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 6, 2021

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.)**
999 Skyway Road, Suite 150 **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 1.01. Entry into a Material Definitive Agreement.

As previously reported, Iovance Biotherapeutics, Inc. (referred to as "we", "us", "our" or the "Company") entered into an Exclusive Patent License Agreement, or the Patent License Agreement, on February 9, 2015 with the National Institutes of Health ("NIH"), an agency of the U.S. Public Health Service within the Department of Health and Human Services, which replaced an earlier license from 2011, and which was subsequently amended on October 2, 2015. Pursuant to the Patent License Agreement as amended on October 2, 2015, the NIH granted us worldwide licenses, including exclusive and non-exclusive licenses, to certain technologies relating to autologous tumor infiltrating lymphocyte adoptive cell therapy products for the treatment of metastatic melanoma, lung, breast, bladder and HPV-positive cancers (the "Indications").

Effective as of May 6, 2021, we have entered into an Amended and Restated Patent License Agreement, which includes the grant of additional exclusive, worldwide patent rights in the Indications to cytokine-tethered tumor infiltrating lymphocyte technology, and expands the non-exclusive, worldwide field of use to all cancers. The Amended and Restated Patent License Agreement requires us to pay royalties based on a percentage of net sales in jurisdictions where patent rights exist, which percentage can fall into a tier that may be less than one percent to mid-single digits depending upon certain events, including the exclusivity of the rights, and a percentage of revenues from sublicensing arrangements, and the Company expects lower overall royalty payments as a result. We also agreed to potential milestone payments on the achievement of certain clinical, regulatory and commercial sales milestones for each of the various indications and other direct costs incurred by the NIH pursuant to the agreement. We anticipate making a milestone payment in the low single-digit millions of dollars in conjunction with the approval of a Biologics License Application for any of our product candidates covered by the Amended and Restated Patent License Agreement. The term of the Amended and Restated Patent License Agreement continues until the expiry of the last-to-expire patent rights licensed thereunder, and the agreement contains standard termination provisions.

The foregoing description of the Amended and Restated Patent License Agreement is qualified in its entirety by reference to the Amended and Restated Patent License Agreement, a copy of which will be filed as an exhibit to the Company's next periodic filing.

Item 2.02. Results of Operations and Financial Condition.

On May 6, 2021, Iovance Biotherapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended March 31, 2021 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 6, 2021.

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 6, 2021

IOVANCE BIOTHERAPEUTICS, INC.

By: /s/ MARIA FARDIS
Maria Fardis, Chief Executive Officer

Exhibit 99.1

Iovance Biotherapeutics Reports First Quarter 2021 Financial Results and Corporate Updates

Expanding First-in-Class TIL Cell Therapy Platform for Solid Tumors

SAN CARLOS, Calif., May 6, 2021 -- 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 2021 financial results and corporate updates.

Maria Fardis, Ph.D., President and Chief Executive Officer of Iovance, stated, "During the first quarter of 2021 we continued to work on our potency assays in support of a BLA for lifileucel, which is our top priority at Iovance. We continued developing multiple assays in parallel and submitted additional potency assay data to the FDA. I am also very pleased to highlight the strength of clinical data for TIL being presented at the recent and upcoming medical meetings and journal publications, including the first clinical data for TIL in combination with pembrolizumab in melanoma at the upcoming ASCO Annual Meeting. We believe durable responses for Iovance TIL in relapsed or refractory metastatic melanoma, paired with data to be presented for TIL in combination with anti-PD1 therapy in earlier treatment settings, solidify the broader potential for Iovance TIL and further demonstrate our leadership in the development, manufacturing, and potential commercialization of TIL cell therapy."

