Iovance Biotherapeutics Reports Financial Results and Corporate Updates for Second Quarter and First Half 2025

August 7, 2025

$60.0M in 2Q25 Total Product Revenue

More than 100 Patients Treated with Amtagvi® in 2Q25

Strategic Restructuring Extends Cash Runway into 4Q26

FY25 Total Product Revenue Guidance of $250M-$300M Reiterated

SAN CARLOS, Calif., Aug. 07, 2025 (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 and first half 2025 financial results and corporate updates.

Frederick Vogt, Ph.D., J.D., Interim President and Chief Executive Officer of Iovance, stated, “In the first half of 2025, we continued to drive U.S. adoption for Amtagvi in advanced melanoma, surpassing more than 100 patients treated within a single quarter. Growth for Amtagvi and Proleukin will continue in the second half of 2025 as existing ATC growth continues and large community practices begin treating patients. We expect our first ex-U.S. regulatory approval imminently and remain on track to provide updates on our clinical programs.”

Second Quarter and First Half 2025 Financial Results, Corporate Guidance and Updates

Product Revenue and Guidance

- **Second Quarter 2025 Total Product Revenue:** Iovance recognized total product revenue of $60.0 million from Amtagvi and Proleukin during the second quarter ended June 30, 2025. Year-over-year product revenue increased by 93% compared to $31.1 million in the second quarter of 2024. The U.S. FDA approved Amtagvi (lifileucel) on February 16, 2024, as the first treatment option for patients with advanced (unresectable or metastatic) melanoma after anti-PD-1 and targeted therapy.
  - **2Q25 Amtagvi Revenue**: Product revenue from U.S. Amtagvi sales was $54.1 million, representing 102 commercial patients treated. Infusion growth was a direct result of increased field activities in existing ATCs and contributions from new ATCs treating patients.
  - **2Q25 Proleukin Revenue:** Product revenue also included $5.9 million in Proleukin sales, reflecting restocking orders from two major U.S. wholesalers to keep pace with increasing Amtagvi utilization. Strong growth in Proleukin revenue in the second half of 2025 is expected to align with Amtagvi demand and year-end restocking patterns at U.S. distributors. In addition to the Amtagvi treatment regimen, Proleukin revenue is recognized from other commercial, clinical, manufacturing, and research sales.
- **Full Year 2025 Total Product Revenue Guidance:** Iovance is reiterating total product revenue guidance within the range of $250 to $300 million in the first full calendar year of Amtagvi sales. The forecast continues to track in line with current and expected ATC growth trajectories, including large community practices and community referral activities. Proleukin sales are also expected to accelerate in the second half of 2025 from restocking at U.S. distributors, ex-U.S. demand, and sales growth for clinical and manufacturing uses. Iovance expects continued growth in total product revenue for the full year 2026 and beyond. Gross margins are expected to increase through near-term optimization of manufacturing capacity utilization over the next several years.

Amtagvi (Lifileucel) Monotherapy U.S. Launch Highlights in Advanced Melanoma

- Real-World Retrospective Study for Commercial Amtagvi
  - The physician-assessed objective response rate (ORR) was 48.8% (20 out of 41 evaluable patients treated with commercial Amtagvi).
  - ORR was higher with earlier Amtagvi monotherapy:
    - 60.9% (14/23) in third-line or earlier patients
    - 33.3% (6/18) in patients following three or more prior lines of therapy
  - Iovance plans to present detailed data at an upcoming medical meeting in 2025.
- Authorized Treatment Centers (ATCs)
  - The Amtagvi treatment network includes more than 80 U.S. ATCs across 35 states and 95% of addressable

patients live within 200 miles of an ATC.
    - New ATCs continue to be onboarded as the network expands beyond top academic centers.
    - U.S. community referral activities are accelerating to drive earlier treatment with Amtagvi.
    - Iovance has entered into a specialty pharmacy agreement with Biologics by McKesson, a key offering within InspiroGene, McKesson's suite of CGT commercialization solutions. This new access channel, added in direct response to requests from large community practices, will be another option for providers to acquire Amtagvi, alongside the traditional direct purchase channel.
- Commercial Manufacturing
    - Manufacturing turnaround time has improved to 33 days from inbound to return shipment to ATCs.
    - The overall commercial manufacturing experience remains consistent with prior clinical experience.

