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**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, and IGOR P. BILINSKY,

Defendants.

Case No.

**CLASS ACTION COMPLAINT FOR
VIOLATIONS OF THE FEDERAL
SECURITIES LAWS**

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

10 NATURE OF THE ACTION AND OVERVIEW

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

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

21 3. On May 8, 2025, after the market closed, Iovance released its first quarter 2025
22 financial results, revealing a quarterly total product revenue of \$49.3 million, a significant decline
23 from the prior quarter’s \$73.7 million. The Company also announced its full fiscal year 2025 total
24 product revenue guidance had been slashed from \$450 million - \$475 million to \$250 million - \$300
25 million, a reduction of over 40% at the midpoint. The Company revealed it was “revising full-year
26 2025 revenue guidance to reflect recent launch dynamics” of Amtagvi. The Company further
27 revealed “[t]he updated forecast considers experience with ATC [authorized treatment center]
28 growth trajectories and treatment timelines for new ATCs.”

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

3 **SUBSTANTIVE ALLEGATIONS**

4 **Background**

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

11 **Materially False and Misleading**

12 **Statements Issued During the Class Period**

13 18. The Class Period begins on May 9, 2024.¹ On that day, Iovance issued a press release
14 announcing its financial results for the first quarter ended March 31, 2024 and an update on recent
15 developments. The press release touted the Company’s financial results, as well as its alleged
16 “strong momentum” in the Amtagvi launch, including as it related to “onboarding” ATCs.
17 Specifically, the press release stated as follows, in relevant part:

18 **Iovance Biotherapeutics Reports First Quarter 2024 Financial Results and
19 Corporate Updates**

20 *Strong Momentum for Amtagvi™ (Lifileucel) U.S. Launch Following U.S. Food
and Drug Administration (FDA) Approval*

21 *100+ Amtagvi Patients Enrolled Across More Than 40 Current Authorized
22 Treatment Centers*

23 *(ATCs), with ~50 Total ATCs On Track by End of May and 70+ Total ATCs by
Year-End 2024*

24 * * *

25 Frederick Vogt, Ph.D., J.D., Interim President and Chief Executive Officer of
26 Iovance, stated, “The first quarter of 2024 was transformative for Iovance following
27 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

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

1 is very high and continues to significantly increase across initial ATCs. As of today,
2 more than 100 patients have already enrolled for Amtagvi therapy. We have
3 successfully manufactured and delivered Amtagvi to many ATCs where commercial
4 patients are being treated. ***We expect our launch momentum to remain strong and
5 continue to build as we ramp up the U.S. launch throughout 2024 with the
6 authorization of additional ATCs. We also continue to execute across our broad
7 clinical pipeline.*** As a fully integrated company, Iovance is well positioned to remain
8 the global leader in innovating, developing, and delivering TIL cell therapy for
9 patients with cancer.”

6 **Recent and First Quarter 2024 Highlights and Corporate Updates**

7 Amtagvi™ (Lifileucel) U.S. Approval and Launch Highlights in Advanced 8 Melanoma

9 • The U.S. FDA approved Amtagvi (lifileucel) on February 16, 2024, as the
10 first treatment option for advanced melanoma after anti-PD-1 and targeted therapy.
11 Amtagvi is also the first and only FDA-approved T cell therapy for a solid tumor
12 indication.

13 • Since approval, more than 100 patients have enrolled for Amtagvi therapy.
14 The first patients have been successfully treated and the balance are moving through
15 the stages of the journey, which includes surgery for cell collection, manufacturing,
16 and the Amtagvi treatment regimen.

17 • ***Onboarding is complete at more than 40 U.S. ATCs, up from 30 initial
18 ATCs at approval. Iovance remains on track to onboard approximately 50 ATCs
19 by the end of May 2024 and expects to have more than 70 ATCs onboarded by the
20 end of 2024.***

21 • Manufacturing turnaround time has been on-target with initial launch
22 expectations of approximately 34 days from inbound to return shipment to ATCs.
23 The commercial manufacturing experience to date is consistent with prior clinical
24 experience.

25 • ***The U.S. launch of Amtagvi, and additional sales of Proleukin® used with
26 the treatment regimen, are expected to drive significant revenue for Iovance in
27 2024.***

28 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.

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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, 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 financial 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

* * *

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

8 **Second Quarter and First Half 2024 Financial Results, Corporate Guidance,** 9 **and Updates**

10 **Product Revenue and Guidance**

11 ● **2Q24 Total Product Revenue:** \$31.1 million for the second quarter ended
12 June 30, 2024, following the initial launch of Amtagvi on February 20, 2024.