First Quarter 2021 Highlights and Recent Corporate Updates

Clinical:

- **TIL therapy, lifileucel, in melanoma:** Updated data from Cohort 2 in the C-144-01 study of lifileucel in advanced melanoma were presented at the American Association for Cancer Research (AACR) 2021 Annual Meeting. As of the December 2020 data cutoff for the presentation, lifileucel showed a 36.4% overall response rate (4.5% complete responses and 31.8% partial responses); median duration of response (DOR) was not reached at 28.1 months of median study follow up as assessed by investigators (n=66). Available care for Cohort 2 patients is chemotherapy, with an overall response rate of four to 10 percent and overall survival of only seven to eight months. Updated Cohort 2 data has been accepted for an oral presentation at the upcoming American Society of Clinical Oncology (ASCO) Annual Meeting. A manuscript of the Cohort 2 data has also been accepted for a forthcoming publication in a high impact oncology journal.
- **TIL therapy, lifileucel, in cervical cancer**: The C-145-04 study of lifileucel, formerly LN-145, is intended to support a BLA submission for metastatic cervical cancer. Inclusion of both pivotal cohort 1 (post-chemotherapy) and cohort 2 (post-anti-PD-1/PDL-1) in the BLA may strengthen the potential label and reflect the expected upcoming treatment landscape in cervical cancer. Patient dosing is complete in both Cohorts 1 and 2, and enrollment continues in Cohort 3 (lifileucel in combination with pembrolizumab in cervical cancer patients who are naïve to anti-PD-1 therapy).

- **TIL therapy in non-small cell lung cancer (NSCLC)**: Iovance has activated 10 U.S. clinical sites and patients have consented in the potential registration-directed study, IOV-LUN-202, to investigate LN-145 in patients with recurrent or metastatic NSCLC, without driver mutations, who previously received a single line of approved systemic therapy (combined checkpoint inhibitor (CPI) plus chemotherapy). The company also continues to investigate LN-145 in several additional NSCLC populations with unmet need across three cohorts in the IOV-COM-202 basket study.
- **TIL therapy in combination with pembrolizumab in melanoma and head and neck squamous cell carcinoma (HNSCC):** Iovance is investigating TIL in combination with pembrolizumab in earlier treatment settings in melanoma and HNSCC. Initial data from Cohort 1A in the IOV-COM-202 study, which is evaluating lifileucel in combination with pembrolizumab in melanoma, will be presented at the upcoming ASCO Annual Meeting. Patients with HNSCC continue to enroll in the expanded Cohort 2A in the IOV-COM-202 study to receive LN-145 in combination with pembrolizumab.
- **TIL clinical program updates:** To date, over 450 patients have been dosed with Iovance TIL products with more than a 90 percent manufacturing success rate.

Regulatory:

- **Potency assays for lifileucel:** Iovance recently submitted additional potency assay data to the FDA, while continuing to evaluate additional assays as backup options in support of the BLA. Submission of the BLA is anticipated during 2021. Expeditious resolution of the potency assay for lifileucel in melanoma is also a key step towards BLA submission plans in cervical cancer.

Manufacturing:

- **Iovance Cell Therapy Center (*i*CTC)**: Activities at the *i*CTC have commenced to support start of clinical manufacturing in late 2021. The expected commercial manufacturing remains on track to start in 2022.
- **Generation 3 (Gen 3) manufacturing**: A shorter 16-day third generation manufacturing process is being explored in a cohort of metastatic melanoma patients in the IOV-COM-202, where patient dosing has initiated using Gen 3. In addition, a cohort of NSCLC patients in the IOV-LUN-202 study will receive product manufactured by this Gen 3 process.

Corporate:

- Cash position of $610.2 million on March 31, 2021 is expected to be sufficient into 2023 to deliver on pipeline programs.
- A strong organization of more than 250 employees, of which 76 percent have more than a year of cell therapy experience, is in place to advance research, development, manufacturing, and commercial launch preparations.
- On May 6, 2021, Iovance entered into an amended license agreement with the National Institutes of Health (NIH), which adds additional exclusive, worldwide patent rights in certain indications to cytokine-tethered TIL technology and expands the non-exclusive, worldwide field of use to all cancers.
- Iovance continues to expand its intellectual property portfolio and currently owns more than 25 granted or allowed U.S. and international patents for compositions and methods of treatment in a broad range of cancers relating to the Gen 2 manufacturing process. Iovance's Gen 2 patent rights are expected to provide exclusivity through 2038. Iovance's portfolio also includes patent applications and granted patents directed towards Gen 3 manufacturing, selected TIL products, stable and transient genetic TIL modifications, tumor digest and fragment compositions and methods (including cryopreservation), and combinations of checkpoint inhibitors and TIL products.