Launch Expansion into New Markets

Amtagvi has the opportunity to address more than 30,000 patients globally with previously treated advanced melanoma.[1] Iovance is gaining momentum to address adult patients with previously treated advanced melanoma in new markets.

- Health Canada is expected to approve Amtagvi monotherapy in the coming weeks as the first T cell therapy for a solid tumor cancer and first treatment option in Canada for previously treated advanced melanoma. Iovance is preparing for a commercial launch in Canada over the next few months.
- Iovance recently withdrew a marketing authorization application (MAA) from the European Medicines Agency (EMA) following interactions with EMA's Committee for Medicinal Products for Human Use. A new strategy is in development to make Amtagvi and TIL therapy broadly accessible to patients in the EU.
- Iovance expects Amtagvi approval in three additional markets:
    - Review in the United Kingdom is on track for potential approval and launch in the first half of 2026.
    - Australia's Therapeutic Goods Administration granted Priority Review with a decision anticipated in early 2026.
    - Swiss Medic recommended Priority Review ahead of the Swiss regulatory submission planned in the fourth quarter of 2025.

Recent Iovance TIL Cell Therapy Pipeline Highlights

- **Lifileucel Franchise in Solid Tumors: Priority Programs**
    - **Combination Therapy in Frontline Advanced Melanoma**: The registrational TILVANCE-301 trial continues with strong momentum to support U.S. approval of Amtagvi in combination with pembrolizumab in frontline advanced melanoma, and full approval in post-anti-PD-1 melanoma. The trial was designed with FDA and EMA input to show the contribution of components for Amtagvi in combination with pembrolizumab compared to pembrolizumab alone.
    - **Lifileucel Monotherapy in Previously Treated Advanced Non-Small Cell Lung Cancer (NSCLC):** Iovance remains on track to share additional data in the second half of 2025 from the IOV-LUN-202 registrational Phase 2 trial to support a potential U.S. accelerated approval of lifileucel monotherapy in post-anti-PD-1 NSCLC in 2027. The FDA previously provided positive regulatory feedback on the IOV-LUN-202 clinical trial design and proposed potency assay matrix to support registration. The single-arm IOV-LUN-202 trial is investigating lifileucel monotherapy in a defined patient population with limited options after approved standard of care. This trial design aligns with FDA guidance for single-arm trials to support accelerated approvals in conditions with unmet medical need.
    - **Lifileucel Monotherapy in Endometrial Cancer:** Iovance is actively enrolling in the IOV-END-201 Phase 2 trial for advanced endometrial cancer, a significant unmet medical need. The trial is investigating lifileucel after platinum-based chemotherapy and anti-PD-1 therapy regardless of mismatch repair (MMR) status, with initial results on track for the second half of 2025.
- **Next Generation TIL Pipeline**
    - **PD-1 Inactivated TIL Cell Therapy (IOV-4001):** Results are anticipated in the second half of 2025 from the Phase 2 efficacy portion of the IOV-GM1-201 trial in previously treated advanced melanoma.
    - **Next Generation Interleukin-2 (IL-2) for TIL Treatment Regimen (IOV-3001):** Patient enrollment continues in a Phase 1/2 clinical trial, IOV-IL2-101, to investigate 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.
    - **Next Generation, Cytokine-Tethered TIL Therapy (IOV-5001):** IND-enabling studies are proceeding for IOV-5001, a genetically engineered, inducible, and tethered interleukin-12 TIL cell therapy, in support of an IND in early 2026 for clinical development for multiple indications.
- **Publications and Presentations**
    - The *Journal of Clinical Oncology* published the final five-year analysis from the Phase 2 C-144-01 clinical trial evaluating one-time lifileucel monotherapy, which represents unprecedented durability and duration of follow-up in

previously treated advanced melanoma patients. The ORR was 31.4% and nearly one third of responders (31.3%) had ongoing responses. Median duration of response (mDOR) was 36.5 months, median overall survival (OS) was 13.9 months and five-year OS was 19.7%. These data were simultaneously presented at the ASCO 2025 annual meeting.

