UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

DIMITRY FARBEROV, Individually and on Behalf of All Others Similarly Situated,

Plaintiff,

v.

IOVANCE BIOTHERAPEUTICS, INC., FREDERICK G. VOGT, JEAN-MARC BELLEMIN, and IGOR P. BILINSKY,

Defendants.

Case No.

CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS

Plaintiff Dimitry Farberov ("Plaintiff"), individually and on behalf of all others similarly situated, by and through his attorneys, alleges the following upon information and belief, except as to those allegations concerning Plaintiff, which are alleged upon personal knowledge. Plaintiff's information and belief is based upon, among other things, his counsel's investigation, which includes without limitation: (a) review and analysis of regulatory filings made by Iovance Biotherapeutics, Inc. ("Iovance" or the "Company") with the United States ("U.S.") Securities and Exchange Commission ("SEC"); (b) review and analysis of press releases and media reports issued by and disseminated by Iovance; and (c) review of other publicly available information concerning Iovance.

NATURE OF THE ACTION AND OVERVIEW

1. This is a class action on behalf of persons and entities that purchased or otherwise acquired Iovance securities between May 9, 2024 and May 8, 2025, inclusive (the "Class Period"). Plaintiff pursues claims against the Defendants under the Securities Exchange Act of 1934 (the "Exchange Act").

2. Iovance is a commercial-stage biopharmaceutical company which develops and commercializes cell therapies for the treatment of metastatic melanoma and other solid tumor cancers. The Company's top priority is the commercialization of Amtagvi® (lifileucel), a tumor-derived autologous T cell immunotherapy used to treat adult patients with unresectable or metastatic melanoma. The Company received FDA approval for Amtagvi on February 16, 2024. The Company commercially launched Amtagvi on February 20, 2024.

3. On May 8, 2025, after the market closed, Iovance released its first quarter 2025 financial results, revealing a quarterly total product revenue of $49.3 million, a significant decline from the prior quarter's $73.7 million. The Company also announced its full fiscal year 2025 total product revenue guidance had been slashed from $450 million - $475 million to $250 million - $300 million, a reduction of over 40% at the midpoint. The Company revealed it was "revising full-year 2025 revenue guidance to reflect recent launch dynamics" of Amtagvi. The Company further revealed "[t]he updated forecast considers experience with ATC [authorized treatment center] growth trajectories and treatment timelines for new ATCs."

4. On this news, the price of Iovance shares declined $1.42 per share, or 44.8%, to close at $1.75 per share on May 9, 2025, on unusually heavy trading volume.

5. Throughout the Class Period, Defendants made materially false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (1) new Authorized Treatment Centers were experiencing longer timelines to begin treating patients with Amtagvi; (2) the Company's sales team and new ATCs were ineffective in patient identification and patient selection for Amtagvi, leading to higher patient drop-offs; (3) the foregoing dynamics led to higher costs and lower revenue because ATCs could not keep pace with manufactured product; and (4) that, as a result of the foregoing, Defendants' positive statements about the Company's business, operations, and prospects were materially misleading and/or lacked a reasonable basis.

6. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

JURISDICTION AND VENUE

7. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

8. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act (15 U.S.C. § 78aa).

9. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1391(b) and Section 27 of the Exchange Act (15 U.S.C. § 78aa(c)). Substantial acts in furtherance of the alleged fraud or the effects of the fraud have occurred in this Judicial District. Many of the acts charged herein, including the dissemination of materially false and/or misleading information, occurred in substantial part in this Judicial District. In addition, the Company's principal executive offices are located in this District.

10. In connection with the acts, transactions, and conduct alleged herein, Defendants directly and indirectly used the means and instrumentalities of interstate commerce, including the United States mail, interstate telephone communications, and the facilities of a national securities exchange.

PARTIES

11. Plaintiff Dimitry Farberov, as set forth in the accompanying certification, incorporated by reference herein, purchased Iovance securities during the Class Period, and suffered damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged herein.

12. Defendant Iovance is incorporated under the laws of Delaware with its principal executive offices located in San Carlos, California. Iovance's common stock trades on the NASDAQ exchange under the symbol "IOVA."

