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): February 28, 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 **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 February 28, 2024, Iovance Biotherapeutics, Inc. (the "Company") issued a press release announcing its financial results for the fourth quarter and fiscal year ended December 31, 2023 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 February 28, 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: February 28, 2024

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

Exhibit 99.1

Iovance Biotherapeutics Reports Fourth Quarter and Full Year 2023 Financial Results and Corporate Updates

Amtagvi™ (lifileucel) U.S. Launch Fully Underway Following U.S. Food and Drug Administration (FDA) Approval as the First and Only One-Time, Individualized T cell Therapy for a Solid Tumor Cancer

Amtagvi Regulatory Submissions on Track in the European Union, United Kingdom, and Canada

Amtagvi Patients Identified at Nearly All of the 30 Authorized Treatment Centers (ATCs), with Approximately 50 ATCs Anticipated to be Ready by the End of May 2024

SAN CARLOS, Calif., February 28, 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 fourth quarter and full year 2023 financial results and corporate updates.

Frederick Vogt, Ph.D., J.D., Interim President and Chief Executive Officer of Iovance, stated, "Throughout 2023, we executed toward our first approval and commercial launch while advancing our pipeline. We are seeing healthy demand and momentum for Amtagvi™ following the recent U.S. FDA approval in advanced melanoma. To expand the launch globally, we plan to submit regulatory dossiers in the European Union in the first half of 2024 and in Canada and the United Kingdom in the second half of 2024. We are also excited about our robust development pipeline across solid tumor cancers. As a fully integrated company, Iovance is well positioned to execute on our regulatory, pipeline, manufacturing, and commercial launch activities to advance our mission to remain the global leader in TIL therapy."

Recent and Fourth Quarter 2023 Highlights and Corporate Updates

Amtagvi™ (lifileucel):

U.S. Approval and Launch Highlights in Advanced Melanoma

- The U.S. FDA approved Amtagvi 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 approximately 30 U.S. authorized treatment centers (ATCs) and approximately 50 ATCs are expected to be onboard by the end of May 2024.
- The Iovance Cell Therapy Center (*i*CTC) began commercial manufacturing for Amtagvi patients within a week of approval. The *i*CTC, and a nearby FDA-approved contract manufacturer, are built today for capacity for several thousands of patients annually.
- The U.S. launch of Amtagvi, and additional sales of Proleukin® used with the treatment regimen, are expected to drive significant revenue for Iovance in 2024.
- Since approval, there are at least 20 Amtagvi patients in process, which includes 10 patients already registered in IovanceCares™ with scheduled or pending manufacturing slots.

Launch Expansion into New Markets and Indications

- Iovance's global expansion strategy can more than double the total addressable patient population for Amtagvi in advanced melanoma. Anticipated regulatory submissions include the following:
  - A marketing authorization application (MAA) in the European Union (EU) in the first half of 2024.
  - An MAA in the U.K. and a new drug submission (NDS) in Canada in the second half of 2024.
  - Regulatory submissions in Australia and additional countries with significant populations of advanced melanoma patients in 2025.
- The registrational Phase 3 TILVANCE-301 trial is underway to support accelerated and full approvals of Amtagvi in combination with pembrolizumab in frontline advanced melanoma.
  - Global site activation and patient enrollment continue with strong momentum in the U.S., Europe, Australia, Canada, and additional countries.
  - Following the U.S. FDA's recent accelerated approval of Amtagvi in post-anti-PD-1 advanced melanoma, TILVANCE-301 is the confirmatory trial to support full approval in this initial indication.
  - An updated data cut for Cohort 1A of the IOV-COM-202 trial, in a presentation on the efficacy and safety of lifileucel and pembrolizumab in patients with immune checkpoint inhibitor-naive advanced melanoma, is planned for a medical meeting this year and is supportive of the rationale for TILVANCE-301.

Manufacturing Highlights

- More than 700 patients have been treated with Iovance TIL therapy manufactured using proprietary Iovance processes as of December 31, 2023.
- Capacity expansion is underway at *i*CTC to supply TIL cell therapies for more than 5,000 patients annually in the next few years.

Iovance TIL Therapy Clinical Pipeline Highlights

- Enrollment in the registrational cohorts in the Phase 2 Trial IOV-LUN-202 in post-anti-PD-1 NSCLC is estimated to complete in 2025. Iovance is working collaboratively with the U.S. FDA to resume new patient enrollment in IOV-LUN-202 following the partial clinical hold for new patients on December 22, 2023.
- A Phase 2 study in endometrial cancer in mismatch repair (MMR) deficient and MMR proficient patient populations is on track to commence in the first half of 2024.
- The first in human IOV-GM1-201 trial is investigating PD-1 inactivated TIL therapy (IOV-4001) in previously treated advanced melanoma and NSCLC.

Corporate Updates

- As of February 22, 2024, Iovance's unaudited cash position is approximately $485.2 million, which includes net proceeds of approximately $197.1 million from a follow-on equity financing in February of 2024. The current cash position and anticipated revenue from Amtagvi and Proleukin are expected to be sufficient to fund current and planned operations well into the second half of 2025.
- Iovance currently owns more than 60 granted or allowed U.S. and international patents for TIL compositions and methods of treatment and manufacturing in a broad range of cancers, with Gen 2 patent rights expected to provide exclusivity into 2038 and additional patent rights expected to provide exclusivity into 2042. More information on Iovance's patent portfolio is available on the Intellectual Property page on www.iovance.com.

Fourth Quarter and Full Year 2023 Financial Results

Iovance had $346.3 million in cash, cash equivalents, investments and restricted cash at December 31, 2023, compared to $478.3 million at December 31, 2022. With the net proceeds of approximately $197.1 million raised in the February 2024 follow-on stock offering and anticipated revenue from Amtagvi and Proleukin, the cash position is expected to be sufficient to fund current and planned operations well into the second half of 2025.