- *Cancer Communications* published a peer-reviewed letter about C-144-01 patients with previously treated advanced mucosal melanoma. Following one-time lifileucel monotherapy in this difficult to treat subgroup, ORR was 50% and mDOR was not reached at a median follow up of 35.7 months.

Corporate Updates

- **Business Optimization:** Iovance is implementing a strategic restructuring to optimize business performance, resulting in more than $100 million in annual cost savings starting in the fourth quarter of 2025 and extending cash runway into the fourth quarter of 2026. No significant changes to the pipeline are expected, and all registrational and early-phase programs remain on track. Net cash burn for the next four quarters through the second quarter of 2026 is expected to be less than $245 million, excluding one-time charges associated with the strategic restructuring. The restructuring includes a workforce reduction of approximately 19% in the third quarter of 2025. Iovance will continue to optimize and refine its cost structure through operational excellence initiatives over the next two to three quarters.
- **Cash Position:** As of June 30, 2025, Iovance had cash, cash equivalents, investments, and restricted cash of approximately $307.1 million. The current cash position and anticipated product revenue, including cost savings from the strategic restructuring, are expected to be sufficient to fund current and planned operations into the fourth quarter of 2026.
- **New Leadership Appointments:** Iovance recently appointed Corleen Roche as Chief Financial Officer and Marc R. Theoret, M.D. as Senior Vice President, Regulatory Strategy.
- **Intellectual Property:** Iovance currently owns approximately 280 granted or allowed U.S. and international patents and patent rights for Amtagvi and other TIL-related technologies that are expected to provide exclusivity through at least 2042. This patent portfolio covers TIL compositions and methods of treatment and manufacturing in a broad range of cancers, with Gen 2 patent rights expected to provide exclusivity for Amtagvi into 2038 and additional patent rights, including methods of treating melanoma and compositions and methods for potency assays, expected to provide exclusivity into 2039 and 2042, respectively. Iovance also owns an industry-leading patent portfolio covering TIL products produced with genetic engineering, using core biopsies and peripheral blood as starting material, and using combinations of TIL products with checkpoint inhibitors, as well as Iovance's proprietary IovanceCares™ system. More information on Iovance's patent portfolio is available on the Intellectual Property page on www.iovance.com.

Second Quarter and First Half 2025 Financial Results

Net loss for the second quarter of 2025 was $111.7 million, or $0.33 per share, compared to a net loss of $97.1 million, or $0.34 per share, for the second quarter of 2024. Net loss for the first half of 2025 was $227.8 million, or $0.69 per share, compared to a net loss of $210.1 million, or $0.76 per share, for the first half of 2024.

Revenue consists of product revenue from Amtagvi and Proleukin. Revenue was $60.0 million for the second quarter of 2025, a 22% increase from $49.3 million in the first quarter of 2025 and a 93% increase over revenue of $31.1 million in the second quarter of 2024. Product revenue was $54.1 million for Amtagvi and $5.9 million for Proleukin in the second quarter of 2025 compared to $12.8 million for Amtagvi and $18.3 million for Proleukin in the second quarter of 2024.

Revenue was $109.3 million for the first half of 2025, an increase of 243% over revenue of $31.8 million in the prior year six-month period. Product revenue from Amtagvi and Proleukin was $97.7 million and $11.6 million, respectively, in the first half of 2025 compared to $12.8 million and $19.0 million, respectively, in the first half of 2024.

The increase in revenue in the second quarter and first half 2025 over the prior year periods was primarily attributable to the U.S. launch and product revenue growth from Amtagvi.

Cost of sales includes inventory, overhead and related cash and non-cash expenses that are directly associated with sales of Amtagvi and Proleukin, as well as manufacturing costs for Amtagvi.

Cost of sales was $56.7 million for the second quarter 2025, including $19.0 million for period costs associated with patient drop off and manufacturing success rates, $5.9 million for non-cash amortization expense for intangible assets and fair value mark up of inventory, $2.1 million for non-cash stock-based compensation, and $1.2 million in royalties payable on product sales. Cost of sales was $31.4 million in the second quarter of 2024. Cost of sales was $106.4 million for the first half of 2025 compared to $38.6 million in the first half of 2024.

