UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

, Individually and on Behalf of All Others Similarly Situated, Plaintiff, v. IOVANCE BIOTHERAPEUTICS, INC., FREDERICK G. VOGT, JEAN-MARC BELLEMIN, IGOR P. BILINSKY, and DANIEL G. KIRBY, Defendants.	Case No. CLASS ACTION **COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS** DEMAND FOR JURY TRIAL

Plaintiff ("Plaintiff"), individually and on behalf of all other persons similarly situated, by his undersigned attorneys, alleges in this Complaint for violations of the federal securities laws (the "Complaint") the following based upon knowledge with respect to his own acts, and upon facts obtained through an investigation conducted by his counsel, which included, *inter alia*: (a) review and analysis of relevant filings made by Iovance Biotherapeutics, Inc. ("Iovance" or the "Company") with the United States Securities and Exchange Commission (the "SEC"); (b) review and analysis of Iovance's public documents, conference calls, press releases, and stock chart; (c) review and analysis of securities analysts' reports and advisories concerning the Company; and (d) information readily obtainable on the internet.

Plaintiff believes that further substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery. Most of the facts supporting the allegations contained herein are known only to the defendants or are exclusively within their control.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of all investors who purchased or otherwise acquired Iovance securities between August 8, 2024, to May 8, 2025, inclusive (the "Class Period"), seeking to recover damages caused by Defendants' violations of the federal securities laws (the "Class").

2. Defendants provided investors with material information concerning Iovance's expected revenue for the fiscal year 2025. Defendants' statements included, among other things, confidence in their continuously reaffirmed forecast to achieve product revenue of $450 to $475 million in the first full calendar year of Amtagvi sales.

3. Defendants provided these overwhelmingly positive statements to investors while, at the same time, disseminating materially false and misleading statements and/or concealing material adverse facts concerning the true state of Iovance's growth potential; notably, that it was not equipped to generate and drive demand or was otherwise ill equipped to capitalize upon the purported existing demand for its treatments through its network of approved treatment centers.

4. On July 25, 2024, Iovance announced its financial results for the second quarter of fiscal 2024 and reduced its revenue guidance for the full fiscal year 2024. The Company attributed its results and lowered guidance on 1) "the iCTC completed annual scheduled maintenance in December" and "capacity was reduced by more than half for about 1 month," 2) "[l]ower Proleukin sales" than the company expected, and 3) "the variable pace at which ATCs began treatment patients."

5. Investors and analysts reacted immediately to Iovance's revelation. The price of Iovance's common stock declined dramatically. From a closing market price of $3.17 per share on May 8, 2025, Iovance's stock price fell to $1.75 per share on May 9, 2025, a decline of about 44.795% in the span of just a single day.

JURISDICTION AND VENUE

6. Plaintiff brings this action, on behalf of himself and other similarly situated investors, to recover losses sustained in connection with Defendants' fraud.

7. The claims asserted herein arise under and pursuant to §§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 1337, and Section 27 of the Exchange Act, 15 U.S.C. §78aa.

9. Venue is proper in this District pursuant to §27 of the Exchange Act and 28 U.S.C. §1391(b), as Defendant Iovance is headquartered in this District and a significant portion of its business, actions, and the subsequent damages to Plaintiff and the Class, took place within this District.

10. In connection with the acts, conduct and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mail, interstate telephone communications and the facilities of the national securities exchange.

THE PARTIES

11. Plaintiff purchased Iovance common stock at artificially inflated prices during the Class Period and was damaged upon the revelation of the Defendants' fraud. Plaintiff's certification evidencing his transaction(s) in Iovance is attached hereto.

12. Iovance Biotherapeutics, Inc. is a California corporation with its principal executive offices located at 825 Industrial Road, Suite 100, San Carlos, CA 94070. During the Class Period, the Company's common stock traded on the NASDAQ Stock Market (the "NASDAQ") under the symbol "IOVA."

