Iovance Biotherapeutics Reports Financial Results and Corporate Updates for Fourth Quarter and Full Year 2024

February 27, 2025

Significant Demand for Amtagvi® (Lifileucel) Continues with Total Product Revenue of $73.7M in 4Q24 and $164.1M in FY24, Achieving Upper End of FY24 Guidance Range of $160M-$165M

Reaffirming FY25 Total Product Revenue Guidance of $450M-$475M

FY25 Cash Burn Anticipated to be Under $300M

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

Enrollment Accelerating Across Global Registrational Trials in Frontline Advanced Melanoma and Previously Treated Advanced NSCLC

SAN CARLOS, Calif., Feb. 27, 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 fourth quarter and full year 2024 financial results and corporate updates.

Frederick Vogt, Ph.D., J.D., Interim President and Chief Executive Officer of Iovance, stated, “In 2024, we successfully drove strong early adoption for our U.S. commercial launch of Amtagvi® for patients with previously treated advanced melanoma. Strong demand and growth are continuing and on track to accelerate for both Amtagvi and Proleukin® in 2025 and beyond in the U.S. and globally. Our top commercial priorities are to drive broader adoption and utilization, increase patient referrals, add large community practices to our authorized treatment center (ATC) network, expand the U.S. market, and secure regulatory approvals in three new markets outside the U.S. I am confident that Iovance is well positioned to remain the global leader in innovating, developing, and delivering current and future generations of TIL cell therapy for patients with cancer.”

Fourth Quarter and Full Year 2024 Financial Results, Corporate Guidance, and Updates

Product Revenue and Guidance

- **Fourth Quarter 2024 Total Product Revenue:** Iovance recognized total revenue of $73.7 million from sales of Amtagvi and Proleukin during the fourth quarter ended December 31, 2024.
  - **Amtagvi Revenue**: Product revenue was $48.7 million from U.S. Amtagvi sales in the fourth quarter of 2024, reflecting strong adoption with increasing demand. Amtagvi revenue is recognized upon patient infusion.
  - **Proleukin Revenue:** Product revenue also included $25.0 million in Proleukin sales in the fourth quarter of 2024. Proleukin is used in the Amtagvi treatment regimen and other commercial, clinical, manufacturing, and research settings, which provide additional revenue. Proleukin revenue is generally recognized upon delivery to distributors and ATCs.
- **Full Year 2024 Total Product Revenue:** Total product revenue was $164.1 million and achieved the high end of the company’s guidance range of $160 to $165 million for the full year 2024. Full year product revenue included the first three quarters of sales following the U.S. launch of Amtagvi on February 20, 2024. The full year 2024 product revenue for Amtagvi and Proleukin was $103.6 million and $60.5 million, respectively.
- **Significant Amtagvi Growth Potential at Approximately 70 ATCs in 2025:** Amongst current ATCs, 76% completed tumor resections, 64% infused one or more patients, and 13% infused more than 10 patients, highlighting significant growth potential at existing ATCs.
- **Full Year 2025 Total Product Revenue Guidance:** Iovance is reaffirming total product revenue guidance within the range of $450 to $475 million for 2025, the first full calendar year of Amtagvi sales. Amtagvi adoption is on track to continue accelerating throughout 2025 with broader utilization, higher demand, and growth in community referrals. Iovance also 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. In line with anticipated growth in Amtagvi demand, Proleukin revenue is also expected to increase significantly in 2025 and beyond.
- **Full Year 2025 Expense Guidance:** Cash burn for full year 2025 is expected to be under $300 million, including completion of construction of the Iovance Cell Therapy Center (*i*CTC) manufacturing expansion.
- **Cash Position:** As of February 26, 2025, Iovance had cash, cash equivalents, investments, and restricted cash of approximately $422 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.

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.
- Approximately 70 U.S. ATCs are active across 32 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 increasing throughout the U.S. to drive additional patient volume to these ATCs. Large community practices are currently onboarding, creating a new and significant opportunity for more patients to receive Amtagvi after frontline therapy.
- Manufacturing turnaround time is aligning with launch expectations of approximately 34 days from inbound to return shipment to ATCs. Efforts are underway to shorten the turnaround time in 2025. The 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 20,000 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.
    - A marketing authorization application (MAA) was submitted to the Medicines and Healthcare products Regulatory Agency in the United Kingdom for potential approval in the first half of 2025.
    - A new drug submission (NDS) to Health Canada was accepted for a prioritized 200-day review process through the Notice of Compliance with Conditions (NOC/c) policy for potential approval in mid-2025.
    - An MAA for all EU member states was accepted for review by the European Medicines Agency for potential approval in the second half of 2025.
    - Named patient programs are planned in the UK, France, Germany, Canada, Switzerland, and Australia in 2025 to provide reimbursed access to treatment prior to approval or final pricing and are also expected to provide initial revenue from these markets.
    - Additional regulatory submissions remain on track in 2025 and 2026, including Australia in the first half of 2025 and Switzerland in the second half of 2025.
    - A total of 15 active ATCs are targeted by year-end to support initial launch markets outside the U.S.