The increase in cost of sales in the second quarter and first half of 2025 over the prior year periods was associated with the initiation and growth of product sales, certain costs associated with patient drop-off and manufacturing success rates, and related cash and non-cash expenses tied to the U.S. launch of Amtagvi that began during the first quarter of 2024.

Research and development expenses were $79.4 million for the second quarter of 2025, an increase of 28% compared to $62.1 million for the second quarter of 2024. Research and development expenses were $156.2 million for the first half of 2025, an increase of 10% compared to $141.9 million for the first half of 2024.

The increases in research and development expenses in the second quarter and first half of 2025 over the prior year periods were primarily attributable to higher headcount and related costs, offset by reductions in stock-based compensation, and clinical trial costs resulting from continued enrollment in existing trials and the resumption of the LUN-202 study. The increases for the first half of 2025 were offset by the transition of Amtagvi to commercial manufacturing.

Selling, general and administrative expenses were $37.7 million for the second quarter of 2025, a decrease of 5% compared to $39.6 million for the second quarter of 2024. The decrease in selling, general and administrative expenses in the second quarter of 2025 compared to the prior year period was primarily attributable to a decrease in stock-based compensation, partially offset by increases in headcount and related costs to support the growth in the overall business and related corporate infrastructure and costs related to the marketing and advertising of Amtagvi.

Selling, general and administrative expenses were $81.6 million for the first half of 2025, an increase of 15% compared to $71.0 million for the first half of 2024. The increase in selling, general and administrative expenses in the first half of 2025 compared to the prior year period was primarily attributable to increases in headcount and related costs, offset by reductions in stock-based compensation, to support the growth in the overall business and related corporate infrastructure, as well as costs incurred to support the distribution and commercialization of Amtagvi and Proleukin.

For additional information, please see the Company's Selected Consolidated Balance Sheets and Statements of Operations below.

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 4:30 p.m. ET. To listen to the live or archived audio webcast, please register at https://edge.media-server.com/mmc/p/cgjzdfym. 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.

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)

	June 30, 2025 (unaudited)	December 31, 2024
Cash, cash equivalents, and investments	$ 301,183	$ 323,781
Restricted cash	$ 5,944	$ 6,359
Total assets	$ 907,437	$ 910,426
Stockholders' equity	$ 698,488	$ 710,405

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,	
Revenue	**2025**	**2024**	**2025**	**2024**
Product revenue	$ 59,952	$ 31,106	$ 109,276	$ 31,821
Total revenue	59,952	31,106	109,276	31,821
Costs and expenses**				
Cost of sales*	$ 56,664	$ 31,368	$ 106,405	$ 38,629
Research and development	79,363	62,084	156,242	141,867
Selling, general and administrative	37,699	39,568	81,624	70,961
Total costs and expenses	173,726	133,020	344,271	251,457
Loss from operations	(113,774)	(101,914)	(234,995)	(219,636)
Other income				
Interest and other income, net	4,104	3,355	7,324	6,693
Net Loss before income taxes	$ (109,670)	$ (98,559)	$ (227,671)	$ (212,943)
Income tax (expense) benefit	(1,988)	1,458	150	2,866
Net Loss	$ (111,658)	$ (97,101)	$ (227,821)	$ (210,077)
Net Loss Per Share of Common Stock, Basic and Diluted	$ (0.33)	$ (0.34)	$ (0.69)	$ (0.76)
Weighted-Average Shares of Common Stock Outstanding, Basic and Diluted	334,511	284,817	328,721	275,518

* Cost of sales includes period costs associated with patient drop off and manufacturing success rates, non-cash stock-based compensation and amortization expense for intangible assets, and royalties payable on product sales.

****Includes stock-based compensation as follows:**

Cost of sales	$ 2,149	$ 2,297	$ 4,569	$ 2,297
Research and development	6,359	13,107	16,276	22,022
Selling, general and administrative	6,435	15,062	17,013	23,325
Total stock-based compensation included in costs and expenses	$ 14,943	$ 30,466	$ 37,858	$ 47,644

CONTACTS

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

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

Source: Iovance Biotherapeutics, Inc.