13. Defendant Frederick G. Vogt ("Vogt") was the Company's Chief Executive Officer ("CEO") at all relevant times.

14. Defendant Jean-Marc Bellemin ("Bellemin") was the Company's Chief Financial Officer ("CFO") at all relevant times.

15. Defendant Igor P. Bilinsky ("Bilinsky") was the Company's Chief Operating Officer at all relevant times.

16. Defendants Vogt, Bellemin, and Bilinsky (collectively the "Individual Defendants"), because of their positions with the Company, possessed the power and authority to control the contents of the Company's reports to the SEC, press releases and presentations to securities analysts, money and portfolio managers and institutional investors, i.e., the market. The Individual Defendants were provided with copies of the Company's reports and press releases alleged herein to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available to them, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public, and that

the positive representations which were being made were then materially false and/or misleading. The Individual Defendants are liable for the false statements pleaded herein.

SUBSTANTIVE ALLEGATIONS

Background

17. Iovance is a commercial-stage biopharmaceutical company which develops and commercializes cell therapies for the treatment of metastatic melanoma and other solid tumor cancers. The Company's top priority is the commercialization of Amtagvi® (lifileucel), a tumor-derived autologous T cell immunotherapy used to treat adult patients with unresectable or metastatic melanoma. The Company received FDA approval for Amtagvi on February 16, 2024. The Company commercially launched Amtagvi on February 20, 2024.

Materially False and Misleading

Statements Issued During the Class Period

18. The Class Period begins on May 9, 2024.[1] On that day, Iovance issued a press release announcing its financial results for the first quarter ended March 31, 2024 and an update on recent developments. The press release touted the Company's finanical results, as well as its alleged "strong momentum" in the Amtagvi launch, including as it related to "onboarding" ATCs. Specifically, the press release stated as follows, in relevant part:

> **Iovance Biotherapeutics Reports First Quarter 2024 Financial Results and Corporate Updates**
>
> *Strong Momentum for Amtagvi™ (Lifileucel) U.S. Launch Following U.S. Food and Drug Administration (FDA) Approval*
>
> *100+ Amtagvi Patients Enrolled Across More Than 40 Current Authorized Treatment Centers*
>
> *(ATCs), with ~50 Total ATCs On Track by End of May and 70+ Total ATCs by Year-End 2024*
>
> * * *
>
> Frederick Vogt, Ph.D., J.D., Interim President and Chief Executive Officer of Iovance, stated, "The first quarter of 2024 was transformative for Iovance following our first FDA approval and our ***strong start for the U.S. commercial launch*** of Amtagvi™ for patients with advanced melanoma. Immediate demand for Amtagvi

[1] Unless otherwise stated, all emphasis in bold and italics hereinafter is added.

> is very high and continues to significantly increase across initial ATCs. As of today, more than 100 patients have already enrolled for Amtagvi therapy. We have successfully manufactured and delivered Amtagvi to many ATCs where commercial patients are being treated. ***We expect our launch momentum to remain strong and continue to build as we ramp up the U.S. launch throughout 2024 with the authorization of additional ATCs. We also continue to execute across our broad clinical pipeline***. As a fully integrated company, Iovance is well positioned to remain the global leader in innovating, developing, and delivering TIL cell therapy for patients with cancer."
>
> **Recent and First Quarter 2024 Highlights and Corporate Updates**
>
> Amtagvi™ (Lifileucel) U.S. Approval and Launch Highlights in Advanced Melanoma
>
> • The U.S. FDA approved Amtagvi (lifileucel) on February 16, 2024, as the first treatment option for advanced melanoma after anti-PD-1 and targeted therapy. Amtagvi is also the first and only FDA-approved T cell therapy for a solid tumor indication.
>
> • Since approval, more than 100 patients have enrolled for Amtagvi therapy. The first patients have been successfully treated and the balance are moving through the stages of the journey, which includes surgery for cell collection, manufacturing, and the Amtagvi treatment regimen.
>
> • ***Onboarding is complete at more than 40 U.S. ATCs, up from 30 initial ATCs at approval. Iovance remains on track to onboard approximately 50 ATCs by the end of May 2024 and expects to have more than 70 ATCs onboarded by the end of 2024.***
>
> • Manufacturing turnaround time has been on-target with initial launch expectations of approximately 34 days from inbound to return shipment to ATCs. The commercial manufacturing experience to date is consistent with prior clinical experience.
>
> • ***The U.S. launch of Amtagvi, and additional sales of Proleukin® used with the treatment regimen, are expected to drive significant revenue for Iovance in 2024.***

19. On May 9, 2024, the Company submitted its quarterly report for the period ended March 31, 2024 on a Form 10-Q filed with the SEC, affirming the previously reported financial results. The report stated the following regarding "factors that ***may*** cause actual results, levels of activity, performance or achievements to be materially different from the information expressed" including the Company's "ability to successfully commercialize Amtagvi." Specifically the report stated as follows, in relevant part:

> These statements involve risks, uncertainties and other factors that ***may*** cause actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements.

