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): May 5, 2022

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 May 5, 2022, Iovance Biotherapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended March 31, 2022 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 May 5, 2022.
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: May 5, 2022

IOVANCE BIOTHERAPEUTICS, INC.

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

Iovance Biotherapeutics Reports First Quarter 2022 Financial Results and Corporate Updates

First Biologics License Application (BLA) Submission Planned in August 2022

SAN CARLOS, Calif., May 5, 2022 -- Iovance Biotherapeutics, Inc. (NASDAQ: IOVA), a late-stage biotechnology company developing novel T cell-based cancer immunotherapies (tumor infiltrating lymphocyte, TIL, and peripheral-blood lymphocyte, PBL), today reported first quarter 2022 financial results and corporate updates.

Frederick Vogt, Ph.D., J.D., Interim President and Chief Executive Officer of Iovance, stated, "Iovance had a positive start to the year across our lead program lifileucel in metastatic melanoma as well as our growing TIL pipeline. We recently reported favorable feedback from the FDA on our potency assays and assay matrix, which brings us a step closer to our planned BLA submission for lifileucel in metastatic melanoma. We continue to enroll patients in clinical studies to investigate our TIL therapies in multiple solid tumors, with plans to initiate a Phase 3 clinical trial of lifileucel in combination with pembrolizumab in frontline melanoma. In addition, the FDA has allowed an IND to proceed with a clinical trial of our PD-1 inactivated, gene-edited TIL therapy, IOV-4001. Our TIL platform, clinical data, and people are a solid foundation to establish TIL as the next class of paradigm-shifting therapy for cancer patients with significant unmet need."

First Quarter 2022 Highlights and Recent Corporate Updates

Regulatory

- **Iovance TIL therapy (lifileucel) in metastatic melanoma (post-anti-PD-1):** Iovance received positive feedback from the U.S. Food and Drug Administration (FDA) on both its potency assay matrix and its proprietary cell co-culture assay included in the potency assay matrix. Iovance expects to request a pre-BLA meeting in July 2022 and to complete a BLA submission for lifileucel by August 2022.

- **IOV-4001 (PD-1 inactivated TIL therapy) Investigational New Drug (IND) Application:** The FDA allowed an IND to proceed for Iovance's first genetically modified TIL therapy, IOV-4001, for the treatment of previously treated advanced melanoma or metastatic non-small cell lung cancer (mNSCLC). IOV-4001 leverages the gene editing TALEN® technology licensed from Cellectis to inactivate PD-1 expression. A clinical trial of IOV-4001 is expected to begin in 2022.

Clinical

- **Iovance TIL therapy (lifileucel) in frontline (anti-PD-1 naïve) metastatic melanoma:**
  - **Updated clinical data (Cohort 1A in the IOV-COM-202 trial, n=12):** Updated clinical data announced in April 2022 demonstrated an overall response rate (ORR) of 67% for lifileucel in combination with pembrolizumab. Eight out of 12 patients had a confirmed objective response, including three complete responses and five partial responses.
  - **Frontline melanoma strategy:** Iovance plans to open a Phase 3 trial of lifileucel in combination with pembrolizumab in frontline metastatic melanoma in late 2022. The FDA previously granted Fast Track Designation for lifileucel in combination with pembrolizumab for the treatment of immune checkpoint inhibitor naïve metastatic melanoma.

- **Iovance TIL therapy (LN-145) in second-line mNSCLC**:
  - Enrollment is ongoing at more than 30 active clinical sites in the U.S., Canada and Europe for the IOV-LUN-202 trial of LN-145 in patients with mNSCLC. A Trial in Progress (TIP) poster on IOV-LUN-202 at the American Association for Cancer Research (AACR) 2022 Annual Meeting featured updated eligibility criteria to broaden enrollment in reflection of the unmet need in mNSCLC.
  - Iovance is engaged in discussions with the FDA about the potential for IOV-LUN-202 to serve as a registrational trial for LN-145 in mNSCLC and intends to execute an updated regulatory strategy based on this dialogue and feedback.

- **Lifileucel in cervical cancer:** Iovance is engaged in regulatory discussions about a potential BLA for lifileucel in cervical cancer and intends to execute an updated registrational strategy based on FDA dialogue and feedback.

Next-Generation Research Programs

- **Data presentations:**
  - **AACR 2022 Annual Meeting:** A poster highlighting preclinical data for IOV-4001 demonstrated that anti-tumor activity of IOV-4001 was superior to non-edited TIL product whether alone or in combination with an anti-PD-1 antibody in a murine model of melanoma.
  - **2022 Transplantation & Cellular Therapy Meetings of ASTCT™ and CIBMTR® Tandem Meetings:** Research posters described TIL products manufactured from cryopreserved tumor samples shipped from Australia and a potential approach to optimize TIL memory-like phenotype and increase functionality during the manufacturing process.