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

14 * * *

15 ● **FY24 and FY25 Total Product Revenue Guidance:** Iovance expects
16 significant quarter-over-quarter growth in product revenue to continue throughout
17 2024, 2025, and beyond as the adoption curve for Amtagvi steepens. More than 55
18 patients have been infused with Amtagvi since the first commercial infusion in April
19 2024, which includes 25 patients infused in the second quarter and over 30 patients
20 infused since the start of the third quarter.

18 * * *

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

23 * * *

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

25 ● The U.S. FDA approved Amtagvi (lifileucel) on February 16, 2024, as the
26 first treatment option for advanced melanoma after anti-PD-1 and targeted therapy.
27 Amtagvi is also the first FDA-approved T cell therapy for a solid tumor indication.

28 ● ***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.

1 *broaden the utilization of Amtagvi, driving a higher volume of patient referrals.*
2 Demand trends are expected to accelerate growth throughout the remainder of the
3 year and over the following years. As such, we are actively pursuing additional
4 regulatory approvals to expand our commercial footprint, driving growth beyond the
5 U.S. into new markets with a high prevalence of advanced melanoma. As a fully
6 integrated company, Iovance is well positioned to remain the global leader in
7 innovating, developing, and delivering current and future generations of TIL cell
8 therapy for patients with cancer.”

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

11 **Product Revenue and Guidance**

12 • **3Q24 Total Product Revenue:** Iovance recognized total revenue of \$58.6
13 million from sales of Amtagvi and Proleukin during the third quarter ended
14 September 30, 2024.

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

19 * * *

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

25 * * *

26 ○ **Revenue Guidance in FY25:** Total product revenue remains on track
27 to be within the range of \$450 to \$475 million in 2025, the first full calendar year of
28 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

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

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

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

13 * * *

- 14 • our ability to successfully commercialize Amtagvi™ (lifileucel) and
15 Proleukin® (aldesleukin), and any other products and/or product candidates for
16 which we obtain or have obtained FDA or other regulatory approvals, including by
17 the European Commission in the European Union, or the EU;

18 24. On February 27, 2025, Iovance issued a press release announcing its financial results
19 for the fourth quarter and fiscal year ended December 31, 2024 and an update on recent
20 developments. The press release touted the Company’s financial results, including the progress of
21 ATC growth trajectories and “Reaffirming FY25 Total Product Revenue Guidance of \$450M-
22 \$475M”. Specifically, the press release stated as follows, in relevant part:

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

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

28 ***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

1 referrals, add large community practices to our authorized treatment center (ATC)
2 network, expand the U.S. market, and secure regulatory approvals in three new
3 markets outside the U.S. I am confident that Iovance is well positioned to remain the
4 global leader in innovating, developing, and delivering current and future generations
5 of TIL cell therapy for patients with cancer.”

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

6 **Product Revenue and Guidance**

7 ● Fourth Quarter 2024 Total Product Revenue: Iovance recognized total
8 revenue of \$73.7 million from sales of Amtagvi and Proleukin during the fourth
9 quarter ended December 31, 2024.

10 – **Amtagvi Revenue:** Product revenue was \$48.7 million from U.S.
11 Amtagvi sales in the fourth quarter of 2024, reflecting strong adoption with
12 increasing demand. Amtagvi revenue is recognized upon patient infusion.

13 * * *

14 ● **Full Year 2024 Total Product Revenue:** Total product revenue was \$164.1
15 million and achieved the high end of the company’s guidance range of \$160 to \$165
16 million for the full year 2024. Full year product revenue included the first three
17 quarters of sales following the U.S. launch of Amtagvi on February 20, 2024. The
18 full year 2024 product revenue for Amtagvi and Proleukin was \$103.6 million and
19 \$60.5 million, respectively.

20 ● **Significant Amtagvi Growth Potential at Approximately 70 ATCs in 2025:**
21 *Amongst current ATCs, 76% completed tumor resections, 64% infused one or
22 more patients, and 13% infused more than 10 patients, highlighting significant
23 growth potential at existing ATCs.*

24 ● **Full Year 2025 Total Product Revenue Guidance:** *Iovance is reaffirming
25 total product revenue guidance within the range of \$450 to \$475 million for 2025,
26 the first full calendar year of Amtagvi sales.* Amtagvi adoption is on track to
27 continue accelerating throughout 2025 with broader utilization, higher demand, and
28 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.