* * *

- our ability to successfully commercialize Amtagvi™ (lifileucel) and Proleukin® (aldesleukin), and any other products and/or product candidates for which we obtain or have obtained FDA, EMA, or other regulatory approvals;

* * *

Successfully commercialize our lead product Amtagvi™ for the treatment of post-anti-PD-1 advanced melanoma

Our top priority is commercialization of Amtagvi™ in the U.S. for the treatment of patients with post-anti-PD-1 advanced melanoma, for which we received FDA approval on February 16, 2024. We have experienced marketing, payer access and distribution teams as well as a sales force with extensive experience in oncology and cell therapy. Our medical affairs team is also in the field educating key opinion leaders, or KOLs, about Amtagvi™ and TIL cell therapy, as well as presenting and publishing our clinical results. More than half of the members of our field teams have prior cell therapy experience.

The four primary areas of our Amtagvi™ launch efforts include:

- onboarding of authorized treatment centers, or ATCs, for commercial launch with the goal of activating 50 ATCs within 90 days of the BLA Prescription Drug User Fee Act date of February 24, 2024;

- collaboration with healthcare professionals, or HCPs, who will be administering our product;

- operational excellence in launch execution, commercial manufacturing and delivery of therapy; and

- ongoing and continuous communication with payors about the value of Amtagvi™.

20. On August 8, 2024, Iovance issued a press release announcing its financial results for the quarter ended June 30, 2024 and an update on recent developments. The press release touted the Company's finanical results, reported "Strong Momentum Continues for Amtagvi" and issued "Total Product Revenue Guidance of… $450-$475 Million for FY25." Specifically the press release stated as follows, in relevant part:

Iovance Biotherapeutics Reports Financial Results and Corporate Updates for Second Quarter and First Half 2024

Strong Momentum Continues for Amtagvi™ (Lifileucel) U.S. Launch with $31.1 Million in Total 2Q24 Revenue

Total Product Revenue Guidance *of $53-$55 Million for 3Q24, $160-$165 Million for FY24, and* ***$450-$475 Million for FY25***

* * *

Frederick Vogt, Ph.D., J.D., Interim President and Chief Executive Officer of Iovance, stated, "The first half of 2024 ushered in our first FDA approval and the start of our U.S. commercial launch of Amtagvi™ for patients with previously treated advanced melanoma. Amtagvi and Proleukin® ***demand remains strong and continues to increase as authorized treatment centers (ATCs) adopt Amtagvi*** and community referral networks are mobilized to drive patients to ATCs. These demand trends, ***as well as broader utilization of Amtagvi among an expanding ATC network, are expected to accelerate quarterly growth throughout this year and next year.*** We expect this growth to continue in 2025, 2026 and beyond. Additionally, we continue to expand our global commercial footprint, proprietary manufacturing capabilities, and broad clinical pipeline. As a fully integrated company, Iovance is well positioned to remain the global leader in innovating, developing, and delivering TIL cell therapy for patients with cancer."

Second Quarter and First Half 2024 Financial Results, Corporate Guidance, and Updates

Product Revenue and Guidance

- **2Q24 Total Product Revenue:** $31.1 million for the second quarter ended June 30, 2024, following the initial launch of Amtagvi on February 20, 2024.

  - **Amtagvi Revenue:** 2Q24 represents the first quarter of Amtagvi sales in the U.S. with product revenue of $12.8 million, which is only recognized upon patient infusion.

* * *

- **FY24 and FY25 Total Product Revenue Guidance:** Iovance expects significant quarter-over-quarter growth in product revenue to continue throughout 2024, 2025, and beyond as the adoption curve for Amtagvi steepens. More than 55 patients have been infused with Amtagvi since the first commercial infusion in April 2024, which includes 25 patients infused in the second quarter and over 30 patients infused since the start of the third quarter.

* * *

  - **Revenue Guidance in FY25:** Robust growth for Amtagvi continues as existing ATC demand increases and new ATCs are onboarded. ***As such, total product revenue for 2025 is anticipated to be within the range of $450 to $475 million, the first full calendar year of Amtagvi sales,*** with gross margins expected to increase to greater than 70% over the next several years. In line with Amtagvi demand, Proleukin revenue is expected to significantly increase in 2025.

