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, 2020

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 2.02. Results of Operations and Financial Condition.

On May 5, 2020, Iovance Biotherapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended March 31, 2020 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, 2020.

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, 2020

IOVANCE BIOTHERAPEUTICS, INC.

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

Exhibit 99.1

Iovance Biotherapeutics Reports First Quarter 2020 Financial Results and Provides a Corporate Update

SAN CARLOS, Calif., May 5, 2020 -- 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 2020 financial results and provided a corporate update.

“We continue making strong progress toward commercializing Iovance TIL for melanoma and cervical cancer indications,” said Maria Fardis, Ph.D., MBA, Iovance President and Chief Executive Officer. “While COVID-19 has impacted healthcare systems globally, we have been able to continue our key business operations due to dedication from our employees and through close collaboration with our clinical sites and other business partners. Cancer patients are still in critical need of access to therapy and a one-time treatment may offer an attractive therapeutic option to patients and treating physicians. With the first potential cell therapy in solid tumors and a broad TIL platform, Iovance remains well-positioned to become the leader in development, manufacturing, and commercialization of TIL cell therapy for cancer.”

First Quarter 2020 Updates

Clinical:

- **Melanoma**: the last patient in the pivotal Cohort 4 of C-144-01 melanoma study was dosed in January 2020. The enrollment of this cohort was completed approximately three months ahead of schedule with over-enrollment due to increased demand for participation.
- **Cervical**: enrollment in the cervical study C-145-04 continues and completion of enrollment in the pivotal program is on track for approximately mid-2020.

Regulatory:

- Iovance continues preparing for submission of a Biologics License Application (BLA) in late 2020 through data compilation as well as internal readiness activities.

Manufacturing:

- Manufacturing at all manufacturing organizations continues as planned for ongoing clinical studies.
- Construction of the Iovance manufacturing facility at the Navy Yard in Philadelphia continues with initiation of the build of clean rooms in April 2020, ahead of schedule.

Corporate:

- Iovance continues to build a strong team with approximately 190 employees across multiple locations and an experienced commercial team in place preparing for launch of lifileucel.
- Iovance has been granted or allowed a total of 12 patents for compositions and methods of treatment in using Iovance TIL in a board range of cancers related to its 22-day second generation (Gen 2) manufacturing process.

Clinical Data Presentations:

- **Oral presentation of updated data from Cohort 2 in the C-144-01 trial in metastatic melanoma at upcoming ASCO 2020:** the abstract #10006 is titled “Long-term follow up of lifileucel (LN-144) cryopreserved autologous tumor infiltrating lymphocyte therapy in patients with advanced melanoma progressed on multiple prior therapies.” The virtual scientific program of the American Society of Clinical Oncology (ASCO) will be held May 29-31, 2020.
- **H. Lee Moffit Cancer Center’s TIL data from Phase 1 lung cancer study presented at American Association for Cancer Research (AACR) Virtual Annual Meeting I**: Moffit’s presentation demonstrated the potential clinical benefit for TIL in non-small cell lung cancer (NSCLC), including two durable complete responses lasting beyond 12 months, in a Phase 1 study supported by Iovance Biotherapeutics, a Stand Up To Cancer Catalyst® grant, and other partners.

First Quarter 2020 Financial Results

Net loss for the first quarter ended March 31, 2020, was $69.6 million, or $0.55 per share, compared to a net loss of $37.0 million, or $0.30 per share, for the first quarter ended March 31, 2019.

Research and development expenses were $57.0 million for the first quarter ended March 31, 2020, an increase of $26.1 million compared to $30.9 million for the first quarter ended March 31, 2019. The increase in first quarter 2020 over the prior year period was primarily attributable to an increase in costs associated with the license to the IOV-3001 IL-2 analog from Novartis, clinical trials due to higher enrollment, growth of the internal research and development team, and increased manufacturing activities.

General and administrative expenses were $13.9 million for the first quarter 2020, an increase of $4.8 million compared to $9.1 million for the first quarter 2019. The increase in first quarter 2020 over the prior year period was primarily attributable to growth of the internal general and administrative team, higher stock-based compensation expenses, as well as higher legal costs.

At March 31, 2020, the company held $251.2 million in cash, cash equivalents, short-term investments and restricted cash compared to $312.5 million at December 31, 2019. The first quarter 2020 spend included upfront license payments and the purchase of clinical materials.