13. Defendant Frederick G. Vogt ("Vogt") was, at all relevant times, the Interim CEO, President, General Counsel, Corporate Secretary, and Director of Iovance.

14. Defendant Jean-Marc Bellemin ("Bellemin") was, at all relevant times, the Chief Financial Officer, Principal Accounting Officer, and Treasurer of Iovance.

15. Defendant Igor P. Bilinsky ("Bilinsky") was, at all relevant times, the Chief Operating Officer of Iovance.

16. Defendant Daniel G. Kirby ("Kirby") was appointed the Chief Commercial Officer of Iovance on February 10, 2025 and remained as such for the remainder of the relevant class period.

17. Defendants Vogt, Bellemin, Bilinsky, and Kirby are sometimes referred to herein as the "Individual Defendants." Iovance together with the Individual Defendants are referred to herein as the "Defendants."

18. The Individual Defendants, because of their positions with the Company, possessed the power and authority to control the contents of Iovance's reports to the SEC, press releases, and presentations to securities analysts, money and portfolio managers, and institutional investors, *i.e.*, the market. Each Individual Defendant was 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 n available to them, each of these 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, as those statements were each "group-published" information, the result of the collective actions of the Individual Defendants.

19. Iovance is liable for the acts of the Individual Defendants, and its employees under the doctrine of respondeat superior and common law principles of agency as all the wrongful acts complained of herein were carried out within the scope of their employment with authorization.

20. The scienter of the Individual Defendants, and other employees and agents of the Company are similarly imputed to Iovance under respondeat superior and agency principles.

SUBSTANTIVE ALLEGATIONS

A. Company Background

21. Iovance is a commercial-stage biopharmaceutical company that develops and commercializes cell therapies using autologous tumor infiltrating lymphocyte for the treatment of metastatic melanoma and other solid tumor cancers.

22. The company's key product is Amtagvi, an autologous T cell immunotherapy to treat adults with unresectable or metastatic melanoma. The company also distributes Proleukin, an interleukin-2 product used in Amtagvi's treatment regimen.

23. Treatments are conducted at authorized treatment centers ("ATCs") in the United States, with regulatory approvals anticipated in both the United Kingdom and Canada in 2025.

B. The Defendants Materially Misled Investors Concerning Iovance's Revenue Outlook for Fiscal Year 2025

August 8, 2024

24. On August 8, 2024, Defendants issued a press release announcing second quarter fiscal 2024 results and pertinently issuing fiscal 2025 guidance as follows:

- 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.

(Emphasis added).

25. During the same-day earnings call, interim CEO, Frederick G. Vogt, reiterated the company's fiscal 2025 guidance, stating, in pertinent part:

> Turning back to launch momentum. This afternoon's press release. We also introduced revenue guidance for the third quarter of full year 2024 and for 2025. This guidance is based upon our ongoing experience and confidence in the strong uptake and significant quarter-over-quarter growth in the Amtagvi demand and corresponding Proleukin sales for the foreseeable future. We used our visibility to the growth rate of infusions, adoption across our ATC network, manufacturing capacity and additional launch dynamics to prepare this guidance.
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> . . .
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> For full year 2025, the first calendar year of our U.S. launch first full calendar year over U.S. launch, we expect significant year-over-year growth driven by scale-up in existing and new ATCs and robust community referral networks contributing to additional demand. As a result, we anticipate total product revenue will increase to $450 million to $475 million in the full year of 2025.
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> In 2026 and beyond, Amtagvi and Proleukin are expected to continue to drive significant additional revenue growth. These products represent more than $1 billion peak opportunity in the U.S. market in the currently approved indication alone. Future revenue growth drivers also include a wider geographic footprint for Amtagvi in previously treated advanced melanoma as well as U.S. and global label expansions to the front line advanced melanoma, non-small cell lung cancer and other indications as we'll discuss later in the call.

(Emphasis added).

