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): November 7, 2023

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 November 7, 2023, Iovance Biotherapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 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 (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 November 7, 2023.
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.

Date: November 7, 2023

IOVANCE BIOTHERAPEUTICS, INC.

By: /s/ Frederick G. Vogt
Frederick G. Vogt, Interim CEO & General Counsel

Exhibit 99.1

Iovance Biotherapeutics Reports Third Quarter and Year-to-Date 2023 Financial Results and Corporate Updates

FDA Priority Review of Biologics License Application (BLA) on Track for Lifileucel in Advanced Melanoma with Prescription Drug User Fee Act Action (PDUFA) Date of February 24, 2023

Positive Regulatory Feedback Supports Lifileucel Regulatory Submissions in Europe and Canada in 2024

Onboarding Completed at Approximately 30 Authorized Treatment Centers (ATCs) in Preparation for Potential U.S. Commercial Launch of Lifileucel as First Approved TIL Therapy

SAN CARLOS, Calif., November 7, 2023 -- Iovance Biotherapeutics, Inc. (NASDAQ: IOVA), a biotechnology company focused on innovating, developing, and delivering novel polyclonal tumor infiltrating lymphocyte (TIL) therapies for patients with cancer, today reported third quarter and year-to-date 2023 financial results and corporate updates.

Frederick Vogt, Ph.D., J.D., Interim President and Chief Executive Officer of Iovance, stated, "Iovance continues to make significant progress toward commercialization while pursuing opportunities for our TIL therapies in additional geographies and solid tumor cancers. The Priority Review of our BLA for lifileucel in advanced melanoma remains on track. We are prepared to rapidly serve the U.S. melanoma community immediately following an FDA approval, with additional regulatory submissions commencing in the first half of next year to expand into Europe and other geographies. We are also excited about our lung cancer development strategy, including positive momentum for our registrational IOV-LUN-202 trial in advanced non-small cell lung cancer patients. We are well positioned to execute on our regulatory, pipeline, manufacturing, and commercial launch activities to advance our mission to be the global leader in TIL therapy."

Recent and Third Quarter 2023 Highlights and Corporate Updates

Lifileucel in Advanced Melanoma
Regulatory Highlights

- The BLA Priority Review remains on track for lifileucel for patients with advanced melanoma with a PDUFA date of February 24, 2024. Iovance continues to work with the FDA to expedite approval of lifileucel in advance of the PDUFA date. All pre-approval inspections of clinical sites, internal and external manufacturing, and testing facilities have been successfully completed.
- Following lifileucel's initial U.S. launch, Iovance's expansion strategy is expected to more than double the total addressable advanced melanoma patient population for lifileucel. Iovance has recently made significant progress toward the goal of bringing lifileucel to new geographies:
    - Following recent positive feedback from the European Medicines Agency (EMA) on Cohorts 2 and 4 of the C-144-01 clinical trial, Iovance plans to submit a marketing authorization application (MAA) in the European Union for lifileucel in advanced melanoma in the first half of 2024.
    - Iovance is also engaged with the Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom (U.K.) and Health Canada. Iovance also plans to submit an MAA for lifileucel in the U.K. and a new drug submission (NDS) in Canada in the second half of 2024.
    - Additional regulatory submissions for lifileucel are planned for Australia and other countries with significant populations of advanced melanoma patients.

- Patient enrollment and global site activation continue in the registrational Phase 3 TILVANCE-301 trial to support accelerated and full approvals of lifileucel in combination with pembrolizumab in frontline advanced melanoma. Recent site activations include additional U.S. sites and the first site in Australia, with regulatory clearances obtained to open sites in the U.K. and Canada. TILVANCE-301 is a confirmatory trial to support full approval of lifileucel in post-anti-PD-1 advanced melanoma. TILVANCE-301 remains on track to be well underway at the time of potential accelerated approval for lifileucel in this initial indication.
- A subanalysis from the C-144-01 trial of patients with advanced mucosal melanoma was presented at the European Society for Medical Oncology (ESMO) Congress 2023, October 20-24, 2023, Madrid, Spain. In these difficult-to-treat patients, a confirmed objective response rate (ORR) of 50.0% was observed, with 67% of responses ongoing at 24+ months.

Manufacturing and Commercial Preparations

- Pre-approval onboarding steps to treat melanoma patients with lifileucel upon approval have been completed at approximately 30 ATCs. Approximately 50 ATCs are expected to be onboard within 90 days of the PDUFA date, demonstrating the strong excitement and demand in the melanoma community for the launch of lifileucel. The Iovance team is partnering with ATCs to build their TIL service lines and working with payers to speed reimbursement. Iovance expects rapid uptake of lifileucel in the U.S. market in 2024 given the extensive commercialization, manufacturing, patient access, and reimbursement preparations, as well as the lack of alternative options for advanced melanoma patients. Following the ongoing successful integration of the Proleukin® acquisition, significant revenue increases from the Proleukin® business are also expected in 2024.
- To date, more than 600 patients have been treated with Iovance TIL therapy manufactured using proprietary Iovance processes, with a manufacturing success rate of more than 90%.
- The Iovance Cell Therapy Center (*i*CTC) is currently manufacturing TIL therapies for clinical trials while executing activities to support BLA review in preparation for initiating commercial supply. The *i*CTC facility currently has annual capacity to supply TIL therapies for 2,000+ patients, with buildable shell space to ultimately supply TIL therapies for 5,000+ patients. Iovance also has additional contract manufacturing flexibility and capacity to meet potential commercial and clinical demand.