Webcast and Conference Call

Iovance will host a conference call today at 4:30 p.m. ET to discuss the first quarter 2020 financial results and to provide a corporate update. The conference call dial-in numbers are 1-844-646-4465 (domestic) or 1-615-247-0257 (international). The conference ID access number for the call is 4564469. 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. After infusion, TIL reach tumor tissue, where they attack tumor cells. The company has completed dosing in the pivotal study in patients with metastatic melanoma and is currently conducting a pivotal study in patients with metastatic cervical cancer. In addition, the company’s TIL therapy is being investigated for the treatment of patients with locally advanced, recurrent or metastatic cancers including head and neck and non-small cell lung cancer. A clinical study to investigate Iovance T cell therapy for blood cancers called peripheral blood lymphocyte (PBL) therapy is open to enrollment. 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. We may, in some cases, use terms such as "predicts," "believes," "potential," "continue," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. The forward-looking statements include, but are not limited to, risks and uncertainties relating to the success, timing, projected enrollment, manufacturing and production capabilities, and cost of our ongoing clinical trials and anticipated clinical trials for our current product candidates (including both Company-sponsored and collaborator-sponsored trials in both the U.S. and Europe), such as statements regarding the timing of initiation and completion of these trials; the timing of and our ability to successfully submit, obtain and maintain FDA or other regulatory authority approval of, or other action with respect to, our product candidates, including those product candidates that have been granted breakthrough therapy designation ("BTD") or regenerative medicine advanced therapy designation ("RMAT") by the FDA and new product candidates in both solid tumor and blood cancers; the strength of the Company's product pipeline; the successful implementation of the Company's research and development programs and collaborations; the Company's ability to obtain tax incentives and credits; the guidance provided for the Company's future cash, cash equivalents, short term investment and restricted cash balances; the success of the Company's manufacturing, license or development agreements; the acceptance by the market of the Company's product candidates, if approved; and other factors, including general economic conditions and regulatory developments, not within the Company's control. The factors discussed herein could cause actual results and developments to be materially different from those expressed in or implied by such statements. Actual results may differ from those set forth in this press release due to the risks and uncertainties inherent in the Company's business, including, without limitation: the COVID-19 pandemic may have an adverse effect on the Company and its clinical trials, including potential slower patient recruitment, inability of clinical trial sites to collect data, inability of the Company or its contract research organizations to monitor patients, as well as FDA availability due to competing priorities; the preliminary clinical results, which may include efficacy and safety results, from ongoing Phase 2 studies may not be reflected in the final analyses of these trials or subgroups within these trials; a slower rate of enrollment may impact the Company's clinical trial timelines; enrollment may need to be adjusted for the Company's 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 the Company's cervical cancer trial may have an adverse effect on the results reported to date; the data within these trials may not be supportive of product approval; changes in patient populations may result in changes in preliminary clinical results; the Company's ability or inability to address FDA or other regulatory authority requirements relating to its clinical programs and registrational plans, such requirements including, but not limited to, clinical, safety, manufacturing and control requirements; the Company's interpretation of communications with the FDA may differ from the interpretation of such communications by the FDA; risks related to the Company's ability to maintain and benefit from accelerated FDA review designations, including BTD and RMAT, which may not result in a faster development process or review of the Company's product candidates (and which may later be rescinded by the FDA), and does not assure approval of such product candidates by the FDA or the ability of the Company to obtain FDA approval in time to benefit from commercial opportunities; the ability or inability of the Company to manufacture its therapies using third party manufacturers or its own facility may adversely affect the Company's potential commercial launch; the results of clinical trials with collaborators using different manufacturing processes may not be reflected in the Company's sponsored trials; and additional expenses may decrease our estimated cash balances and increase our estimated capital requirements. A further list and description of the Company's risks, uncertainties and other factors can be found in the Company's most recent Annual Report on Form 10-K and the Company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov or www.iovance.com. The forward-looking statements are made only as of the date of this press release and the Company undertakes no obligation to publicly update such forward-looking statements to reflect subsequent events or circumstances.

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

	March 31, 2020 (Unaudited)	December 31, 2019
Cash, cash equivalents, and short-term investments	$ 245,652	$ 307,081
Restricted cash	$ 5,525	$ 5,450
Total assets	$ 288,298	$ 344,655
Stockholders' equity	$ 243,313	$ 298,971

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

	For the Three Months March 31, 2020	2019
Revenues	**$ -**	**$ -**
Costs and expenses		
Research and development expenses	56,952	30,905
General and administrative expenses	13,858	9,081
Total costs and expenses	70,810	39,986
Loss from operations	(70,810)	(39,986)
Other income		
Interest income, net	1,215	3,036
Net Loss	$ (69,595)	$ (36,950)
Net Loss Per Common Share, Basic and Diluted	$ (0.55)	$ (0.30)
Weighted-Average Common Shares Outstanding, Basic and Diluted	126,568	123,415
*** Includes stock-based compensation as follows**		
Research and development	$ 4,318	$ 2,701
General and administrative	5,094	3,145
	$ 9,412	$ 5,846