November 7, 2024

26. On November 7, 2024, Defendants issued a press release announcing Iovance's third quarter fiscal 2024 results and reiterating the company's fiscal 2025 guidance, in pertinent part:

- **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.
  - **Proleukin Revenue**: Product revenue also included $16.5 million of Proleukin sales in the third quarter of 2024. Proleukin is used in the Amtagvi treatment regimen and other commercial and clinical settings. Proleukin revenue is recognized upon delivery to distributors and ATCs and purchased several months in advance of anticipated infusions and Amtagvi revenue recognition.

- **Year to Date Total Product Revenue and Infusions**: Through the end of the third quarter of 2024, $90.4 million in total product revenue has been recognized following the U.S. launch of Amtagvi on February 20, 2024.
  - **Amtagvi Infusions**: A total of 146 patients have been infused with Amtagvi since the first commercial infusion in April 2024, including 25 patients infused in the second quarter, 82 patients infused in the third quarter, and 39 patients infused since the start of the fourth quarter.
  - **Amtagvi and Proleukin Revenue**: Amtagvi and Proleukin revenue is $54.9 million and $35.5 million year to date, respectively.

. . .

  - **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.

27. During the earnings call accompanying Iovance's third quarter fiscal 2024 results, Defendant Vogt elaborated on their anticipations for fiscal 2025, stating, in pertinent part:

> We also reiterate our full year 2025 guidance of $450 million to $475 million in total product revenue. We expect a significant increase in year-over-year growth as ATC's broaden utilization and new ATCs as well as community referral networks contribute to additional demands.

. . .

> With a fully integrated infrastructure and growing interest in Amtagvi outside the U.S., Iovance is well positioned to continue scaling globally. Our ex-U.S. teams are being built and regulatory dossiers are under review, submitted our plans across multiple international markets with potential for our first ex-U.S. approval in the first half of 2025. European Medicines Agency validated and accepted our marketing authorization application, or MAA, for a review for all EU member states with potential approval in the second half of 2025. The Medicines and Healthcare Products Regulatory Agency in the United Kingdom is reviewing a separate MAA submission for potential approval in the first half of 2025.
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> Our new drug submission is also underway for near-term submission in Canada and will include a prioritized review process for potential approval in mid-2025. Additional regulatory dossiers remain on track for submission in Australia and Switzerland in 2025, and we'll target additional markets with highly concentrated populations of advanced melanoma patients in the future.

(Emphasis added).

February 27, 2025

28. On February 27, 2025, Defendants published their fourth quarter and full-year fiscal 2024 results, and again reaffirmed their fiscal 2025 guidance, stating, in pertinent part:

- **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

(Emphasis added).

29. An earnings call was conducted the same day, during which Defendant Vogt spoke to the company's projections, stating in pertinent part:

> Today, I'm pleased to highlight continued growth in total product revenue for both Amtagvi and Proleukin. Total product revenue was $73.7 million in the fourth quarter and $164.1 million in the full year 2024. Importantly, our full year revenue achieved the upper end of our 2024 guidance range of $160 million to $165 million, and we finished above the full year Street consensus. Total revenue consisted of $48.7 million for Amtagvi and $25.0 million for Proleukin in the fourth quarter with $103.6 million for Amtagvi and $60.5 million for Proleukin in the full year period.
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> Our full year product revenue reflects more than 200 patients already treated with Amtagvi in the partial first year of launch. We are pleased with the robust initial uptake and increasing strong demand for Amtagvi as well as continuing momentum in global Proleukin sales. ***Our team's successful execution as well as the unmet need in advanced melanoma, high awareness, broad patient access and a motivated expanding network of authorized treatment centers or ATCs continue to drive increasing demand for Amtagvi and Proleukin.***
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> Our manufacturing network is well prepared to supply the current and anticipated demand for Amtagvi. Today, we have staffed capacity to supply more than 1,200 patients per year and continue to scale up for additional U.S. and global launch growth. In the back half of last year, we augmented our investment in focused community referral initiatives. ***These efforts in the field are targeted at driving additional demand in our ATCs, as they scale up to treat more patients.***
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> ***Looking ahead, we are reiterating our full year 2025 guidance of $450 million to $475 million in total product revenue. We expect a significant increase in year-over-year growth in both Amtagvi and Proleukin, as ATCs broaden utilization, while new ATCs as well as community referral networks are expected to contribute increasing demand through the year***

(Emphasis added).