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 accelerated and full U.S. approvals of Amtagvi in combination with pembrolizumab in frontline advanced melanoma, as well as full approval of Amtagvi in post-anti-PD-1 melanoma.

- **Lifileucel in Previously Treated Advanced Non-Small Cell Lung Cancer (NSCLC)**
    - Iovance expects 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.
    - Enrollment in IOV-LUN-202 continues with high demand at clinical sites in the U.S., Canada, and Europe with additional site activations underway in new regions with strong track records for enrollment in NSCLC studies.

- **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. This regimen will be investigated in a new Cohort 3D in IOV-COM-202 trial. Cohort 3D results will 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 which is investigating lifileucel for advanced endometrial cancer patients who have progressed after platinum-based chemotherapy and anti-PD-1 therapy regardless of mismatch repair (MMR) status.
- IOV-END-201 is supported by preclinical and manufacturing success data, as well as positive feedback from gynecological oncology experts. Initial results from IOV-END-201 are expected in the second half of 2025. There are no currently approved therapies for endometrial cancer following frontline post-anti-PD-1 therapy and chemotherapy, representing a significant opportunity for TIL cell therapy to address an additional unmet medical need in the post-anti-PD-1 treatment setting.

- **Next Generation TIL Pipeline**

  - **PD-1 Inactivated TIL Cell Therapy (IOV-4001):** The Phase 2 efficacy portion of the IOV-GM1-201 trial in previously treated advanced melanoma and NSCLC continues to enroll rapidly. Iovance utilizes the TALEN® technology licensed from Cellectis to develop 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:** A Phase 1/2 clinical trial was initiated to investigate IOV-3001, a second-generation, modified IL-2 analog for use in the TIL therapy treatment regimen. Non-human primate and IND-enabling studies of IOV-3001 demonstrated the potential for improved safety with strong effector T cell expansion.
  - **Next Generation, Cytokine-Tethered TIL Therapy:** IND-enabling studies are proceeding for IOV-5001, a genetically engineered, inducible, and tethered interleukin-12 (IL-12) TIL cell therapy. A clinical trial of a prior generation IL-12 TIL therapy at the National Cancer Institute showed improved efficacy with low cell doses, without the use of IL-2, and provides the rationale for modifications in IOV-5001 to enhance TIL efficacy while optimizing safety. In preclinical studies, IOV-5001 drove superior antitumor activity in a simulated tumor microenvironment. Iovance plans to submit an IND in 2025 to support clinical development for multiple indications.

Manufacturing Capacity Expansion

- The *i*CTC, and an FDA-approved legacy contract manufacturer, currently have capacity to treat several thousand patients annually.
  - The company completed annual scheduled maintenance at the *i*CTC and successfully restarted full production.
  - Expansion is currently underway for the *i*CTC campus to supply TIL cell therapies to more than 5,000 patients annually in the next few years.
  - Iovance is also developing a manufacturing network to address more than 10,000 patients annually.

Corporate Updates

- Dan Kirby joined Iovance's Executive Leadership Team in the newly created role of Chief Commercial Officer in February 2025.
- Raj Puri, M.D., Ph.D., was promoted to the newly created role of Chief Regulatory Officer in November 2024.
- Iovance currently owns more than 250 granted or allowed U.S. and international patents and patent rights for Amtagvi and other TIL-related technologies that are expected to provide Amtagvi with 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.

Fourth Quarter and Full Year 2024 Financial Results

As of February 26, 2025, Iovance's cash position is approximately $422 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 fourth quarter of 2024 was $78.6 million, or $0.26 per share, compared to a net loss of $116.4 million, or $0.45 per share, for the fourth quarter of 2023. Net loss for the full year 2024 was $372.2 million, or $1.28 per share, compared to a net loss of $444.0 million, or $1.89 per share, for the full year 2023.

Revenue was $73.7 million for the fourth quarter of 2024 and consisted of product revenue from Amtagvi and Proleukin sales. Iovance recognized $48.7 million in revenue from Amtagvi infusions that were completed during the fourth quarter of 2024 and $25.0 million in global revenue for Proleukin. An additional $0.5 million in cash was received in the fourth quarter of 2024 for Amtagvi sales that will be recognized as revenue in the first quarter of 2025. Revenue for the fourth quarter of 2023 was $0.5 million for global sales of Proleukin.