* * *

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 advanced melanoma after anti-PD-1 and targeted therapy. Amtagvi is also the first FDA-approved T cell therapy for a solid tumor indication.

- ***Onboarding is complete at more than 50 U.S. ATCs across 29 states and more than 90% of addressable patients are now located within 200 miles of an ATC. More than 70 ATCs remain on track to be onboarded by the end of 2024.***

- Manufacturing turnaround time has been on-target with initial launch expectations of approximately 34 days from inbound to return shipment to ATCs, with efforts underway to reduce the turnaround time in the near term. The commercial manufacturing experience is consistent with prior clinical experience.

21. On August 8, 2024, the Company submitted its quarterly report for the period ended June 30, 2024 on a Form 10-Q filed with the SEC, affirming the previously reported financial results. The report purported to report the Company's net product revenue for the period, representing sales of Amtagvi as well as "factors that ***may*** cause actual results, levels of activity, performance or achievements to be materially different from the information expressed" including the Company's "ability to successfully commercialize Amtagvi." Specifically the report stated as follows, in relevant part:

> These statements involve risks, uncertainties and other factors that ***may*** cause actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements.
>
> * * *
>
> - our ability to successfully commercialize Amtagvi™ (lifileucel) and Proleukin® (aldesleukin), and any other products and/or product candidates for which we obtain or have obtained FDA, EMA, or other regulatory approvals;

22. On November 7, 2024, Iovance issued a press release announcing its financial results for the quarter ended September 30, 2024 and an update on recent developments. The press release touted the Company's financial results, the progress with onboarding ATCs, and reaffirmed guidance of "$450-$475M for FY25 of Total Product Revenue." Specifically, the press release stated as follows, in relevant part:

> **Iovance Biotherapeutics Reports Financial Results and Corporate Updates for Third Quarter and Year to Date 2024**
>
> *Significant Demand for Amtagvi™ (Lifileucel) Continues with $58.6M in Total 3Q24 Product Revenue*
>
> ***Reaffirming Guidance of $160-$165M for FY24 and $450-$475M for FY25 of Total Product Revenue***
>
> * * *
>
> Frederick Vogt, Ph.D., J.D., Interim President and Chief Executive Officer of Iovance, stated, "Iovance is executing a successful U.S. commercial launch of Amtagvi™ for patients with previously treated advanced melanoma. ***Robust demand for Amtagvi and Proleukin® continues to grow as our expanding network of authorized treatment centers (ATCs) and outreach to community oncologists***

broaden the utilization of Amtagvi, driving a higher volume of patient referrals. Demand trends are expected to accelerate growth throughout the remainder of the year and over the following years. As such, we are actively pursuing additional regulatory approvals to expand our commercial footprint, driving growth beyond the U.S. into new markets with a high prevalence of advanced melanoma. As a fully integrated company, 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."

Third Quarter and Year to Date 2024 Financial Results, Corporate Guidance, and Updates

Product Revenue and Guidance

- **3Q24 Total Product Revenue:** Iovance recognized total revenue of $58.6 million from sales of Amtagvi and Proleukin during the third quarter ended September 30, 2024.

  - **Amtagvi Revenue**: Product revenue was $42.1 million from U.S. Amtagvi sales in the third quarter of 2024, reflecting increasing strong demand and adoption. The Amtagvi launch, with revenue recognized upon patient infusion, began during the second quarter of 2024.

* * *

- **FY24 and FY25 Total Product Revenue Guidance:** Amtagvi adoption is on track to continue accelerating, driven by broader utilization, higher demand from our expanding ATC network, and growth in community referrals. Iovance is reaffirming its guidance for FY24 and FY25 and expects quarter-over-quarter product revenue growth for the fourth quarter of 2024, full year 2025, and beyond.

* * *

  - **Revenue Guidance in FY25:** Total product revenue remains on track to be within the range of $450 to $475 million in 2025, the first full calendar year of Amtagvi sales. Gross margins are increasing as the launch advances and are expected 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.

* * *

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.

- ***Onboarding is complete at 56 U.S. ATCs across 29 states and more than 90% of addressable patients are now located within 200 miles of an ATC. Approximately 70 ATCs remain on track to be onboarded by the end of 2024.***

- Manufacturing turnaround time has been on target, with launch expectations of approximately 34 days from inbound to return shipment to ATCs. With efforts

> underway, turnaround time is expected to be reduced in the near term. The commercial manufacturing experience is consistent with prior clinical experience.