- **Additional updates:**
  - Several additional targets for genetic modification using the TALEN® technology, including double genetic knock-out programs, are advancing in preclinical development.
  - Additional research and preclinical studies of next generation TIL therapies and related technologies include approaches to increase TIL potency using CD39/69 double negative TILs and gene knock-in targets as well as development of a novel interleukin-2 (IL-2) analog (IOV-3001).

Manufacturing

- The Iovance Cell Therapy Center (*i*CTC) was awarded an Honorable Mention by the International Society for Pharmaceutical Engineering (ISPE) in the 2022 Facility of the Year Awards.

Corporate

- Cash position of $516.0 million at March 31, 2022 is expected to be sufficient into 2024.

- Iovance currently owns more than 40 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 can be found on the Intellectual Property page on www.iovance.com.

First Quarter 2022 Financial Results

Iovance had $516.0 million in cash, cash equivalents, investments and restricted cash at March 31, 2022, compared to $602.1 million at December 31, 2021. The cash position is expected to be sufficient to fund current and planned operations into 2024.

Jean-Marc Bellemin, Chief Financial Officer of Iovance, said, “With late-stage clinical assets in our pipeline, as well as a strong balance sheet and investments focused on launch preparations, we are well positioned to execute our mission to innovate, develop and deliver TIL therapy for patients with cancer while enhancing shareholder value.”

Net loss for the first quarter ended March 31, 2022, was $91.6 million, or $0.58 per share, compared to a net loss of $75.4 million, or $0.51 per share, for the first quarter ended March 31, 2021.

Research and development expenses were $68.3 million for the first quarter ended March 31, 2022, an increase of $12.4 million compared to $55.9 million for the first quarter ended March 31, 2021. The increase in research and development expenses in the first quarter 2022 over the prior year period was primarily attributable to growth of the internal research and development team, including stock-based compensation expense, as well as facility-related costs.

General and administrative expenses were $23.4 million for the first quarter ended March 31, 2022, an increase of $3.8 million compared to $19.6 million for the first quarter ended March 31, 2021. The increase in general and administrative expenses in the first quarter 2022 compared to the prior year period was primarily attributable to growth of the internal general and administrative and commercial teams, including stock-based compensation expense, facility-related costs associated with the build out of the new corporate headquarters, increases in intellectual property filing and legal expenses and enhancements to the information technology infrastructure.

For additional information, please see the Company’s Selected Condensed Consolidated Balance Sheet and Statement of Operations below.

Webcast and Conference Call

Iovance will host a conference call today at 4:30 p.m. ET to discuss first quarter 2022 financial results and corporate updates. The conference call dial-in numbers are 1 (844) 646-4465 (domestic) or 1 (615) 247-0257 (international), the conference ID is #4655146. The live webcast can be accessed in the Investors section of the company’s website at http://www.iovance.com. The archived webcast will be available for a year in the Investors section at www.iovance.com.

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 and maintain U.S. Food and Drug Administration (“FDA”) 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 approval; 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 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 or other regulatory authorities; the risk that our interpretation of the results of our clinical trials or communications with the FDA may differ from the interpretation of such results or communications by the FDA; the acceptance by the market of our product candidates and their potential reimbursement by payors, if approved; 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 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)

	March 31, 2022 (Unaudited)	December 31, 2021
Cash, cash equivalents, and investments	$ 509,890	$ 595,998
Restricted cash	$ 6,084	$ 6,084
Total assets	$ 701,251	$ 777,333
Stockholders' equity	$ 551,992	$ 621,659

(Unaudited, in thousands, except per share information)

	For the Three Months Ended March 31, 2022	2021
Costs and expenses*		
Research and development	$ 68,300	$ 55,949
General and administrative	23,413	19,621
Total costs and expenses	91,713	75,570
Loss from operations	(91,713)	(75,570)
Other income		
Interest income, net	106	121
Net Loss	$ (91,607)	$ (75,449)
Net Loss Per Common Share, Basic and Diluted	$ (0.58)	$ (0.51)
Weighted-Average Common Shares Outstanding, Basic and Diluted	157,113	147,370
***Includes stock-based compensation as follows**		
Research and development	$ 13,651	$ 9,202
General and administrative	8,614	7,739
	$ 22,265	$ 16,941

CONTACTS

Iovance Biotherapeutics, Inc.:
Sara Pellegrino, IRC
Vice President, Investor Relations & Public Relations
650-260-7120 ext. 264
Sara.Pellegrino@iovance.com

Jen Saunders
Director, Investor Relations & Public Relations
267-485-3119
Jen.Saunders@iovance.com