Iovance TIL Therapy in Advanced Non-Small Cell Lung Cancer (NSCLC)

- **Registrational Phase 2 Trial IOV-LUN-202 in Post-Anti-PD-1 NSCLC:** Enrollment in IOV-LUN-202 is ongoing at more than 40 clinical sites in the U.S., Canada, and Europe, and is on track to be completed in the second half of 2024. There is strong physician interest and momentum for center participation following the positive preliminary data analysis and FDA regulatory feedback that the design of the single-arm IOV-LUN-202 trial may be acceptable for approval of LN-145 TIL therapy in post-anti-PD-1 NSCLC.
- **NSCLC Clinical Trial Regulatory Update:** Iovance is planning to meet with the FDA in early 2024 to discuss a potential registrational trial of lifileucel in combination with pembrolizumab after standard of care chemotherapy to serve as the confirmatory trial for IOV-LUN-202 in post-anti-PD-1 melanoma and to support accelerated approval in frontline advanced NSCLC.
- **Iovance TIL Therapy in Combination with Anti-PD-1 in Frontline Advanced NSCLC:** Detailed results from Cohort 3A of the IOV-COM-202 clinical trial, exploring TIL in combination with pembrolizumab in anti-PD-1 naïve advanced NSCLC patients, were presented at an oral session during the IASLC 2023 World Congress on Lung Cancer (WCLC 2023).

Iovance TIL Therapy in Endometrial Cancer

- Iovance is expanding its robust clinical portfolio with a new TIL therapy program in post-anti-PD-1 and post-chemotherapy advanced endometrial cancer. Advanced endometrial cancer represents a significant opportunity for TIL therapy, with no currently approved therapies in the emerging second-line setting, post-anti-PD1 therapy and chemotherapy. A Phase 1/2 study in mismatch repair (MMR) deficient and MMR proficient patient populations is expected to commence in the first half of 2024. More than 10,000 women are expected to die in the U.S. in 2023 from endometrial cancer, representing a significant patient population with unmet medical need.[1]

Additional Pipeline Highlights

- Additional clinical trials of Iovance TIL therapies include IOV-GM1-201 to investigate PD-1 inactivated TIL therapy (IOV-4001) in previously treated advanced melanoma or NSCLC as well as pivotal Cohort 2 in the ongoing C-145-04 trial of lifileucel to support a BLA in cervical cancer following progression on or after chemotherapy and pembrolizumab.
- A novel interleukin-2 (IL-2) analog (IOV-3001) is in Investigational New Drug (IND)-enabling studies supporting its use as part of the TIL treatment regimen following TIL infusion.
- Additional research and preclinical studies are exploring approaches to increase TIL potency using CD39/69 double negative TILs and stable gene incorporation enhancements such as tethered cytokines.

Corporate Updates

- As of September 30, 2023, Iovance's unaudited cash position is approximately $427.8 million. Following strategic portfolio prioritization, as well as completion of many one-time commercial and manufacturing readiness activities, quarterly and annual operating expenses are expected to be reduced in the remainder of 2023 and 2024, while continuing all key clinical programs and utilizing internal manufacturing capabilities.
- 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. More information on Iovance's patent portfolio is available on the Intellectual Property page on www.iovance.com.

Third Quarter and Year-to-Date Financial Results

Iovance had $427.8 million in cash, cash equivalents, investments and restricted cash at September 30, 2023, compared to $478.3 million at December 31, 2022. The combined net proceeds in the third quarter of 2023 from the Company's public offering in July 2023 and the at-the market (ATM) equity financing facility were approximately $203.2 million. The current cash position and anticipated revenue in 2024 from lifileucel and Proleukin® is expected to be sufficient to fund current and planned operations into 2025.

Net loss for the third quarter ended September 30, 2023, was $113.8 million, or $0.46 per share, compared to a net loss of $99.6 million, or $0.63 per share, for the third quarter ended September 30, 2022. Net loss for the nine months ended September 30, 2023, was $327.7 million, or $1.44 per share, compared to a net loss of $290.6 million, or $1.85 per share, for the same period ended September 30, 2022.

Revenue for the third quarter and nine months ended September 30, 2023, was $0.5 million and $0.7 million, respectively, and comprised of product sales following the Proleukin® acquisition in May 2023. There was no revenue for the third quarter and nine months ended September 30, 2022. Cost of sales for the third quarter and nine months ended September 30, 2023, was $4.3 million and $6.4 million, respectively, and comprised of cost of inventory associated with sales of Proleukin® as well as $4.0 million and $5.9 million, respectively, of non-cash amortization expenses of the acquired intangible asset for developed technology. There was no cost of revenues for the third quarter and nine months ended September 30, 2022.