23. On November 7, 2024, the Company submitted its quarterly report for the period ended September 30, 2024 on a Form 10-Q filed with the SEC, affirming the previously reported financial results. The report purported to report the Company's net product revenue for the period, representing sales of Amtagvi as well as "factors that ***may*** cause actual results, levels of activity, performance or achievements to be materially different from the information expressed" including the Company's "ability to successfully commercialize Amtagvi." Specifically the report stated as follows, in relevant part:

> These statements involve risks, uncertainties and other factors that ***may*** cause actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements.
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> * * *
>
> ● our ability to successfully commercialize Amtagvi™ (lifileucel) and Proleukin® (aldesleukin), and any other products and/or product candidates for which we obtain or have obtained FDA or other regulatory approvals, including by the European Commission in the European Union, or the EU;

24. On February 27, 2025, Iovance issued a press release announcing its financial results for the fourth quarter and fiscal year ended December 31, 2024 and an update on recent developments. The press release touted the Company's finanical results, including the progress of ATC growth trajectories and "Reaffirming FY25 Total Product Revenue Guidance of $450M-$475M". Specifically, the press release stated as follows, in relevant part:

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

* * *

- **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.

* * *

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.

25. On February 27, 2025, the Company submitted its annual report for the fiscal year ended December 31, 2024 on a Form 10-K filed with the SEC (the "FY24 10-K"). The FY24 10-K affirmed the previously reported financial results. The FY24 10-K asserted the Company was "***executing the U.S. launch of Amtagvi.***" The FY24 10-K further purported to report "factors that ***may*** cause actual results, levels of activity, performance or achievements to be materially different from the information expressed" including the Company's "ability to successfully commercialize Amtagvi" as well as "the number of ATCs [] onboard[ed] to administer" Amtagvi. Specifically the FY24 10-K stated as follows, in relevant part:

> These statements involve risks, uncertainties and other factors that ***may*** cause actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements.
>
> * * *
>
> - our ability to successfully commercialize Amtagvi® (lifileucel) and Proleukin® (aldesleukin), and any other products and/or product candidates for which we obtain or have obtained FDA or other regulatory approvals, including by the European Commission in the European Union, or the EU;
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> * * *
>
> ***In addition to marketing our product, we will need current and future ATCs both inside and outside the U.S. that are prepared and have the capacity and experience to administer our therapies to patients.*** Even if we are able to obtain approval for a product candidate in a country or region, we may not be able to approve enough treatment centers for the provision of our product to a broad patient population. ***The number of ATCs we onboard to administer our product may fluctuate and affect our product launch, and even if we onboard a large number of ATCs, this does not ensure the uptake of our products. Additionally, certain areas do not have hospitals with the facilities to safely administer our therapy.*** Accordingly, we may only be able to launch our products with a limited number of ATCs, which could ultimately reduce the uptake of our products. Although we have a team allocated to authorize

> and monitor our ATCs, substantial resources and investment from us and each treatment center may be required. Additionally, the treatment center onboarding process can be complicated and requires extensive training, technical equipment, and coordination of processes. Once authorized, ATCs will be required to ensure that their training, facilities, and treatment capabilities are adequately maintained.
>
> We have limited prior experience in the marketing, sale, and distribution of biopharmaceutical products, and there are significant risks involved in the building and managing of a commercial infrastructure. The establishment and development of commercial capabilities, including a comprehensive healthcare compliance program, to market any products we may develop will be expensive and time consuming and could delay any product launch, and we may not be able to successfully develop this capability. We, or our collaborators, will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train, manage, and retain marketing, sales, and commercial support personnel. Although we have developed a commercial infrastructure, in the event we are

26. The above statements identified in ¶¶ 18-25 were materially false and/or misleading, and failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants failed to disclose to investors: (1) new Authorized Treatment Centers were experiencing longer timelines to begin treating patients with Amtagvi; (2) the Company's sales team and new ATCs were ineffective in patient identification and patient selection for Amtagvi, leading to higher patient drop-offs; (3) the foregoing dynamics led to higher costs and lower revenue because ATCs could not keep pace with manufactured product; and (4) that, as a result of the foregoing, Defendants' positive statements about the Company's business, operations, and prospects were materially misleading and/or lacked a reasonable basis.

