**UNITED STATES**
**SECURITIES AND EXCHANGE COMMISSION**
**Washington, D.C. 20549**

**FORM 8-K**

**Current Report**

**Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

Date of Report (date of earliest event reported): August 8, 2024

# IOVANCE BIOTHERAPEUTICS, INC.

(Exact Name of Registrant as Specified in Charter)

| **Delaware** | |
|---|---|
| **(State of Incorporation)** | |
| **001-36860** | **75-3254381** |
| **Commission File Number** | **(I.R.S. Employer Identification No.)** |
| **825 Industrial Road, 4th Floor**<br>**San Carlos, California** | **94070** |
| **(Address of Principal Executive Offices)** | **(Zip Code)** |

**(650) 260-7120**
**(Registrant's Telephone Number, Including Area Code)**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425).

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12).

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b)).

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c)).

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter). Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Securities registered pursuant to Section 12(b) of the Act:

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|---|---|---|
| Common stock, par value $0.000041666 per share | IOVA | The Nasdaq Stock Market LLC |

**Item 2.02. Results of Operations and Financial Condition.**

On August 8, 2024, Iovance Biotherapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended June 30, 2024 and an update on recent developments. A copy of that press release is furnished as Exhibit 99.1.

The information furnished under this Item 2.02, including the accompanying Exhibit 99.1, shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of such section, nor shall such information be deemed to be incorporated by reference in any subsequent filing by the Company under the Securities Act of 1933, as amended, or the Exchange Act, regardless of the general incorporation language of such filing, except as specifically stated in such filing.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits.

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release of Iovance Biotherapeutics, Inc., dated August 8, 2024. |
| 104 | Cover Page Interactive Data File (embedded as Inline XBRL document) |

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**Iovance Biotherapeutics, Inc.**

Dated: August 8, 2024

By: /s/ Frederick G. Vogt
Name: Frederick G. Vogt, Ph.D., J.D.
Title: Interim CEO and President, and General Counsel

**Exhibit 99.1**

**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*

**SAN CARLOS, Calif., August 8, 2024 --** Iovance Biotherapeutics, Inc. (NASDAQ: IOVA), a commercial biotechnology company focused on innovating, developing, and delivering novel polyclonal tumor infiltrating lymphocyte (TIL) therapies for patients with cancer, today reported second quarter and first half 2024 financial results and corporate updates.

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

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

**Product Revenue and Guidance**

- **2Q24 Total Product Revenue:** $31.1 million for the second quarter ended June 30, 2024, following the initial launch of Amtagvi on February 20, 2024.
  - **Amtagvi Revenue**: 2Q24 represents the first quarter of Amtagvi sales in the U.S. with product revenue of $12.8 million, which is only recognized upon patient infusion.
  - **Proleukin Revenue:** 2Q24 product revenue also includes $18.3 million in sales for Proleukin, which is used in the Amtagvi treatment regimen and in global commercial and clinical uses in other settings. Proleukin revenue is recognized upon delivery to distributors and ATCs and purchased several months in advance of anticipated infusions and revenue recognition for Amtagvi use.
- **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 3Q24:** With utilization broadening and the rate of infusions substantially increasing, total infusions during the third quarter have markedly exceeded infusions in the second quarter. Total product revenue in the third quarter of 2024 is expected to be within the range of $53 to $55 million.
  - **Revenue Guidance in FY24:** Total product revenue for the full year 2024 is anticipated to be within the range of $160 to $165 million, reflecting three quarters of Amtagvi sales following FDA approval in mid-February. Additionally, demand for Proleukin remains strong and continues to be a leading indicator of Amtagvi sales.

- **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.

- **Cash Position:** As of July 24, 2024, Iovance had cash, cash equivalents, investments, and restricted cash of $449.6 million, compared to $346.3 million at December 31, 2023. The current cash position and anticipated product revenue are expected to be sufficient to fund current and planned operations, including manufacturing expansion, into early 2026.