Net loss for the fourth quarter ended December 31, 2023, was $116.4 million, or $0.45 per share, compared to a net loss of $105.3 million, or $0.64 per share, for the fourth quarter ended December 31, 2022. Net loss for the year ended December 31, 2023 was $444.0 million, or $1.89 per share, compared to a net loss of $395.9 million, or $2.49 per share, for the year ended December 31, 2022. The net loss for the year ended December 31, 2023 includes amortization of intangible assets acquired as part of the Proleukin transaction.

Revenue for the fourth quarter and year ended December 31, 2023, was $0.5 million and $1.2 million, respectively, and comprised of product sales following the Proleukin® acquisition in May 2023. There was no revenue for the fourth quarter and year ended December 31, 2022. Cost of sales for the fourth quarter and year ended December 31, 2023, was $4.4 million and $10.8 million, respectively, and comprised of cost of inventory associated with sales of Proleukin® as well as $3.9 million and $9.7 million, respectively, of non-cash amortization expenses of the acquired intangible asset for developed technology. There was no cost of revenues for the fourth quarter and year ended December 31, 2022.

Research and development expenses were $87.5 million for the fourth quarter ended December 31, 2023, an increase of $6.9 million compared to $80.6 million for the same period ended December 31, 2022. Research and development expenses were $344.1 million for the year ended December 31, 2023, an increase of $49.3 million compared to $294.8 million for the same period ended December 31, 2022.

The increases in research and development expenses in the fourth quarter and the year ended December 31, 2023, over the prior year periods were primarily attributable to increases in headcount and related costs to support internal manufacturing and clinical development activities, manufacturing costs to support increased production and commercial manufacturing readiness, clinical trial costs driven primarily by the initiation of our Phase 3 TILVANCE-301 clinical trial, and facility and related costs to expand manufacturing capacity.

Selling, general and administrative expenses were $29.9 million for the fourth quarter ended December 31, 2023, an increase of $3.4 million compared to $26.5 million for the same period ended December 31, 2022. Selling, general and administrative expenses were $106.9 million for the year ended December 31, 2023, an increase of $2.8 million compared to $104.1 million for the same period ended December 31, 2022.

The increase in selling, general and administrative expenses in the fourth quarter and the year ended December 31, 2023, compared to prior year periods was primarily attributable to increases in headcount and related costs to support the growth in the overall business and related corporate infrastructure, professional fees and travel costs, including costs associated with Proleukin® integration. These increases were partially offset by a decrease in stock-based compensation expenses, legal and other costs. For additional information, please see the Company’s Selected Condensed Consolidated Balance Sheet and Statement of Operations below.

Webcast and Conference Call

To participate in the live conference call Q&A, please register at https://register.vevent.com/register/BI289df7d30f474a72a72e1c4f7a754c92. To listen to the live or archived audio webcast, please register at https://edge.media-server.com/mmc/p/6gd5c9ve. The live and archived webcast can be accessed in the Investors section of the Company's website, IR.Iovance.com. The archived webcast will be available for one year.

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," "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 and Proleukin, for which we obtain U.S. Food and Drug Administration ("FDA"), European Medicines Agency ("EMA"), or other regulatory authority approval; the risk that the EMA or other regulatory authorities may not approve or may delay approval for our biologics license application ("BLA") 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; our ability or inability to manufacture our therapies using third party manufacturers or at 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 risk that future competitive or other market factors may adversely affect the commercial potential for Amtagvi or Proleukin; 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 effects of the COVID-19 pandemic; and other factors, including general economic conditions and regulatory developments, not within our control.

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

	December 31, 2023	December 31, 2022
Cash, cash equivalents, and investments	$ 279,867	$ 471,845
Restricted cash	66,430	6,430
Total assets	780,351	663,982
Stockholders' equity	584,613	499,638

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

	For the Three Months Ended December 31,		For the Year Ended December 31,	
	2023 (unaudited)	2022 (unaudited)	2023	2022
Revenue				
Product revenue	$ 482	$ —	$ 1,189	$ —
Total revenue	482	—	1,189	—
Costs and expenses*				
Cost of sales	$ 4,365	$ —	$ 10,755	$ —
Research and development	87,470	80,573	344,077	294,781
Selling, general and administrative	29,903	26,463	106,916	104,097
Total costs and expenses	121,738	107,036	461,748	398,878
Loss from operations	(121,256)	(107,036)	(460,559)	(398,878)
Other income				
Interest income, net	3,118	1,717	13,043	2,985
Net Loss before income taxes	$ (118,138)	$ (105,319)	$ (447,516)	$ (395,893)
Income tax benefit	1,759	—	3,479	—
Net Loss	$ (116,379)	$ (105,319)	$ (444,037)	$ (395,893)
Net Loss Per Share of Common Stock, Basic and Diluted	$ (0.45)	$ (0.64)	$ (1.89)	$ (2.49)
Weighted-Average Shares of Common Stock Outstanding, Basic and Diluted	255,951	164,765	235,131	159,259
***Includes stock-based compensation as follows:**				
Research and development	$ 7,890	$ 11,379	$ 34,926	$ 50,242
Selling, general and administrative	6,509	8,130	27,699	33,780
Total stock-based compensation included in costs and expenses	$ 14,399	$ 19,509	$ 62,625	$ 84,022

CONTACTS

Iovance Biotherapeutics, Inc.:
Sara Pellegrino, IRC
SVP, Investor Relations & Corporate Communications
650-260-7120 ext. 264
Sara.Pellegrino@iovance.com

Jen Saunders
Senior Director, Investor Relations & Corporate Communications
267-485-3119
Jen.Saunders@iovance.com