Disclosures at the End of the Class Period

27. On May 8, 2025, after the market closed, Iovance released its first quarter 2025 financial results, revealing a quarterly total product revenue of $49.3 million, a significant decline from the prior quarter's $73.7 million. The Company also announced its full fiscal year 2025 total product revenue guidance had been slashed from $450 million - $475 million to $250 million - $300 million, a reduction of over 40% at the midpoint. The Company stated it was "revising full-year 2025 revenue guidance to reflect recent launch dynamics" of the Company's T cell immunotherapy, Amtagvi. Specifically, on that day, Iovance issued a press release that stated, in relevant part:

Iovance Biotherapeutics Reports Financial Results and Corporate Updates for First Quarter 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

* * *

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 (iCTC). Since full production has now resumed at the iCTC, 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 iCTC. 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.

* * *

- **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.

28. Also on May 8, 2025, the Company held a conference call in connection with first quarter 2025 financial results. During the call, Defendant Vogt attributed the revenue decline to three factors, including "the variable pace at which ATCs began treating patients," which "differs from center to center." In response to an analyst question, Defendant Vogt explained, in relevant part:

> Back in August, we were trying to give investors our best line of sight to what we thought was going to happen. At that point, we were very well aware of the high demand for the product, and we were ramping up our manufacturing as fast as we could. So, we built our model on the back of how many manufacturing slots we would make available maximum ramp.
>
> Now, as we've gone, we've learned a lot about the launch, especially recently as we watch some of the dynamics with the ATCs, we looked at our experience with growth trajectories there. We look at the time lines it takes for new ATCs to come on board and begin treating their first patients and how they work through their processes. We're onboarding these large community practices, which takes some time, and we're doing the community referral process, which takes a lot of time, too.
>
> And as we looked at that, we just decided that it was better and more accurate for us to forecast guidance that we gave today to show you that we can still make this product grow very, very substantially.
>
> But now what we're going to do is we're just going to limit some of our manufacturing slots. It ends up being essentially almost a neutral with respect to how we use our cash, and we'll roll forward and we'll continue to succeed on the launch. But we think we'll do it on terms that are, I think, a little bit more in line with what we actually see at the ATCs.

29. Defendant Bellemin stated that "[c]osts of sales for the first quarter of 2025 was $49.7 million, including $15 million in period costs associated with patient drop-off and manufacturing success rates, an increase quarter-over-quarter." When an analyst asked "what drove the higher patient drops or lower manufacturing success in the quarter," Defendant Bilinsky replied: "Some of this – or much of this – is related to patient selection and the tumor procurement technique. . . What gives us confidence in the success rate trends that we see among ATCs who have been up and running for a long time and the experience curve that they've been able to achieve."

30. On this news, the price of Iovance shares declined $1.42 per share, or 44.8%, to close at $1.75 per share on May 9, 2025, on unusually heavy trading volume.

CLASS ACTION ALLEGATIONS

31. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class, consisting of all persons and entities that purchased or otherwise acquired Iovance securities between May 9, 2024 and May 8, 2025, inclusive, and who were damaged thereby (the "Class"). Excluded from the Class are Defendants, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors, or assigns, and any entity in which Defendants have or had a controlling interest.

32. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Iovance's shares actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can only be ascertained through appropriate discovery, Plaintiff believes that there are at least hundreds or thousands of members in the proposed Class. Millions of Iovance shares were traded publicly during the Class Period on the NASDAQ. Record owners and other members of the Class may be identified from records maintained by Iovance or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

33. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

34. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation.

35. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether the federal securities laws were violated by Defendants' acts as alleged herein;

(b) whether statements made by Defendants to the investing public during the Class Period omitted and/or misrepresented material facts about the business, operations, and prospects of Iovance; and

(c) to what extent the members of the Class have sustained damages and the proper measure of damages.

36. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation makes it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

UNDISCLOSED ADVERSE FACTS

37. The market for Iovance's securities was open, well-developed and efficient at all relevant times. As a result of these materially false and/or misleading statements, and/or failures to disclose, Iovance's securities traded at artificially inflated prices during the Class Period. Plaintiff and other members of the Class purchased or otherwise acquired Iovance's securities relying upon the integrity of the market price of the Company's securities and market information relating to Iovance, and have been damaged thereby.

38. During the Class Period, Defendants materially misled the investing public, thereby inflating the price of Iovance's securities, by publicly issuing false and/or misleading statements and/or omitting to disclose material facts necessary to make Defendants' statements, as set forth herein, not false and/or misleading. The statements and omissions were materially false and/or misleading because they failed to disclose material adverse information and/or misrepresented the truth about Iovance's business, operations, and prospects as alleged herein.