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

- The U.S. FDA approved Amtagvi (lifileucel) on February 16, 2024, as the first treatment option for advanced melanoma after anti-PD-1 and targeted therapy. Amtagvi is also the first FDA-approved T cell therapy for a solid tumor indication.
- Onboarding is complete at more than 50 U.S. ATCs across 29 states and more than 90% of addressable patients are now located within 200 miles of an ATC. More than 70 ATCs remain on track to be onboarded by the end of 2024.
- Manufacturing turnaround time has been on-target with initial launch expectations of approximately 34 days from inbound to return shipment to ATCs, with efforts underway to reduce the turnaround time in the near term. The commercial manufacturing experience is consistent with prior clinical experience.
- Amtagvi is a preferred second-line or subsequent therapy in the National Comprehensive Cancer Network® guidelines for treatment of cutaneous melanoma.
- Reimbursement remains successful, with an average financial clearance time of about three weeks.
- Approximately 75% of enrolled Amtagvi patients are covered by private payers. To date, payers covering more than 225 million lives have already added Amtagvi to policies during the first five months of launch.

**Lifileucel Launch Expansion into New Markets and Indications**

- Amtagvi has the potential to address more than 20,000 patients annually with previously treated advanced melanoma across the U.S. and multiple global markets where regulatory dossiers have been submitted or are planned in 2024 and 2025.[1]
- A marketing authorization application was submitted to the European Medicines Agency for lifileucel for the treatment of adult patients with unresectable or metastatic melanoma previously treated with a PD-1 blocking antibody, and if BRAF V600 mutation positive, a BRAF inhibitor with or without a MEK inhibitor. If approved, lifileucel will be the first and only approved therapy in this treatment setting in all European Union member states.
- Regulatory dossiers remain on track for submission in the following markets with significant populations of previously treated advanced melanoma patients:
  - UK and Canada in the second half of 2024
  - Australia in the first half of 2025
  - Additional countries, including Switzerland, in the second half of 2025 and early 2026

**Iovance TIL Cell Therapy Pipeline Highlights**

- **Lifileucel in Frontline Advanced Melanoma**
  - Updated clinical data from Cohort 1A of the IOV-COM-202 trial was presented at ASCO 2024 and demonstrated an unprecedented rate, depth and durability of responses, including a 30% confirmed complete response rate, and a differentiated safety profile in advanced melanoma patients who were naive to immune checkpoint inhibitors. These results further support the rationale for the registrational Phase 3 TILVANCE-301 trial and the global opportunity for lifileucel in combination with pembrolizumab as a frontline therapy for advanced melanoma.
  - A new cohort, 1D, will begin in the IOV-COM-202 trial in solid tumors to investigate lifileucel in combination with nivolumab and relatlimab in patients with frontline advanced melanoma, representing another potential best-in-class frontline alternative for physicians and patients in the U.S.
  - Strong momentum continues with global site activation and patient enrollment in the TILVANCE-301 trial, with more than 40 active sites across 10 countries including the U.S., Europe, Australia, and Canada, and an additional 60 sites across 18 countries committed to join the trial. TILVANCE-301 is intended to support accelerated and full U.S. approvals of Amtagvi in combination with pembrolizumab in frontline advanced melanoma, as well as full approval of Amtagvi in post-anti-PD-1 melanoma.

- **Lifileucel in Non-Small Cell Lung Cancer (NSCLC)**
  - Enrollment is accelerating in the IOV-LUN-202 registrational Phase 2 trial in post-anti-PD-1 NSCLC with high demand at clinical sites in the U.S., Canada, and Europe. Iovance is also activating sites in additional regions with strong track records for enrollment in NSCLC studies.
  - The FDA previously provided positive regulatory feedback on the proposed potency matrix for lifileucel in NSCLC, as well as the single-arm IOV-LUN-202 trial design to support accelerated approval of lifileucel in post-anti-PD-1 NSCLC.
  - Iovance expects to complete enrollment and report topline data from the registrational cohorts in IOV-LUN-202 in 2025 to support a potential supplemental biologics license application for lifileucel in 2026 for potential accelerated approval.

