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 7, 2019

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 value	IOVA	The Nasdaq Stock Market, LLC

Item 2.02. Results of Operations and Financial Condition.

On May 7, 2019, Iovance Biotherapeutics, Inc. (the "Company") issued a press release announcing its financial results for the first quarter ended March 31, 2019 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 7, 2019.

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 7, 2019

IOVANCE BIOTHERAPEUTICS, INC.

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

Exhibit 99.1

Iovance Biotherapeutics Reports First Quarter 2019 Financial Results and Provides Corporate Update

- First patient dosed in pivotal Cohort 4 in study of lifileucel in advanced melanoma;
regulatory submission planned for late 2020 -

- New interim data from melanoma Cohort 2 and cervical cancer studies to be presented in June at the
2019 American Society of Clinical Oncology (ASCO) meeting -

- Company to host conference call at 4:30 p.m. EDT today -

SAN CARLOS, Calif., May 7, 2019 -- Iovance Biotherapeutics, Inc. (NASDAQ: IOVA), a late-stage biotechnology company developing novel cancer immunotherapies based on tumor-infiltrating lymphocyte (TIL) technology, today reported first quarter 2019 financial results and provided a corporate update.

“We have made great progress in recent months in advancing TIL therapy toward commercialization. In April, we dosed the first patient in the pivotal study, Cohort 4 of the innovaTIL-01 melanoma trial, bringing us a step closer to our goal of filing for regulatory approval of lifileucel in 2020,” commented Maria Fardis, Ph.D., MBA, president and chief executive officer of Iovance Biotherapeutics. “We are pleased that three Iovance abstracts submitted to ASCO have been accepted, two of which include data updates from our fully enrolled Cohort 2 of our melanoma program and data from our ongoing LN-145 cervical study being presented for the first time in a medical conference at the 2019 meeting.”

Recent Achievements and Upcoming Milestones

Clinical

- In April 2019, the company announced that the first patient was dosed in Cohort 4 of the pivotal innovaTIL-01 study of lifileucel in metastatic melanoma.
- New interim data from Cohort 2 of the innovaTIL-01 melanoma study and data from the ongoing innovaTIL-04 cervical cancer study will be presented on June 1, 2019 at the American Society of Clinical Oncology (ASCO) annual meeting.
- The company closed the IOV-LUN-201 study and instead will add an additional arm to the IOV-COM-202 study, adapting clinical development plans to reflect advances in the treatment landscape for non-small cell lung cancer.
- The protocol for innovaTIL-04, the Phase 2 study in cervical cancer, was amended to increase the sample size to 59 and to modify the primary endpoint of Objective Response Rate (ORR) to be determined by a Blinded Independent Review Committee (BIRC). The company made the changes in anticipation of a meeting with the U.S. Food and Drug Administration (FDA) planned for later this year to discuss the registration pathway for LN-145 in cervical cancer.

Regulatory

- In February 2019, LN-145 received Fast Track designation from the FDA for the cervical cancer indication.

Research

- In April 2019, persistence and biomarker data from Cohort 2 of the innovaTIL-01 study of lifileucel in the treatment of advanced melanoma were presented at the American Association for Cancer Research (AACR) annual meeting. The presentation described results of an analysis of circulating T cells at 42 days post-infusion, highlighting the uniqueness of clonal profiles in TIL therapy in melanoma. The results support potential use of a polyclonal product such as Iovance bulk TIL in the treatment of melanoma and likely other cancers with high mutational load solid tumors.
- Researchers at Iovance have generated data in collaboration with Roswell Park Cancer Center from the 22-day Gen 2 process of generating TIL from patient derived bladder cancer tumor tissue. An abstract describing the data has been accepted for presentation at the upcoming AACR "Bladder Cancer: Transforming the Field" conference taking place May 18-21, 2019.

Corporate

- In May 2019, the company opened a satellite office in Philadelphia, Pennsylvania. The office will house various functions including members of the Iovance legal and manufacturing teams.

First Quarter 2019 Financial Results

Net loss for the quarter ended March 31, 2019 was $37.0 million, or $0.30 per share, compared to net loss of $26.5 million, or $0.31 per share for the quarter ended March 31, 2018.