39. At all relevant times, the material misrepresentations and omissions particularized in this Complaint directly or proximately caused or were a substantial contributing cause of the damages sustained by Plaintiff and other members of the Class. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false and/or misleading statements about Iovance's financial well-being and prospects. These material misstatements and/or

omissions had the cause and effect of creating in the market an unrealistically positive assessment of the Company and its financial well-being and prospects, thus causing the Company's securities to be overvalued and artificially inflated at all relevant times. Defendants' materially false and/or misleading statements during the Class Period resulted in Plaintiff and other members of the Class purchasing the Company's securities at artificially inflated prices, thus causing the damages complained of herein when the truth was revealed.

LOSS CAUSATION

40. Defendants' wrongful conduct, as alleged herein, directly and proximately caused the economic loss suffered by Plaintiff and the Class.

41. During the Class Period, Plaintiff and the Class purchased Iovance's securities at artificially inflated prices and were damaged thereby. The price of the Company's securities significantly declined when the misrepresentations made to the market, and/or the information alleged herein to have been concealed from the market, and/or the effects thereof, were revealed, causing investors' losses.

SCIENTER ALLEGATIONS

42. As alleged herein, Defendants acted with scienter since Defendants knew that the public documents and statements issued or disseminated in the name of the Company were materially false and/or misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth elsewhere herein in detail, the Individual Defendants, by virtue of their receipt of information reflecting the true facts regarding Iovance, their control over, and/or receipt and/or modification of Iovance's allegedly materially misleading misstatements and/or their associations with the Company which made them privy to confidential proprietary information concerning Iovance, participated in the fraudulent scheme alleged herein.

APPLICABILITY OF PRESUMPTION OF RELIANCE

(FRAUD-ON-THE-MARKET DOCTRINE)

43. The market for Iovance's securities was open, well-developed and efficient at all relevant times. As a result of the materially false and/or misleading statements and/or failures to disclose, Iovance's securities traded at artificially inflated prices during the Class Period. On May 9, 2024, the Company's share price closed at a Class Period high of $13.45 per share. Plaintiff and other members of the Class purchased or otherwise acquired the Company's securities relying upon the integrity of the market price of Iovance's securities and market information relating to Iovance, and have been damaged thereby.

44. During the Class Period, the artificial inflation of Iovance's shares was caused by the material misrepresentations and/or omissions particularized in this Complaint causing the damages sustained by Plaintiff and other members of the Class. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false and/or misleading statements about Iovance's business, prospects, and operations. These material misstatements and/or omissions created an unrealistically positive assessment of Iovance and its business, operations, and prospects, thus causing the price of the Company's securities to be artificially inflated at all relevant times, and when disclosed, negatively affected the value of the Company shares. Defendants' materially false and/or misleading statements during the Class Period resulted in Plaintiff and other members of the Class purchasing the Company's securities at such artificially inflated prices, and each of them has been damaged as a result.

45. At all relevant times, the market for Iovance's securities was an efficient market for the following reasons, among others:

(a) Iovance shares met the requirements for listing, and was listed and actively traded on the NASDAQ, a highly efficient and automated market;

(b) As a regulated issuer, Iovance filed periodic public reports with the SEC and/or the NASDAQ;

(c) Iovance regularly communicated with public investors via established market communication mechanisms, including through regular dissemination of press releases on the

national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and/or

(d) Iovance was followed by securities analysts employed by brokerage firms who wrote reports about the Company, and these reports were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

46. As a result of the foregoing, the market for Iovance's securities promptly digested current information regarding Iovance from all publicly available sources and reflected such information in Iovance's share price. Under these circumstances, all purchasers of Iovance's securities during the Class Period suffered similar injury through their purchase of Iovance's securities at artificially inflated prices and a presumption of reliance applies.

47. A Class-wide presumption of reliance is also appropriate in this action under the Supreme Court's holding in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972), because the Class's claims are, in large part, grounded on Defendants' material misstatements and/or omissions. Because this action involves Defendants' failure to disclose material adverse information regarding the Company's business operations and financial prospects—information that Defendants were obligated to disclose—positive proof of reliance is not a prerequisite to recovery. All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered them important in making investment decisions. Given the importance of the Class Period material misstatements and omissions set forth above, that requirement is satisfied here.