30. Defendant Kirby then detailed Iovance's expectations for the ATC network's growth in 2025, pertinently providing the following:

> ***Throughout 2024, we scaled up our ATC network to meet the growing patient demand and fulfill significant interest among health care providers to offer Amtagvi to their patients.*** After launching with an unprecedented ***30 ATCs on day 1***, we reached our target of approximately ***70 ATCs at the end of 2024***. Our ATC network now spans 32 states and nearly all treated melanoma patients live within a 2-hour drive of the closest center.
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> ***We treated more than 200 patients with commercial Amtagvi within the first 3 quarters of launch, and Amtagvi is positioned for significant growth across our ATC network in 2025 and beyond.***
>
> Amongst the 70 current ATCs, 76% completed tumor resections, 64% infused Amtagvi, 53% infused 2 or more patients and 13% infused more than 10 patients. These metrics demonstrate significant growth potential, as our ATCs scale up to accommodate growing patient demand.
>
> New ATCs are preparing to treat initial patients. ***Our more experienced ATCs are steadily growing or plan to increase utilization throughout 2025, and we expect new ATCs will follow similar trends, as we add steadily throughout 2025***. These additional ATCs will be selected for high quality and volume of eligible patients, including large community practices.
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> ***To further drive adoption, earlier patient identification and higher referral volume into our ATC network, Iovance field teams are actively engaging top community oncologists and large community practices with a focus on high-volume markets***. Additionally, we are aligned with leadership at key community organizations on their preferred ATCs for patient referrals. As more patients embark on their treatment journey, we are making steady progress to speed up the time to intact the infusion.

(Emphasis added).

31. Defendant Bellemin further highlighted that the company was reaffirming its fiscal 2025 guide, adding, in pertinent part, that Defendants "continue to reiterate our prior total product revenue guidance within the range of $450 million to $475 million for the full year 2025."

32. Defendant Bilinsky spoke to the company's current and pending maintenance requirements, stating pertinently that:

> Each of our facilities is currently required to schedule a brief annual maintenance, which entails a short pause in production. I'm pleased to report that iCTC

successfully completed annual maintenance and resumed production promptly at full volume with no issues. We expect the same positive outcome following the upcoming scheduled maintenance at our contract manufacturer.

33. During the question-and-answer segment of the earnings call, Defendants elaborated on the company's current growth trends and outlook for 2025 during the following pertinent exchanges:

<Q: Andrea R. Newkirk – Goldman Sachs Group, Inc. – Research Analyst> Fred, on prior calls you've provided an update on the number of patients infused thus far in the quarter. Just wondering if you'd be willing to share where you stand as of today? And then just remind us or help us understand what gives you the confidence that the range for full year '25, which was set when you're only 1 quarter into the launch is still intact.

<A: Frederick G. Vogt> Yes, sure, Andrea. We're not -- from -- in the press release and on the call, ***we're not going to be providing the infusions right now***. We're not sure how useful that metric was to long investors. And as some of you know, ***it's prone to overinterpretation***. We provide some different metrics this time around, including the potential for growth at the ATCs. ***And that actually is a part of the answer to your second question, if you look at our press release and heard Dan's commentary, within the 70 ATCs that we have right now, only 13% of infused in more than 10 patients, which gives you a very good idea of the upside that we're expecting, the acceleration we're expecting in the second half and second quarter of 2025 here as we go through. So we still have confidence in those numbers because the growth curve for this type of product can accelerate quite a bit, and we see that happening across our ATC network right now. We see the potential for that in the ATCs***.

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<Q: Colleen Margaret Kusy – Robert W. Baird & Co. Inc. – Senior Research Analyst> I understand you're not giving intra-quarter updates going forward, but since you did provide in 4Q. Can you speak, was there a slowdown in infusions in the back half of the quarter? And did you see any seasonality in 4Q?