First Quarter 2021 Financial Results

Iovance held $610.2 million in cash, cash equivalents, investments and restricted cash at March 31, 2021 compared to $635.0 million at December 31, 2020. The company anticipates that the year-end balance of cash, cash equivalents, investments and restricted cash will be sufficient into 2023.

Jean-Marc Bellemin, Chief Financial Officer, stated, “The continued strength of our balance sheet puts Iovance in an excellent position to fulfill our operating plan and advance our pipeline. We are judicious in our investments to maximize value and deliver on our commitments for patients and our shareholders.”

Net loss for the first quarter ended March 31, 2021, was $75.4 million, or $0.51 per share, compared to a net loss of $69.6 million, or $0.55 per share, for the first quarter ended March 31, 2020.

Research and development expenses were $55.9 million for the first quarter ended March 31, 2021, a decrease of $1.0 million compared to $57.0 million for the first quarter ended March 31, 2020.

The decrease in research and development expenses in the first quarter 2020 over the prior year period was primarily attributable to a decrease in manufacturing and clinical costs following the completion of enrollment in the pivotal cohorts for melanoma and cervical cancer.

General and administrative expenses were $19.6 million for the first quarter ended March 31, 2021, an increase of $5.8 million compared to $13.9 million for the first quarter ended March 31, 2020.

The increases in general and administrative expenses in the first quarter 2021 compared to the prior year period was primarily attributable to growth of the internal general and administrative team and higher stock-based compensation expenses.

Webcast and Conference Call

Iovance will host a conference call today at 4:30 p.m. ET to discuss the first quarter 2021 financial results and corporate updates. The conference call dial-in numbers are 1-800-773-2954 (domestic) or 1-847-413-3731 (international) and the access code is 50155289. 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 improve patient care by making T cell-based immunotherapies broadly accessible for the treatment of patients with solid tumors and blood cancers. Tumor infiltrating lymphocyte (TIL) therapy uses a patient's own immune cells to attack cancer. TIL cells are extracted from a patient's own tumor tissue, expanded through a proprietary process, and infused back into the patient. Upon infusion, TIL reach tumor tissue, where they attack cancer cells. The company has completed dosing in pivotal programs in patients with metastatic melanoma and cervical cancer. In addition, the company's TIL therapy is being investigated in a registration-supporting study for the treatment of patients with locally advanced, recurrent or metastatic non-small cell lung cancer. Clinical studies are also underway to evaluate TIL in earlier stage cancers in combination with currently approved treatments, and to investigate Iovance peripheral blood lymphocyte (PBL) T cell therapy for blood cancers. 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 may not be reflected in the final analyses of our ongoing clinical trials or subgroups within these trials; 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 new version of the protocol which further defines the patient population to include more advanced patients in our cervical cancer trial may have an adverse effect on the results reported to date; 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 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, 2021	December 31, 2020
	(Unaudited)	
Cash, cash equivalents, and investments	$ 604,157	$ 629,437
Restricted cash	$ 6,084	$ 5,525
Total assets	$ 750,573	$ 768,458
Stockholders' equity	$ 647,431	$ 656,498

IOVANCE BIOTHERAPEUTICS, INC.
Condensed Consolidated Statements of Operations
(Unaudited, in thousands, except per share information)

	For the Three Months Ended March 31,	
	2021	2020
Costs and expenses		
Research and development expenses	55,949	56,952
General and administrative expenses	19,621	13,858
Total costs and expenses	75,570	70,810
Loss from operations	(75,570)	(70,810)
Other income		
Interest income, net	121	1,215
Net Loss	$ (75,449)	$ (69,595)
Net Loss Per Common Share, Basic and Diluted	$ (0.51)	$ (0.55)
Weighted-Average Common Shares Outstanding, Basic and Diluted	147,370	126,568
*** Includes stock-based compensation as follows**		
Research and development	$ 9,202	$ 4,318
General and administrative	7,739	5,094
	$ 16,941	$ 9,412

CONTACTS

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