NO SAFE HARBOR

48. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. The statements alleged to be false and misleading herein all relate to then-existing facts and conditions. In addition, to the extent certain of the statements alleged to be false may be characterized as forward looking, they were not identified as "forward-looking statements" when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to

differ materially from those in the purportedly forward-looking statements. In the alternative, to the extent that the statutory safe harbor is determined to apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the speaker had actual knowledge that the forward-looking statement was materially false or misleading, and/or the forward-looking statement was authorized or approved by an executive officer of Iovance who knew that the statement was false when made.

FIRST CLAIM

Violation of Section 10(b) of The Exchange Act and

Rule 10b-5 Promulgated Thereunder

Against All Defendants

49. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

50. During the Class Period, Defendants carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; and (ii) cause Plaintiff and other members of the Class to purchase Iovance's securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each defendant, took the actions set forth herein.

51. Defendants (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (iii) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices for Iovance's securities in violation of Section 10(b) of the Exchange Act and Rule 10b-5. All Defendants are sued either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.

52. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a

continuous course of conduct to conceal adverse material information about Iovance's financial well-being and prospects, as specified herein.

53. Defendants employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of Iovance's value and performance and continued substantial growth, which included the making of, or the participation in the making of, untrue statements of material facts and/or omitting to state material facts necessary in order to make the statements made about Iovance and its business operations and future prospects in light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities during the Class Period.

54. Each of the Individual Defendants' primary liability and controlling person liability arises from the following facts: (i) the Individual Defendants were high-level executives and/or directors at the Company during the Class Period and members of the Company's management team or had control thereof; (ii) each of these defendants, by virtue of their responsibilities and activities as a senior officer and/or director of the Company, was privy to and participated in the creation, development and reporting of the Company's internal budgets, plans, projections and/or reports; (iii) each of these defendants enjoyed significant personal contact and familiarity with the other defendants and was advised of, and had access to, other members of the Company's management team, internal reports and other data and information about the Company's finances, operations, and sales at all relevant times; and (iv) each of these defendants was aware of the Company's dissemination of information to the investing public which they knew and/or recklessly disregarded was materially false and misleading.

55. Defendants had actual knowledge of the misrepresentations and/or omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them. Such defendants' material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing Iovance's financial well-being and prospects from the investing public and

supporting the artificially inflated price of its securities. As demonstrated by Defendants' overstatements and/or misstatements of the Company's business, operations, financial well-being, and prospects throughout the Class Period, Defendants, if they did not have actual knowledge of the misrepresentations and/or omissions alleged, were reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

56. As a result of the dissemination of the materially false and/or misleading information and/or failure to disclose material facts, as set forth above, the market price of Iovance's securities was artificially inflated during the Class Period. In ignorance of the fact that market prices of the Company's securities were artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants, or upon the integrity of the market in which the securities trades, and/or in the absence of material adverse information that was known to or recklessly disregarded by Defendants, but not disclosed in public statements by Defendants during the Class Period, Plaintiff and the other members of the Class acquired Iovance's securities during the Class Period at artificially high prices and were damaged thereby.

57. At the time of said misrepresentations and/or omissions, Plaintiff and other members of the Class were ignorant of their falsity, and believed them to be true. Had Plaintiff and the other members of the Class and the marketplace known the truth regarding the problems that Iovance was experiencing, which were not disclosed by Defendants, Plaintiff and other members of the Class would not have purchased or otherwise acquired their Iovance securities, or, if they had acquired such securities during the Class Period, they would not have done so at the artificially inflated prices which they paid.

58. By virtue of the foregoing, Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

59. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's securities during the Class Period.

SECOND CLAIM

Violation of Section 20(a) of The Exchange Act

Against the Individual Defendants

60. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

61. Individual Defendants acted as controlling persons of Iovance within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions and their ownership and contractual rights, participation in, and/or awareness of the Company's operations and intimate knowledge of the false financial statements filed by the Company with the SEC and disseminated to the investing public, Individual Defendants had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements which Plaintiff contends are false and misleading. Individual Defendants were provided with or had unlimited access to copies of the Company's reports, press releases, public filings, and other statements alleged by Plaintiff to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

62. In particular, Individual Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

63. As set forth above, Iovance and Individual Defendants each violated Section 10(b) and Rule 10b-5 by their acts and omissions as alleged in this Complaint. By virtue of their position as controlling persons, Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment, as follows:

(a) Determining that this action is a proper class action under Rule 23 of the Federal Rules of Civil Procedure;

(b) Awarding compensatory damages in favor of Plaintiff and the other Class members against all defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

(c) Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

(d) Such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury.

DATED: May 15, 2025