1 and monitor our ATCs, substantial resources and investment from us and each
2 treatment center may be required. Additionally, the treatment center onboarding
3 process can be complicated and requires extensive training, technical equipment, and
4 coordination of processes. Once authorized, ATCs will be required to ensure that
5 their training, facilities, and treatment capabilities are adequately maintained.

6 We have limited prior experience in the marketing, sale, and distribution of
7 biopharmaceutical products, and there are significant risks involved in the building
8 and managing of a commercial infrastructure. The establishment and development
9 of commercial capabilities, including a comprehensive healthcare compliance
10 program, to market any products we may develop will be expensive and time
11 consuming and could delay any product launch, and we may not be able to
12 successfully develop this capability. We, or our collaborators, will have to compete
13 with other pharmaceutical and biotechnology companies to recruit, hire, train,
14 manage, and retain marketing, sales, and commercial support personnel. Although
15 we have developed a commercial infrastructure, in the event we are

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

25 **Disclosures at the End of the Class Period**

26 27. On May 8, 2025, after the market closed, Iovance released its first quarter 2025
27 financial results, revealing a quarterly total product revenue of \$49.3 million, a significant decline
28 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

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

2 *FY25 Operating Expenses Reduced and 2H26 Cash Runway Guidance Maintained*

3 * * *

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

16 **First Quarter 2025 Financial Results, Corporate Guidance, and Updates**

17 **Product Revenue and Guidance**

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

21 - 1Q25 Amtagvi Revenue: Product revenue from U.S. Amtagvi sales
22 was \$43.6 million, impacted by a reduction in capacity during annual scheduled
23 maintenance at the iCTC. Production has resumed enabling full capacity for
24 infusions in the second quarter 2025. Iovance currently anticipates infusing between
25 100 and 110 commercial patients in the second quarter.

26 * * *

27 • **Amtagvi Growth Potential at U.S. ATCs in 2025:** As of today, Iovance’s
28 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.

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

6 Back in August, we were trying to give investors our best line of sight to what we
7 thought was going to happen. At that point, we were very well aware of the high
8 demand for the product, and we were ramping up our manufacturing as fast as we
9 could. So, we built our model on the back of how many manufacturing slots we
10 would make available maximum ramp.

11 Now, as we’ve gone, we’ve learned a lot about the launch, especially recently as we
12 watch some of the dynamics with the ATCs, we looked at our experience with growth
13 trajectories there. We look at the time lines it takes for new ATCs to come on board
14 and begin treating their first patients and how they work through their processes.
15 We’re onboarding these large community practices, which takes some time, and
16 we’re doing the community referral process, which takes a lot of time, too.

17 And as we looked at that, we just decided that it was better and more accurate for us
18 to forecast guidance that we gave today to show you that we can still make this
19 product grow very, very substantially.

20 But now what we’re going to do is we’re just going to limit some of our
21 manufacturing slots. It ends up being essentially almost a neutral with respect to how
22 we use our cash, and we’ll roll forward and we’ll continue to succeed on the launch.
23 But we think we’ll do it on terms that are, I think, a little bit more in line with what
24 we actually see at the ATCs.

25 29. Defendant Bellemin stated that “[c]osts of sales for the first quarter of 2025 was
26 \$49.7 million, including \$15 million in period costs associated with patient drop-off and
27 manufacturing success rates, an increase quarter-over-quarter.” When an analyst asked “what drove
28 the higher patient drops or lower manufacturing success in the quarter,” Defendant Bilinsky replied:
29 “Some of this – or much of this – is related to patient selection and the tumor procurement technique.
30 . . . What gives us confidence in the success rate trends that we see among ATCs who have been up
31 and running for a long time and the experience curve that they’ve been able to achieve.”

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

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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;

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

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

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

11 **UNDISCLOSED ADVERSE FACTS**

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

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

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

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

7 **LOSS CAUSATION**

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

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

15 **SCIENTER ALLEGATIONS**

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

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

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

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

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

22 **NO SAFE HARBOR**

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

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

8 **FIRST CLAIM**

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

10 **Rule 10b-5 Promulgated Thereunder**

11 **Against All Defendants**

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

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

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

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

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

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

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

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

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

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

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

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

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

28

1 **SECOND CLAIM**

2 **Violation of Section 20(a) of The Exchange Act**

3 **Against the Individual Defendants**

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

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

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

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

27 **PRAYER FOR RELIEF**

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

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

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

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

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

9 **JURY TRIAL DEMANDED**

10 Plaintiff hereby demands a trial by jury.

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12 DATED:

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