<A: Frederick G. Vogt> Colleen, no, we don't see any seasonality. As Igor mentioned, we did have a manufacturing maintenance period there. So we have those kind of things in cell therapy. If you look at the launch curves for ABECMA, YESCARTA and CARVYKTI, you'll see there's little peaks and dips and valleys in those as things like that happen so -- but nothing in terms of a holiday seasonality. That's what you're asking.

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<Q: Nicholas Lorusso – TD Cowen – Associate> This is Nick on for Tyler. Thinking about guidance -- 2025 guidance, is the potential price increase currently included in that guidance? And also, how should we think about the global ex-U.S. expansion having a potential impact on guidance?

<A: Frederick G. Vogt> Yes. The price increase that's coming in April has been factored into that guidance for both Proleukin and Amtagvi. And right now, the guidance doesn't include any contribution from ex-U.S.

. . .

<Q: Lin Tsai – Jefferies LLC – Equity Analyst> Appreciate the updates, look forward to 2025. So a quick one is, in terms of the launch uptake, what exactly would you say is the bottleneck at this juncture? If it's not patient demand nor supply chain nor even beds at sites, ***what is the gating factor to seeing an acceleration in sales for 2025 like you guided***?

<A: Frederick G. Vogt> So I think, ***above all, the ATCs that are starting up now have to get their feet under them and get running***. We've got some ATCs that are performing very, very well right now. And we've got a lot more that are working their way up. I think in each ATC, there's a difference -- ***each individual ATC has its own little bottlenecks or whatever it might be. Some of them have staffing issues, some of them have financial clearance challenges that we're helping out with. But all these things are pretty easily resolvable, and we've been able to show that a good portion of our ATCs can really fly right now, and we think we can get a lot more there pretty soon***. Dan, go ahead.

<A: Daniel G. Kirby> Sure. And Andrew, I think one thing to add on top of what Fred said regarding not really a bottleneck, but there's a process they go through. They have to make sure they operationally can do it again. We're the first TIL in the market. So there's a learning curve there. As you see, we said 13% have hit 10% or more, that number continues to grow. ***So once they hit that wave where they understand how to use the product with it, then the lever really is to pull the referrals and drive more patients in there. And that's where we're working with the community, not only at the clinic level, but also the leadership level and the community to make sure that those centers are getting to see the most patients.***

(Emphasis added).

March 13, 2025

34. On March 13, 2025, Defendants presented at Barclays 27th Annual Global Healthcare Conference 2025, during which Defendant Kirby discussed their fiscal 2025 guidance, in pertinent part, as follows:

<Q: Peter Richard Lawson – Barclays Bank PLC – Research Analyst> … you've mentioned the product and the launch, just how should we think about the factors

> influencing guidance, what brings you to the top and bottom end of those ranges and what are the moving parts?
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> <A: Daniel G. Kirby> Sure. So the factors for the guidance really are our existing ATCs. We have 70 ATCs that are stood up right now. And of those, over 3/4 have done a tumor tissue procurement. Over 2/3 have done an actual infusion to a patient and over half of them have infused multiple patients, 13% are at that expert level of 10 plus. Our guidance really is about maximizing for this year their progress through that spectrum to keep treating more and more patients and to maximize the potential inside of those accounts.
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> We also simultaneously this year with the upper end, we have other initiatives that are getting into the referral patterns with the community and looking at where they're sending patients, sending those to the expert accounts and standing up new ATCs where we know patients are flowing in. So that's the perspective on the guidance with it. We can do it with our existing ATCs, but we're also being opportunistic to see if we can get more volume of patients by increasing the referral patterns into them.
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> <Q: Peter Richard Lawson> … are things positioned where 1Q could show an acceleration of growth? Or is it more back-end loaded? How should we be thinking about it?
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> <A: Daniel G. Kirby> It's a great question. We don't want to talk about first quarter right now until we have the earnings call. But what I would say is if you look at our initiatives with the accounts that are ramping up, we're having more enter into that expert level of 10-plus infusions. And then the other ones are ramping along and progressing with it. We're expecting significant half of this year with it, but we do feel that it will be more of a yearly look than a quarterly look.