- **Lifileucel in Endometrial Cancer**
  - The IOV-END-201 Phase 2 trial was initiated in the second quarter of 2024 to investigate lifileucel for advanced endometrial cancer patients who have progressed after platinum-based chemotherapy and anti-PD-1 therapy regardless of mismatch repair (MMR) status. IOV-END-201 is supported by positive feedback from gynecological oncology experts as well as preclinical and manufacturing success data to be presented at a conference in 2024.
  - Endometrial cancer represents a significant opportunity for TIL cell therapy to address an additional unmet medical need in the post-anti-PD-1 treatment setting and may address both MMR deficient and proficient tumors. There are no currently approved therapies in the emerging second-line setting after frontline post-anti-PD1 therapy and chemotherapy.

- **Next Generation TIL Pipeline**
  - **IOV-4001 (PD-1 Inactivated TIL Cell Therapy):** The Phase 1 safety portion concluded in the first in human IOV-GM1-201 trial to investigate PD-1 inactivated TIL cell therapy (IOV-4001) in previously treated advanced melanoma and NSCLC, and the trial is progressing successfully into the multi-center Phase 2 efficacy stage. Iovance continues to utilize the TALEN® technology licensed from Cellectis to develop other investigational gene-edited TIL cell therapies with multiple knockout targets to potentially improve efficacy.

- **Next Generation IL-2 for TIL Treatment Regimen:** Iovance plans to submit an Investigational New Drug application (IND) for a Phase 1/2 clinical trial of IOV-3001, a second-generation, modified interleukin-2 (IL-2) analog, for use in the TIL therapy treatment regimen in the third quarter of 2024. Results from non-human primate and IND-enabling studies of IOV-3001 were presented at ASCO 2024 and demonstrated the potential for improved safety with strong effector T cell expansion.
- **Next Generation, Cytokine-Tethered TIL Therapy:** A genetically engineered, inducible, and tethered IL-12 TIL cell therapy, designated IOV-5001, is in IND-enabling studies. In preclinical studies, IOV-5001 augmented anti-tumor activity *in vitro*, and a clinical trial of a prior generation IL-12 TIL therapy at the National Cancer Institute showed improved efficacy. An IND submission is planned in 2025.

**Manufacturing Capacity Expansion**

- The Iovance Cell Therapy Center (*i*CTC), and an FDA-approved contract manufacturer, currently have capacity to treat several thousands of patients annually. Expansion is currently underway for the *i*CTC campus to supply TIL cell therapies for more than 5,000 patients annually in the next few years. The long-term goal is to establish a manufacturing network to address more than 10,000 patients annually.

**Corporate Updates**

- Iovance currently owns more than 210 granted or allowed U.S. and international patents and patent rights for Amtagvi and other TIL-related technologies that are expected to provide Amtagvi with exclusivity through at least 2042. This patent portfolio covers TIL compositions and methods of treatment and manufacturing in a broad range of cancers, with Gen 2 patent rights expected to provide exclusivity for Amtagvi into 2038 and additional patent rights, including methods of treating melanoma and compositions and methods for potency assays, expected to provide exclusivity into 2040 and 2042, respectively. Iovance also owns an industry-leading patent portfolio covering TIL products produced with genetic engineering, using core biopsies and peripheral blood as starting material, and using combinations of TIL products with checkpoint inhibitors, as well as Iovance's proprietary IovanceCares™ system. More information on Iovance's patent portfolio is available on the Intellectual Property page on www.iovance.com.
- Iovance recently renewed its Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute (NCI). Over the five-year term of the CRADA, Iovance and NCI teams will collaborate closely on preclinical and clinical development of enhanced tumor reactive TIL products for the treatment of a broad range of common epithelial cancers. Iovance retains an option to negotiate an exclusive license to inventions developed under the CRADA.