Research and development expenses were $87.5 million for the third quarter ended September 30, 2023, an increase of $15.0 million compared to $72.5 million for the same period ended September 30, 2022. Research and development expenses were $256.6 million for the nine months ended September 30, 2023, an increase of $42.4 million compared to $214.2 million for the same period ended September 30, 2022.

[1] American Cancer Statistics. Key Statistics for Endometrial Cancer, https://www.cancer.org/cancer/endometrial-cancer/about/key-statistics.html.

The increases in research and development expenses in the third quarter and the nine months ended September 30, 2023, over the prior year periods were primarily attributable to growth of the internal research and development team, as well as higher costs related to facilities and the initiation of new clinical trials, including the Phase 3 TILVANCE trial, which were partially offset by a decrease in stock-based compensation expense.

Selling, general and administrative expenses were $27.0 million for the third quarter ended September 30, 2023, a decrease of $0.9 million compared to $27.9 million for the same period ended September 30, 2022. Selling, general and administrative expenses were $77.0 million for the nine months ended September 30, 2023, a decrease of $0.6 million compared to $77.6 million for the same period ended September 30, 2022.

The decrease in selling, general and administrative expenses in the third quarter and the nine months ended September 30, 2023, compared to prior year periods was primarily attributable to the decrease in stock-based compensation expense and other costs related to the timing of spend compared to the prior year period, including marketing, advertising, and legal costs, partially offset by costs associated with the growth in the overall business. 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 conference call Q&A and live audio webcast, please register at https://register.vevent.com/register/BIfd1787749ef747f19a491cb371d60fab. To listen to the live or archived webcast, please register at https://edge.media-server.com/mmc/p/n9gmq93h. 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 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. Our lead late-stage TIL product candidate, lifileucel for metastatic melanoma, has the potential to become the first approved one-time cell therapy for a solid tumor cancer. The Iovance TIL platform has demonstrated promising clinical data across multiple solid tumors. 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"). All such written or oral statements made in this press release, other than statements of historical fact, are forward-looking statements and are intended to be covered by the safe harbor for forward-looking statements provided by 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 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 effects of the COVID-19 pandemic; risks related to the timing of and our ability to successfully develop, submit, obtain, or maintain U.S. Food and Drug Administration ("FDA"), European Medicines Agency ("EMA"), or other regulatory authority approval of, or other action with respect to, our product candidates, and our ability to successfully commercialize any product candidates for which we obtain FDA, EMA, or other regulatory authority approval; 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 the prior pre-BLA meeting with the FDA and/or regarding our prior meetings with the FDA regarding our NSCLC clinical trials); the risk that the FDA, EMA, or other regulatory authorities may not approve or may delay approval for our BLA submission for lifileucel in metastatic melanoma; the acceptance by the market of our product candidates and their potential reimbursement by payors, if approved, in the U.S. and other international markets; our ability or inability to manufacture our therapies using third party manufacturers or our own facility may adversely affect our potential 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 may not generate sufficient revenue from product sales, and we may not become profitable in the near term, or at all; the risk that unanticipated expenses may decrease our estimated cash balances and forecasts and increase our estimated capital requirements; and other factors, including general economic conditions and regulatory developments, not within our control.

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

	September 30, 2023 (unaudited)	December 31, 2022
Cash, cash equivalents, and investments	$ 361,374	$ 471,845
Restricted cash	$ 66,430	$ 6,430
Total assets	$ 852,315	$ 663,982
Stockholders' equity	$ 674,008	$ 499,638

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenue				
Product revenue	$ 469	$ —	$ 707	$ —
Total revenue	469	—	707	—
Costs and expenses*				
Cost of sales	$ 4,340	$ —	$ 6,390	$ —
Research and development	87,526	72,502	256,607	214,208
Selling, general and administrative	26,964	27,893	77,013	77,634
Total costs and expenses	118,830	100,395	340,010	291,842
Loss from operations	(118,361)	(100,395)	(339,303)	(291,842)
Other income				
Interest income, net	3,358	777	9,925	1,268
Net Loss before income taxes	$ (115,003)	$ (99,618)	$ (329,378)	$ (290,574)
Income tax benefit	1,243	—	1,720	—
Net Loss	$ (113,760)	$ (99,618)	$ (327,658)	$ (290,574)
Net Loss Per Share of Common Stock, Basic and Diluted	$ (0.46)	$ (0.63)	$ (1.44)	$ (1.85)
Weighted-Average Shares of Common Stock Outstanding, Basic and Diluted	245,817	157,817	228,115	157,404
***Includes stock-based compensation as follows:**				
Research and development	$ 8,787	$ 11,272	$ 27,036	$ 38,863
Selling, general and administrative	7,034	8,508	21,190	25,650
Total stock-based compensation included in costs and expenses	$ 15,821	$ 19,780	$ 48,226	$ 64,513

CONTACTS

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