(Emphasis added).

35. The above statements in Paragraphs 24 to 34 were false and/or materially misleading. Defendants created the false impression that they possessed reliable information pertaining to the Company's projected revenue outlook and anticipated growth while also minimizing risk from seasonality and macroeconomic fluctuations. In truth, Iovance's optimistic reports of growth, an unmet need for its treatment, demand for the same, and the company's ability to grow and increase utilization of ATCs fell short of reality as they relied far too heavily on the Iovance's ability to scale ATCs to treat patients as fast as treatment could be manufacturer. Iovance

was simply not equipped to accurately forecast the demand for their product or otherwise was ill equipped to capitalize on that growth due to the ramping speed of its ATCs.

C. The Truth Emerges during Iovance's First Quarter Earnings Report

May 8, 2025

36. On May 8, 2025, Defendants released their Q1FY25 results below expectations and significantly lowered FY25 projections:

- **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.
  - **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.

. . .

- **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.

(Emphasis added).

37. During the associated earnings call Defendant Vogt elaborated on the quarter's underperformance and the cut guidance, stating, in pertinent part:

> First, our internal manufacturing facility, ***the iCTC completed annual scheduled maintenance in December*** of last year, as we previously discussed on last quarter's call.
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> As a result of limited production starts for multi-week Amtagvi manufacturing across our network, ***capacity was reduced by more than half for about 1 month***. In addition, volume was impacted by higher rates of patient drop-off and lower manufacturing success rates, but has since rebounded. Today, we are seeing healthy demand with a record number of production starts in the second quarter.
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> ***Lower Proleukin sales were the second factor*** contributing to lower first quarter revenue. We expect 2 of the 3 largest U.S. [ship] wholesalers to start replenishing Proleukin in line with growing Amtagvi demand in the second quarter.
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> We're also growing the other components of our franchise, including sales of Proleukin to third parties for use with manufacturing and clinical research.
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> ***The third contributor to first quarter revenue was the variable pace at which ATCs began treating patients and this differs from center to center***. For context, 16% of ATCs have treated more than 10 patients. Our ATCs have ample room to grow, and we anticipate near-term contributions from ATCs that came online in the latter half of 2024 into 2025.
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> We revised our guidance to between $250 million and $300 million in total product revenue for the full year 2025.
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> We consider our experience with growth trajectory with the ATCs, time lines for new ATCs to begin treating their first patients and expectations for large community practices and community referrals to drive momentum in the second half of 2025. These demand trends are consistent with the trajectory of other cell therapy launches moving from year 1 to year 2.
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> After aligning our manufacturing slot plans with our new demand forecast, we are maintaining our prior cash runway guidance into the second half of 2026.

(Emphasis added).

38. A question-and-answer segment followed the company's prepared remarks, during which Defendant Vogt elaborated further on management's decision to cut the fiscal 2025 guidance during the following pertinent exchange:

> <Q: Reni John Benjamin – Citizens JMP Securities, LLC – MD & Equity Research Analyst> . . . it's a revised guidance. I guess we were all kind of surprised to begin with on last year, you provided guidance for this year. I'm kind of curious as to -- I get being conservative now, why provide guidance for 2025 way back in 2024 to begin with?
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> <A: Frederick G. Vogt> 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***.
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> Now, as we've gone, we've learned a lot about the launch, especially recently as we watch some of the dynamics with ATCs, we looked at our experience with growth trajectories there. ***We've looked 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 you 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.***
>
> Will end up being essentially almost a neutral one with respect to how we use our cash, and we'll roll forwards, 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.

(Emphasis added).