**Second Quarter and First Half 2024 Financial Results**

As of July 24, 2024, Iovance's unaudited cash position is approximately $449.6 million, which includes net proceeds of approximately $200.0 million raised from an at-the market (ATM) equity financing facility during the second and third quarter of 2024. The current cash position and anticipated product revenue are expected to be sufficient to fund current and planned operations into early 2026. Iovance had $346.3 million in cash, cash equivalents, investments, and restricted cash at December 31, 2023.

Net loss for the second quarter of 2024 was $97.1 million, or $0.34 per share, compared to a net loss of $106.5 million, or $0.47 per share, for the second quarter ended June 30, 2023. Net loss for the first half of 2024 was $210.1 million, or $0.76 per share, compared to a net loss of $213.9 million, or $0.98 per share, for the six-month period ended June 30, 2023.

Revenue was $31.1 million for the second quarter of 2024 and consisted of product revenue from the initial quarter of Amtagvi sales as well as recurring revenue from Proleukin. Iovance recognized $12.8 million in revenue from Amtagvi infusions that were completed during the second quarter of 2024 and $18.3 million in global revenue for Proleukin.

Revenue for the first half of 2024 was $31.8 million and reflected product revenue from Proleukin and Amtagvi. Revenue for the first half of 2023 was $0.2 million for global sales of Proleukin, which Iovance began to recognize during the three-month period ended June 30, 2023.

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

Cost of sales for the three and six months ended June 30, 2024 was $31.4 million and $38.6 million, respectively, primarily related to costs associated with sales of Amtagvi and Proleukin, certain costs associated with patient drop off and manufacturing success rates, non-cash amortization expense for intangible assets, and royalties payable on product sales. Cost of sales for both the three and six months ended June 30, 2023 was $2.1 million, primarily related to non-cash amortization for intangible assets.

The increases in cost of sales in the second quarter and first half of 2024 over the prior year periods were primarily attributable to the initiation of commercial manufacturing and related costs for the U.S. launch of Amtagvi during the first half of 2024.

Research and development expenses were $62.1 million for the second quarter of 2024, a decrease of $24.2 million compared to $86.3 million for the same period ended June 30, 2023. Research and development expenses were $141.9 million for the first half of 2024, a decrease of $27.2 million compared to $169.1 million for the same period ended June 30, 2023.

The decreases in research and development expenses in the second quarter and first half of 2024 over the prior year periods were primarily attributable to the transition of Amtagvi to commercial manufacturing, decreased costs associated with certain clinical activities in the first half of 2024, and the completion of pre-commercial qualification activities in 2023. These decreases in research and development were partially offset by increases in stock-based compensation resulting from growth in headcount.

Selling, general and administrative expenses were $39.6 million for the second quarter of June 2024, an increase of $17.7 million compared to $21.9 million for the same period ended June 30, 2023. Selling, general and administrative expenses were $71.0 million for the first half of 2024, an increase of $21.0 million compared to $50.0 million for the same six-month period ended June 30, 2023.

The increase in selling, general and administrative expenses in the second quarter and first half of 2024 compared to the prior year periods was primarily attributable to increases in headcount and related costs, including stock-based compensation, to support the growth in the overall business and related corporate infrastructure, as well as legal costs and costs incurred to support the commercialization of Amtagvi and Proleukin.

For additional information, please see the Company's Selected Condensed Consolidated Balance Sheets and Statements of Operations below.

**Webcast and Conference Call**

Management will host a conference call and live audio webcast to discuss these results and provide a corporate update today at 4:30 p.m. ET. To listen to the live or archived audio webcast, please register at https://edge.media-server.com/mmc/p/uhudv42k. The live and archived webcast can be accessed in the Investors section of the Company's website, IR.Iovance.com, for one year.