Research and development expenses were $30.9 million for the quarter ended March 31, 2019, an increase of $11.0 million, compared to $19.9 million for the same period ended March 31, 2018. The increase in research and development expenses was primarily attributable to an increase in the total number of patients in our clinical studies which in turn results in higher manufacturing and clinical study costs, technology transfer expenses and an increase in research and development headcount.

General and administrative expenses were $9.1 million for the quarter ended March 31, 2019, an increase of $2.1 million compared to $7.0 million for the same period ended March 31, 2018. The increase was primarily attributable to an increase in general and administrative headcount and higher stock based compensation.

Cash, Cash Equivalents and Short-term Investments

At March 31, 2019, the company held $440.0 million in cash, cash equivalents, and short-term investments compared to $468.5 million at December 31, 2018.

Webcast and Conference Call

Iovance will host a conference call and live audio webcast to discuss financial results and provide a corporate update today at 4:30 p.m. EDT.

To participate in the conference call, please dial 1-844-646-4465 (domestic) or 1-615-247-0257 (international) and reference the access code 7393657. The live webcast can be accessed under "News & Events: Investor Calendar" in the Investors section of the Company's website at www.iovance.com or at the link: https://edge.media-server.com/m6/p/ika42eku. An archived webcast will be available in the Investors section of www.iovance.com for thirty days following the call.

About Iovance Biotherapeutics, Inc.

Iovance Biotherapeutics intends to commercialize lifileucel, an autologous cell therapy product using TIL technology that amplifies the body's own immune response to eradicate solid tumors or attack blood cancers. The company is currently conducting the pivotal study innovaTIL-01 in patients with metastatic melanoma. In addition, the company's TIL therapies are being investigated for the treatment of patients with locally advanced, recurrent or metastatic cancers including cervical, head and neck, and non-small cell lung 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"). We may, in some cases, use terms such as "predicts," "believes," "potential," "continue," "estimates," "anticipates," "expects," "likely," "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 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 obtain and maintain U.S. Food and Drug Administration or other regulatory authority approval of, or other action with respect to, our product candidates; the strength of the Company's product pipeline; the successful implementation of the Company's research and development programs and collaborations; 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 FDA may not agree with the Company's interpretation of the results of its clinical trials; later developments with the FDA that may be inconsistent with already completed FDA meetings; the preliminary clinical results, including efficacy and safety results, from ongoing Phase 2 studies may not be reflected in the final analyses of these trials, including new cohorts within these trials, and may not be supportive of product approval; the FDA or other regulatory authorities may potentially delay the timing of their approval of, or other action with respect to, the Company's product candidates (specifically, the Company's description of FDA interactions are subject to FDA's interpretation, as well as FDA's authority to request new or additional information); the Company's ability to address FDA or other regulatory authority requirements relating to its clinical programs and registrational plans, such requirements including, but not limited to, clinical and safety requirements as well as manufacturing and control requirements; risks related to the Company's accelerated FDA review designations, including the Company's ability to maintain and benefit from such designations; and the ability of the Company to manufacture its therapies using third party manufacturers. 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.

Investor Relations Contacts:
Annie Chang
Solebury Trout
646-378-2972
achang@troutgroup.com

Chad Rubin
Solebury Trout
646-378-2947
crubin@troutgroup.com

Media Relations Contact:
Rich Allan
Solebury Trout
646-378-2958
rallan@troutgroup.com

IOVANCE BIOTECHNOLOGIES, INC.
Selected Consolidated Balance Sheet Data
(Unaudited, in thousands)

	March 31, 2019	December 31, 2018
Cash, cash equivalents, and short-term investments	$ 440,018	$ 468,523
Total assets	$ 461,502	$ 480,821
Stockholders' equity	$ 434,932	$ 466,193

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

	For the Three Months March 31, 2019	2018
Revenues	$ -	$ -
Costs and expenses		
Research and development expenses	30,905	19,912
General and administrative expenses	9,081	6,965
Total costs and expenses	39,986	26,877
Loss from operations	(39,986)	(26,877)
Other income		
Interest income, net	3,036	362
Net Loss	$ (36,950)	$ (26,515)
Net Loss Per Common Share, Basic and Diluted	$ (0.30)	$ (0.31)
Weighted-Average Common Shares Outstanding, Basic and Diluted	123,415	84,350
*** Includes stock-based compensation as follows**		
Research and development	$ 2,701	$ 2,000
General and administrative	3,145	2,104
	$ 5,846	$ 4,104