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

May 8, 2025

1Q25 Total Product Revenue of $49.3M

FY25 Total Product Revenue Guidance Revised to $250M-$300M

FY25 Operating Expenses Reduced and 2H26 Cash Runway Guidance Maintained

2025 Regulatory Approvals for Amtagvi® Expected in the UK, EU, and Canada

On Track to Report Updated Clinical Data for Registrational Trial in Previously Treated Advanced NSCLC in 2H25

SAN CARLOS, Calif., May 08, 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 first quarter 2025 financial results and corporate updates.

Frederick Vogt, Ph.D., J.D., Interim President and Chief Executive Officer of Iovance, stated, “During the start of the new year, our first quarter revenue was impacted by a significant reduction in capacity during the annual scheduled maintenance at the Iovance Cell Therapy Center (*i*CTC). Since full production has now resumed at the *i*CTC, we now expect infusions to grow in the second quarter as compared to the first quarter. Additionally, based on our experience to date, we are revising full-year 2025 revenue guidance to reflect recent launch dynamics. In the first 12 months of our U.S. launch, we have executed toward our long-term adoption goals by treating more than 275 Amtagvi patients and generating more than $210 million in revenue. Beyond the U.S. launch, we are on track this year for potential Amtagvi regulatory approvals in three new ex-U.S. markets as well as a clinical data update from our registrational trial in non-small cell lung cancer.”

First Quarter 2025 Financial Results, Corporate Guidance, and Updates

Product Revenue and Guidance

First Quarter 2025 Total Product Revenue: Iovance recognized total revenue of $49.3 million from sales of Amtagvi and Proleukin during the first quarter ended March 31, 2025.

- **1Q25 Amtagvi Revenue**: Product revenue from U.S. Amtagvi sales was $43.6 million, impacted by a reduction in capacity during annual scheduled maintenance at the *i*CTC. Production has resumed enabling full capacity for infusions in the second quarter 2025. Iovance currently anticipates infusing between 100 and 110 commercial patients in the second quarter.
- **1Q25 Proleukin Revenue:** Product revenue also included $5.7 million in Proleukin sales, primarily reflecting clinical and manufacturing use after stocking at major U.S. wholesalers in 2024. Significant orders are expected in the current quarter. Proleukin is used in the Amtagvi treatment regimen and other commercial, clinical, manufacturing, and research settings, which provide additional revenue.

- **Amtagvi Growth Potential at U.S. ATCs in 2025:** As of today, Iovance’s treatment network of more than 80 ATCs includes an initial wave of 70 ATCs and more than 10 ATCs in process to become a second wave. Fifty-six ATCs completed tumor resections, 48 infused one or more patients, and 11 infused more than 10 patients. These trends highlight growing adoption and significant growth potential. Several new ATCs are expected to treat their first patients in the remaining weeks of the second quarter of 2025.
- **Full Year 2025 Total Product Revenue Guidance:** Iovance is revising total product revenue guidance within the range of $250 to $300 million in the first full calendar year of Amtagvi sales. The updated forecast considers experience with ATC growth trajectories and treatment timelines for new ATCs. Beyond ATCs, large community practices are expected to expand market opportunity. Amtagvi adoption will accelerate in 2025 with broader utilization and higher demand. Proleukin sales are also expected to accelerate throughout the remainder of 2025 with restocking to U.S. distributors and sales growth to manufacturers and for other clinical and manufacturing uses. Iovance expects significant growth in total product revenue for full year 2026 and beyond. Gross margins are expected to increase over time and remain on track to surpass 70% over the next several years.
- **Full Year 2025 Expense Guidance and Cash Position:** As of March 31, 2025, Iovance had cash, cash equivalents, investments, and restricted cash of approximately $366 million. The current cash position and anticipated product revenue are expected to be sufficient to fund current and planned operations, including manufacturing expansion, into the second half of 2026. Cash burn for full year 2025 is expected to remain in line with prior guidance of less than $300 million, with a

strong focus on optimizing spending and reducing expenses throughout the organization, including flat operating expenses related to Amtagvi manufacturing headcount expansion for the latter half of 2025.
- **Macroeconomic and Geopolitical Trends:** Iovance is well-positioned to operate in the current macroeconomic and geopolitical environment. Amtagvi manufacturing and intellectual property are fully located in the U.S., providing a strategic advantage within the biopharma industry. All of Iovance's investigational TIL products are manufactured in the U.S.