1. World Health Organization International Agency for Research on Cancer (IARC) GLOBOCAN 2022.

**About Iovance Biotherapeutics, Inc.**

Iovance Biotherapeutics, Inc. aims to be the global leader in innovating, developing, and delivering tumor infiltrating lymphocyte (TIL) therapies for patients with cancer. We are pioneering a transformational approach to cure cancer by harnessing the human immune system's ability to recognize and destroy diverse cancer cells in each patient. The Iovance TIL platform has demonstrated promising clinical data across multiple solid tumors. Iovance's Amtagvi™ is the first FDA-approved T cell therapy for a solid tumor indication. We are committed to continuous innovation in cell therapy, including gene-edited cell therapy, that may extend and improve life for patients with cancer. For more information, please visit www.iovance.com.

**Forward-Looking Statements**

Certain matters discussed in this press release are “forward-looking statements” of Iovance Biotherapeutics, Inc. (hereinafter referred to as the “Company,” “we,” “us,” or “our”) within the meaning of the Private Securities Litigation Reform Act of 1995 (the “PSLRA”). Without limiting the foregoing, we may, in some cases, use terms such as “predicts,” “believes,” “potential,” “continue,” “estimates,” “anticipates,” “expects,” “plans,” “intends,” “forecast,” “guidance,” “outlook,” “may,” “can,” “could,” “might,” “will,” “should,” or other words that convey uncertainty of future events or outcomes and are intended to identify forward-looking statements. Forward-looking statements are based on assumptions and assessments made in light of management’s experience and perception of historical trends, current conditions, expected future developments, and other factors believed to be appropriate. Forward-looking statements in this press release are made as of the date of this press release, and we undertake no duty to update or revise any such statements, whether as a result of new information, future events or otherwise. Forward-looking statements are not guarantees of future performance and are subject to risks, uncertainties, and other factors, many of which are outside of our control, that may cause actual results, levels of activity, performance, achievements, and developments to be materially different from those expressed in or implied by these forward-looking statements. Important factors that could cause actual results, developments, and business decisions to differ materially from forward-looking statements are described in the sections titled "Risk Factors" in our filings with the U.S. Securities and Exchange Commission, including our most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q, and include, but are not limited to, the following substantial known and unknown risks and uncertainties inherent in our business: the risks related to our ability to successfully commercialize our products, including Amtagvi, for which we have obtained U.S. Food and Drug Administration (“FDA”) approval, and Proleukin, for which we have obtained FDA and European Medicines Agency (“EMA”) approval; the risk that the EMA or other ex-U.S. regulatory authorities may not approve or may delay approval for our marketing authorization application submission for lifileucel in metastatic melanoma; the acceptance by the market of our products, including Amtagvi and Proleukin, and their potential pricing and/or reimbursement by payors, if approved (in the case of our product candidates), in the U.S. and other international markets and whether such acceptance is sufficient to support continued commercialization or development of our products, including Amtagvi and Proleukin, or product candidates, respectively; future competitive or other market factors may adversely affect the commercial potential for Amtagvi or Proleukin; the risk regarding our ability or inability to manufacture our therapies using third party manufacturers or at our own facility, including our ability to increase manufacturing capacity at such third party manufacturers and our own facility, may adversely affect our commercial launch; the results of clinical trials with collaborators using different manufacturing processes may not be reflected in our sponsored trials; the risk regarding the successful integration of the recent Proleukin acquisition; the risk that the successful development or commercialization of our products, including Amtagvi and Proleukin, may not generate sufficient revenue from product sales, and we may not become profitable in the near term, or at all; the risks related to the timing of and our ability to successfully develop, submit, obtain, or maintain FDA, EMA, or other regulatory authority approval of, or other action with respect to, our product candidates; whether clinical trial results from our pivotal studies and cohorts, and meetings with the FDA, EMA, or other regulatory authorities may support registrational studies and subsequent approvals by the FDA, EMA, or other regulatory authorities, including the risk that the planned single arm Phase 2 IOV-LUN-202 trial may not support registration; preliminary and interim clinical results, which may include efficacy and safety results, from ongoing clinical trials or cohorts may not be reflected in the final analyses of our ongoing clinical trials or subgroups within these trials or in other prior trials or cohorts; the risk that enrollment may need to be adjusted for our trials and cohorts within those trials based on FDA and other regulatory agency input; the risk that the changing landscape of care for cervical cancer patients may impact our clinical trials in this indication; the risk that we may be required to conduct additional clinical trials or modify ongoing or future clinical trials based on feedback from the FDA, EMA, or other regulatory authorities; the risk that our interpretation of the results of our clinical trials or communications with the FDA, EMA, or other regulatory authorities may differ from the interpretation of such results or communications by such regulatory authorities (including from our prior meetings with the FDA regarding our non-small cell lung cancer clinical trials); the risk that clinical data from ongoing clinical trials of Amtagvi will not continue or be repeated in ongoing or planned clinical trials or may not support regulatory approval or renewal of authorization; the risk that unanticipated expenses may decrease our estimated cash balances and forecasts and increase our estimated capital requirements; the risk that we may not be able to recognize revenue for our products; the risk that Proleukin revenues may not continue to serve as a leading indicator for Amtagvi revenues; the risks regarding our anticipated operating and financial performance, including our financial guidance and projections; the effects of global pandemic; the effects of global and domestic geopolitical factors; and other factors, including general economic conditions and regulatory developments, not within our control. Financial guidance as stated above in this press release assumes the following: no material change in our ability to manufacture our products; no material change in payor coverage; no material change in revenue recognition policies; no new business development transactions not completed as of the period covered by this press release; and no material fluctuation in exchange rates.