39. The aforementioned press releases and statements made by the Individual Defendants are in direct contrast to statements they made during the August 8, 2024, November 7, 2024, February 27, 2025, and March 13, 2025, earnings and shareholder calls. On those calls, Defendants continually praised their alleged growth, the unmet need and significant awareness for

their treatment, the rapid expansion of the Iovance's ATCs for Amtagvi and Proleukin, and the ability of those ATCs to drive demand for the company's infusions, while continually failing to account for the potential of a demand plateu or the ability of the ATCs to scale at the rapid pace assured by management.

40. Investors and analysts reacted immediately to Iovance's revelation. The price of Iovance's common stock declined dramatically. From a closing market price of $3.17 per share on May 8, 2025, Iovance's stock price fell to $1.75 per share on May 9, 2025, a decline of about 44.795% in the span of just a single day.

41. A number of well-known analysts who had been following Iovance lowered their price targets in response to Iovance's disclosures. For example, Baird, while downgrading to a neutral rating and slashing their price target by 85%, highlighted that "[f]ollowing a big 1Q25 miss and a significant decrease in FY25 sales guidance, on top of a high burn rate, it's harder for us to model breakeven within a reasonable timeframe."

42. Speaking to "this new FY25 guidance," the analyst also indicated their model was "lowering our Amtagvi sales in 2026 and beyond … which pushes out the revenue that we think will be required to reach breakeven … ***we now see uncertain timing to reach a point where sales outpace expenses***. When we add all of this to a challenging environment in the biotech capital markets, ***we think this setup represents a significant change for IOVA***" (emphasis added).

43. Similarly, H.C. Wainwright and Co. highlighted the difficulty Iovance was having with its ATCs: "A recurring theme from yesterday's call was the need to work more closely with ATCs. We believe a major hurdle standing between Iovance and its commercial goals is the lagging growth of ATCs."

44. The fact that these analysts, and others, discussed Iovance's shortfall and below-expectation projections suggests the public placed significant weight on Iovance's prior revenue and sales estimates. The frequent, in-depth discussion of Iovance's guidance confirms that Defendants' statements during the Class Period were material.

D. Loss Causation and Economic Loss

45. During the Class Period, as detailed herein, Defendants made materially false and misleading statements and engaged in a scheme to deceive the market and a course of conduct that artificially inflated the price of Iovance's common stock and operated as a fraud or deceit on Class Period purchasers of Iovance's common stock by materially misleading the investing public. Later, Defendants' prior misrepresentations and fraudulent conduct became apparent to the market, the price of Iovance's common stock materially declined, as the prior artificial inflation came out of the price over time. As a result of their purchases of Iovance's common stock during the Class Period, Plaintiff and other members of the Class suffered economic loss, *i.e.*, damages under federal securities laws.

46. Iovance's stock price fell in response to the corrective event on May 8, 2025, as alleged *supra*. On May 8, 2025, Defendants disclosed information that was directly related to their prior misrepresentations and material omissions concerning Iovance's forecasting processes and growth guidance.

47. In particular, on May 8, 2025, Iovance announced results for the first quarter of fiscal year 2025 that fell well short of expectations and, resultantly, slashed their prior guidance for the full fiscal year 2025 by more than 40%.

E. Presumption of Reliance; Fraud-On-The-Market

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

(a) Iovance's common stock met the requirements for listing and was listed and actively traded on the NASDAQ during the Class Period, a highly efficient and automated market;

(b) Iovance communicated with public investors via established market communication mechanisms, including disseminations of press releases on the national circuits of major newswire services and other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services;

(c) Iovance was followed by several securities analysts employed by major brokerage firms who wrote reports that were distributed to the sales force and certain customers of their

respective brokerage firms during the Class Period. Each of these reports was publicly available and entered the public marketplace; and

(d) Unexpected material news about Iovance was reflected in and incorporated into the Company's stock price during the Class Period.

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

50. Alternatively, reliance need not be proven in this action because the action involves omissions and deficient disclosures. Positive proof of reliance is not a prerequisite to recovery pursuant to ruling of the United States Supreme Court in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972). All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered the omitted information important in deciding whether to buy or sell the subject security.