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

- The U.S. FDA approved Amtagvi (lifileucel) on February 16, 2024, as the first treatment option for patients with advanced melanoma after anti-PD-1 and targeted therapy. Amtagvi is the first FDA-approved T cell therapy for a solid tumor indication.
- More than 80 U.S. ATCs have joined or are about to join our network across 35 states and 95% of addressable patients live within 200 miles of an ATC. Additional U.S. ATCs will be added steadily throughout 2025, focusing on quality ATCs with a high volume of eligible patients, including large community practice ATCs.
- Community referral activities are accelerating rapidly throughout the U.S. to drive additional patient volume to the ATCs. Large community practices are currently onboarding, creating a new and significant opportunity for more patients to receive Amtagvi quickly after frontline therapy.
- Manufacturing turnaround time is aligning with launch expectations of approximately 34 days from inbound to return shipment to ATCs. Iovance expects to shorten the manufacturing turnaround time in 2025. The overall commercial manufacturing experience remains consistent with prior clinical experience.
- Amtagvi is a preferred second-line or subsequent therapy in the National Comprehensive Cancer Network® guidelines for treatment of cutaneous melanoma.
- Reimbursement remains successful, with an average financial clearance time of about three weeks.
- Approximately 75% of Amtagvi patients are covered by private payers. To date, payers or plans covering more than 250 million lives have added Amtagvi to policies since its launch.

Launch Expansion into New Markets

- Amtagvi has the potential to address more than 30,000 patients annually with previously treated advanced melanoma across the U.S. and initial global markets with significant populations of previously treated advanced melanoma patients.[1]
- Regulatory dossiers are under review, submitted, or planned across multiple international markets for lifileucel for the treatment of adult patients with unresectable or metastatic melanoma after anti-PD-1 and targeted therapy. If approved, lifileucel will be the first and only approved therapy in this treatment setting in all markets.
    - Amtagvi has the potential to be approved in three new markets in 2025, including the United Kingdom, Canada, and all EU member states. Recently, the *i*CTC and Iovance's contract manufacturer successfully completed regulatory inspections by the European Medicines Agency.
    - Fifteen ATCs are targeted by year-end to support initial launch markets outside the U.S.
    - Named patient programs are planned outside the U.S. to provide early access to treatment prior to national reimbursement and are also expected to provide initial revenue from these markets.
    - Additional regulatory submissions remain on track for Australia in the first half of 2025 and Switzerland in the second half of 2025.

Recent Iovance TIL Cell Therapy Pipeline Highlights

- **Lifileucel in Frontline Advanced Melanoma**
    - Strong momentum continues with global site activation and patient enrollment in the registrational TILVANCE-301 trial, which is intended to support U.S. approval of Amtagvi in combination with pembrolizumab in frontline advanced melanoma, and full approval in post-anti-PD-1 melanoma.
    - Cohort 1D in the IOV-COM-202 trial is investigating lifileucel in combination with nivolumab and relatlimab in frontline advanced melanoma.
- **Lifileucel 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 in post-anti-PD-1 NSCLC.
    - The IOV-LUN-202 trial is intended to support a potential accelerated approval of lifileucel in post-anti-PD-1 NSCLC in the U.S., with an anticipated regulatory decision in 2027. The FDA previously provided positive regulatory feedback on the proposed potency matrix in NSCLC and the IOV-LUN-202 clinical trial design.
- **Lifileucel in Frontline Advanced NSCLC**
    - Iovance is pursuing a frontline therapy strategy to integrate lifileucel plus pembrolizumab following chemotherapy for patients with EGFR wild type NSCLC, representing most patients with an unmet medical need in this setting.
    - Cohorts 3D and 3E in IOV-COM-202 trial are investigating this regimen to inform a registrational and confirmatory trial design in frontline advanced NSCLC.
- **Lifileucel in Endometrial Cancer**

    - Iovance is actively enrolling in the IOV-END-201 Phase 2 trial for advanced endometrial cancer, with initial results expected in the second half of 2025. The trial is investigating lifileucel after platinum-based chemotherapy and anti-PD-1 therapy regardless of mismatch repair (MMR) status, which represents a significant unmet medical need.
- **Next Generation TIL Pipeline**
    - **PD-1 Inactivated TIL Cell Therapy (IOV-4001):** The Phase 2 efficacy portion of the IOV-GM1-201 trial continues to enroll patients to evaluate IOV-4001 in previously treated advanced melanoma and NSCLC. Iovance utilizes the TALEN® technology licensed from Cellectis to develop IOV-4001 and other investigational gene-edited TIL cell therapies with multiple knockout targets to potentially improve efficacy.
    - **Next Generation Interleukin-2 (IL-2) for TIL Treatment Regimen (IOV-3001):** A Phase 1/2 clinical trial, IOV-IL2-101, is enrolling patients 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 with strong effector T cell expansion.
    - **Next Generation, Cytokine-Tethered TIL Therapy (IOV-5001):** IND-enabling studies are proceeding as planned for IOV-5001, a genetically engineered, inducible, and tethered interleukin-12 (IL-12) TIL cell therapy, in support of an IND in 2025 for clinical development for multiple indications.