**IOVANCE BIOTHERAPEUTICS, INC.**
**Selected Condensed Consolidated Balance Sheets**
**(in thousands)**

| | June 30, 2024 (unaudited) | December 31, 2023 |
|---|---|---|
| Cash, cash equivalents, and investments | $ 412,542 | $ 279,867 |
| Restricted cash | $ 6,430 | $ 66,430 |
| Total assets | $ 964,322 | $ 780,351 |
| Stockholders' equity | $ 768,540 | $ 584,613 |

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

| | For the Three Months Ended June 30, | | For the Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2024 | 2023 | 2024 | 2023 |
| **Revenue** | | | | |
| Product revenue | $ 31,106 | $ 238 | $ 31,821 | $ 238 |
| Total revenue | 31,106 | 238 | 31,821 | 238 |
| | | | | |
| **Costs and expenses*** | | | | |
| Cost of sales | $ 31,368 | $ 2,050 | $ 38,629 | $ 2,050 |
| Research and development | 62,084 | 86,347 | 141,867 | 169,081 |
| Selling, general and administrative | 39,568 | 21,927 | 70,961 | 50,049 |
| Total costs and expenses | 133,020 | 110,324 | 251,457 | 221,180 |
| | | | | |
| **Loss from operations** | (101,914) | (110,086) | (219,636) | (220,942) |
| **Other income** | | | | |
| Interest income, net | 3,355 | 3,081 | 6,693 | 6,567 |
| **Net Loss before income taxes** | $ (98,559) | $ (107,005) | $ (212,943) | $ (214,375) |
| Income taxes benefit | 1,458 | 477 | 2,866 | 477 |
| **Net Loss** | $ (97,101) | $ (106,528) | $ (210,077) | $ (213,898) |
| | | | | |
| **Net Loss Per Share of Common Stock, Basic and Diluted** | $ (0.34) | $ (0.47) | $ (0.76) | $ (0.98) |
| | | | | |
| **Weighted-Average Shares of Common Stock Outstanding, Basic and Diluted** | 284,817 | 224,481 | 275,518 | 219,117 |
| | | | | |
| ***Includes stock-based compensation as follows:** | | | | |
| Cost of sales | $ 2,297 | $ - | $ 2,297 | $ - |
| Research and development | 13,107 | 9,390 | 22,022 | 18,249 |
| Selling, general and administrative | 15,062 | 7,350 | 23,325 | 14,156 |
| Total stock-based compensation included in costs and expenses | $ 30,466 | $ 16,740 | $ 47,644 | $ 32,405 |

**CONTACTS**

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