Revenue for the full year 2024 was $164.1 million and reflected product revenue of $103.6 million from Amtagvi and $60.5 million from Proleukin. Revenue for the prior full year period 2023 was $1.2 million for global sales of Proleukin which Iovance began to recognize during the three-month period ended June 30, 2023.

The increases in revenue in the fourth quarter and full year 2024 over the prior year periods were primarily attributable to the U.S. launch of Amtagvi, including revenue recognized for Amtagvi, as well as significant growth in U.S. Proleukin revenue for use in the Amtagvi treatment regimen and global Proleukin sales.

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 three months ended December 31, 2024 was $45.5 million, primarily attributed to $9.1 million in 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, and $6.0 million in royalties payable on product sales. Cost of sales for the three months ended December 31, 2023 was $4.4 million, primarily related to non-cash amortization for intangible assets.

Cost of sales for the full year 2024 was $124.0 million, primarily related to $26.3 million in certain costs associated with patient drop off and manufacturing success rates, $26.2 million in non-cash amortization expense for intangible assets and fair value mark-up of inventory, and $14.2 million royalties payable on product sales. Cost of sales for the full year 2023 was $10.8 million, primarily related to non-cash amortization for intangible assets.

Increases in cost of sales in the fourth quarter and full year 2024 over the prior year periods were primarily attributable to the initiation of product sales, commercial manufacturing, 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 $72.2 million for the fourth quarter of 2024, a decrease of $15.3 million compared to $87.5 million for the fourth quarter of 2023. Research and development expenses were $282.3 million for the full year 2024, a decrease of $61.8 million compared to $344.1 million for the full year 2023.

The decreases in research and development expenses in the fourth quarter over the prior year period were primarily attributable to the transition of Amtagvi to commercial manufacturing. This decrease was partially offset by increases in headcount and related costs, including stock-based compensation, and clinical trial costs. The decrease in research and development expenses in the full year 2024 over the prior full year period was primarily attributable to the transition of Amtagvi to commercial manufacturing and lower clinical costs. These decreases were partially offset by increases in headcount and related costs, including stock-based compensation and lab and consumable costs.

Selling, general and administrative expenses were $42.5 million for the fourth quarter of 2024, an increase of $12.6 million compared to $29.9 million for the same period ended December 31, 2023. Selling, general and administrative expenses were $153.0 million for the full year 2024, an increase of $46.1 million compared to $106.9 million for the prior full year period.

The increase in selling, general and administrative expenses in the fourth quarter and full year 2024 compared to the prior year periods 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 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/hw2g9axf/. 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 Consolidated Balance Sheets
(in thousands)

	December 31, 2024	December 31, 2023
Cash, cash equivalents, and investments	$ 323,781	$ 279,867
Restricted cash	$ 6,359	$ 66,430
Total assets	$ 910,426	$ 780,351
Stockholders' equity	$ 710,405	$ 584,613

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

	For the Three Months Ended December 31,		For the Year Ended December 31,	
	2024 (unaudited)	2023 (unaudited)	2024	2023
Revenues				
Product revenue	$ 73,694	$ 482	$ 164,070	$ 1,189
Total revenue	73,694	482	164,070	1,189
Costs and expenses*				
Cost of sales	45,543	4,365	123,995	10,755
Research and development	72,224	87,470	282,336	344,077
Selling, general and administrative	42,503	29,903	153,017	106,916
Total costs and expenses	160,270	121,738	559,348	461,748
Loss from operations	(86,576)	(121,256)	(395,278)	(460,559)
Other income				
Interest and other income, net	9,575	3,118	20,273	13,043
Net Loss before income taxes	(77,001)	(118,138)	(375,005)	(447,516)
Income tax (expense) benefit, net	(1,558)	1,759	2,828	3,479
Net Loss	$ (78,559)	$ (116,379)	$ (372,177)	$ (444,037)

Net Loss Per Share of Common Stock, Basic and Diluted	$ (0.26)	$ (0.45)	$ (1.28)	$ (1.89)
Weighted-Average Shares of Common Stock Outstanding, Basic and Diluted	304,890	255,951	289,877	235,131
***Includes stock-based compensation as follows:**				
Cost of sales	$ 3,192	$ —	$ 8,554	$ —
Research and development	13,445	7,890	49,270	34,926
Selling, general and administrative	14,336	6,509	51,799	27,699
Total stock-based compensation included in costs and expenses	$ 30,973	$ 14,399	$ 109,623	$ 62,625

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Source: Iovance Biotherapeutics, Inc.