Manufacturing Capacity Expansion

- Iovance's U.S.-based manufacturing network, consisting of the *i*CTC and an FDA-approved contract manufacturer, supplies clinical and commercial TIL cell therapies to patients globally.
    - The *i*CTC facility, representing the bulk of Amtagvi and clinical TIL product production, completed annual scheduled maintenance and successfully restarted full production.
    - The Iovance manufacturing network currently has staffed capacity for more than 1,300 patients annually and is built to serve several thousand patients annually with commercial Amtagvi and for clinical trials across North America, Europe and Asia Pacific. Expansion is currently underway at the *i*CTC facility to supply TIL cell therapies to more than 5,000 patients annually in the next few years, with additional expansion opportunities also in development.

Corporate Updates

- 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.

First Quarter 2025 Financial Results

As of March 31, 2025, Iovance's cash position is approximately $366 million. The current cash position and anticipated product revenue are expected to be sufficient to fund current and planned operations into the second half of 2026.

Net loss for the first quarter of 2025 was $116.2 million, or $0.36 per share, compared to a net loss of $113.0 million, or $0.42 per share, for the first quarter of 2024.

Revenue was $49.3 million for the first quarter of 2025 and consisted of product revenue from Amtagvi and Proleukin sales. Iovance recognized $43.6 million in revenue from Amtagvi infusions that were completed during the first quarter of 2025 and $5.7 million in global revenue for Proleukin. Revenue for the first quarter of 2024 was $0.7 million for global sales of Proleukin.

The increase in revenue in the first quarter 2025 over the prior year period was primarily attributable to the U.S. launch of Amtagvi, including revenue recognized for Amtagvi, as well as Proleukin revenue in the U.S.

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 for the first quarter 2025 was $49.7 million, which included $15.0 million for period costs associated with patient drop off and manufacturing success rates, $5.4 million for non-cash amortization expense for intangible assets and fair value mark up of inventory, and $1.3 million in royalties payable on product sales. For the first quarter 2024, cost of sales of $7.3 million was primarily related to non-cash amortization for intangible assets.

Increases in cost of sales in the first quarter over the prior year period were primarily attributable to costs 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 $76.9 million for the first quarter of 2025, a decrease of 4% compared to $79.8 million for the first quarter of 2024. The decreases in research and development expenses in the first quarter 2025 over the prior year period were primarily attributable to the transition of Amtagvi to commercial manufacturing. This decrease was partially offset by higher headcount and related costs, including stock-based

compensation, and clinical trial costs resulting from continued enrollment in existing trials.

Selling, general and administrative expenses were $43.9 million for the first quarter of 2025, an increase of 40% compared to $31.4 million for the first quarter of 2024. The increase in selling, general and administrative expenses in the first quarter compared to the prior year period was primarily attributable to increases in headcount and related costs, including stock-based compensation, to support the growth in the overall business and related corporate infrastructure, as well as marketing and legal costs and costs incurred to support the 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/wi5b4tnt. 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 regarding the successful integration of the recent Proleukin acquisition; 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 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)

	March 31, 2025 (unaudited)	December 31, 2024
Cash, cash equivalents, and investments	$ 359,713	$ 323,781
Restricted cash	$ 6,381	$ 6,359
Total assets	$ 966,740	$ 910,426
Stockholders' equity	$ 767,865	$ 710,405

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

	For the Three Months Ended March 31,	
	2025	2024
Revenue		
Product revenue	$ 49,324	$ 715
Total revenue	49,324	715
Costs and expenses*		
Cost of sales	$ 49,741	$ 7,261
Research and development	76,879	79,783
Selling, general and administrative	43,925	31,393
Total costs and expenses	170,545	118,437
Loss from operations	(121,221)	(117,722)
Other income		
Interest and other income, net	3,220	3,338
Net Loss before income taxes	$ (118,001)	$ (114,384)
Income tax benefit	1,838	1,408
Net Loss	$ (116,163)	$ (112,976)
Net Loss Per Share of Common Stock, Basic and Diluted	$ (0.36)	$ (0.42)
Weighted-Average Shares of Common Stock Outstanding, Basic and Diluted	322,868	266,220
***Includes stock-based compensation as follows:**		
Cost of sales	$ 2,420	$ —
Research and development	9,917	8,915
Selling, general and administrative	10,578	8,263
Total stock-based compensation included in costs and expenses	$ 22,915	$ 17,178

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Source: Iovance Biotherapeutics, Inc.