$ 6,005	$ 5,980
Total assets	$ 915,531	$ 913,170
Stockholders' equity	$ 736,045	$ 698,583

Condensed Consolidated Statements of Operations
(unaudited; in thousands, except per share information)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2026	2025	2026	2025
Revenue				
Product revenue, net	$ 99,313	$ 59,952	$ 170,743	$ 109,276
Total revenue	99,313	59,952	170,743	109,276
Costs and expenses*				
Cost of sales**	$ 43,595	$ 48,881	$ 86,093	$ 91,595
Research and development**	58,851	77,928	121,338	153,895
Selling, general, and administrative**	39,272	37,567	78,221	81,366
Depreciation and amortization	9,500	9,350	18,039	17,415
Total costs and expenses	151,218	173,726	303,691	344,271
Loss from operations	(51,905)	(113,774)	(132,948)	(234,995)
Other income				
Interest and other income, net	3,217	4,104	4,550	7,324
Net Loss before income taxes	(48,688)	(109,670)	(128,398)	(227,671)
Income tax benefit (expense)	1,373	(1,988)	2,038	(150)
Net Loss	$ (47,315)	$ (111,658)	$ (126,360)	$ (227,821)
Net Loss Per Share of Common Stock, Basic and Diluted	$ (0.11)	$ (0.33)	$ (0.29)	$ (0.69)
Weighted Average Shares of Common Stock Outstanding, Basic and Diluted	450,189	334,511	434,437	328,721
***Non-cash stock-based compensation included in cost of sales and operating expenses**				
Cost of sales	$ 1,536	$ 2,149	$ 2,555	$ 4,569
Research and development	5,078	6,359	10,195	16,276
Selling, general, and administrative	5,119	6,435	10,252	17,013
	$ 11,733	$ 14,943	$ 23,002	$ 37,858

**** Excludes depreciation and amortization**

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