F. No Safe Harbor; Inapplicability of Bespeaks Caution Doctrine

51. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the material misrepresentations and omissions alleged in this Complaint. As alleged above, Defendants' liability stems from the fact that they provided investors with revenue projections while at the same time failing to maintain adequate forecasting processes. Defendants provided the public with forecasts that failed to account for this decline in sales and/or adequately disclose the fact that the Company at the current time did not have adequate forecasting processes.

52. To the extent certain of the statements alleged to be misleading or inaccurate 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.

53. Defendants are also liable for any false or misleading "forward-looking statements" pleaded because, at the time each "forward-looking statement" was made, the speaker knew the "forward-looking statement" was false or misleading and the "forward-looking statement" was authorized and/or approved by an executive officer of Iovance who knew that the "forward-looking statement" was false. Alternatively, none of the historic or present-tense statements made by Defendants were assumptions underlying or relating to any plan, projection, or statement of future economic performance, as they were not stated to be such assumptions underlying or relating to any projection or statement of future economic performance when made, nor were any of the projections or forecasts made by the defendants expressly related to or stated to be dependent on those historic or present-tense statements when made.

CLASS ACTION ALLEGATIONS

54. 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 those who purchased or otherwise acquired Iovance's common stock during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosure. Excluded from the Class are defendants herein, 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.

55. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Iovance's common stock were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. 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. As of February 21, 2025, there were 327.877 million shares of the Company's common stock outstanding. Upon information and belief, these shares are held by

thousands, if not millions, of individuals located throughout the country and possibly the world. Joinder would be highly impracticable.

56. 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.

57. 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. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

58. 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 misrepresented material facts about the business, operations and management of Iovance;

(c) whether the Individual Defendants caused Iovance to issue false and misleading financial statements during the Class Period;

(d) whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;

(e) whether the prices of Iovance's common stock during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and

(f) whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

59. 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 make 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.

COUNT I

Against All Defendants for Violations of

Section 10(b) and Rule 10b-5 Promulgated Thereunder

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

61. This Count is asserted against defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

62. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon. Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Iovance common stock; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Iovance's securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

63. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Iovance's securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about the Company.

64. By virtue of their positions at the Company, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended

thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of defendants were committed willfully or with reckless disregard for the truth. In addition, each defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

65. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within defendants' knowledge and control. As the senior managers and/or directors of the Company, the Individual Defendants had knowledge of the details of Iovance's internal affairs.

66. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of the Company. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Iovance's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of Iovance's common stock was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning the Company which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Iovance's common stock at artificially inflated prices and relied upon the price of the common stock, the integrity of the market for the common stock and/or upon statements disseminated by Defendants, and were damaged thereby.

67. During the Class Period, Iovance's common stock was traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares

of Iovance's common stock at prices artificially inflated by defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said common stock, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of Iovance's common stock was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Iovance's common stock declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

68. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

69. 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, acquisitions and sales of the Company's common stock during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT II

Against the Individual Defendants

for Violations of Section 20(a) of the Exchange Act

70. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

71. During the Class Period, the Individual Defendants participated in the operation and management of the Company, and conducted and participated, directly and indirectly, in the conduct of the Company's business affairs. Because of their senior positions, they knew the adverse non-public information about Iovance's misstatements.

72. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information, and to correct promptly any public statements issued by Iovance which had become materially false or misleading.

73. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which Iovance disseminated in the marketplace during the Class Period concerning the misrepresentations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Iovance to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling persons" of the Company within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Iovance's common stock.

74. Each of the Individual Defendants, therefore, acted as a controlling person of the Company. By reason of their senior management positions and/or being directors of the Company, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause Iovance to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of the Company and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

75. By reason of the above conduct, the Individual Defendants and/or Iovance are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by the Company.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demand judgment against defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representatives;

B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class pre-judgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.

Dated: May 15, 2025