

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): August 1, 2019

IOVANCE BIOTHERAPEUTICS, INC.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State of Incorporation)

001-36860

Commission File Number

75-3254381

(I.R.S. Employer Identification No.)

999 Skyway Road, Suite 150
San Carlos, California

(Address of Principal Executive Offices)

94070

(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 August 1, 2019, Iovance Biotherapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the first quarter ended June 30, 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 August 1, 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: August 1, 2019

IOVANCE BIOTHERAPEUTICS, INC.

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



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

- Regulatory submission for LN-145 in advanced cervical cancer expected in the second half of 2020 -

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

SAN CARLOS, Calif., Aug. 1, 2019 -- Iovance Biotherapeutics, Inc. (NASDAQ: IOVA), a late-stage biotechnology company developing novel cancer immunotherapies based on tumor-infiltrating lymphocyte (TIL) technology, today reported financial results from second quarter and first six months of 2019 and provided a corporate update.

“We have had a highly productive second quarter at Iovance,” commented Maria Fardis, Ph.D., MBA, president and chief executive officer of Iovance Biotherapeutics. “We presented data for both melanoma and cervical programs at ASCO, met with the FDA to define our registration path for LN-145, received Breakthrough Therapy Designation for LN-145, and broke ground for our commercial manufacturing facility. Based on FDA feedback, we expect to submit a Biologics License Application (BLA) for LN-145 for advanced cervical cancer in late 2020. This time frame potentially overlaps with the expected timing of a submission in the advanced melanoma indication. In addition, we continue to expand the Iovance team and build our corporate infrastructure in anticipation of making TIL therapy broadly accessible to all patients that may benefit from this treatment approach.”

Recent Achievements and Upcoming Milestones

Clinical

- Data from the C-144-01 melanoma study and from the C-145-04 cervical cancer study were presented in June 2019 at the American Society of Clinical Oncology (ASCO) annual meeting. Data from the C-145-04 study in 27 patients demonstrated an objective response rate (ORR) of 44 percent. At 7.4-month median follow-up, the median duration of response (DOR) had not been reached. Interim results from the C-144-01 study in 66 patients demonstrated an ORR of 38 percent. At 8.8-month median follow-up, median DOR had not been reached.
 - Enrollment for Cohort 4, the pivotal cohort of the C-144-01, is on target for completion of enrollment in the first quarter of 2020.
 - Study C-145-04 has been expanded to dose 75 patients to address the expected sample size in anticipation of a BLA submission in late 2020.
 - The first patient has been dosed in the IOV-COM-202 study evaluating TIL monotherapy or TIL plus pembrolizumab in patients with melanoma, head and neck cancer, or non-small cell lung cancer (NSCLC). The company has amended the protocol for IOV-COM-202 to add an additional cohort to treat PD-1 naive NSCLC patients with TIL and pembrolizumab. The total number of patients expected to enroll in the study was increased to 48. This study has received regulatory approval for conduct in EU and Canada.
 - To date, over 200 patients have been treated with TIL therapy at Iovance.
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Regulatory

- In May 2019, LN-145 was granted Breakthrough Therapy designation from the U.S. Food and Drug Administration (FDA) for the treatment of advanced cervical cancer patients who have progressed during or after chemotherapy.
- At an End of Phase 2 meeting, the FDA acknowledged that the ongoing C-145-04 study of TIL therapy LN-145 may be sufficient to support registration in the treatment of patients with advanced cervical cancer. We plan to include in the BLA, patients who have progressed following initial systemic therapy for recurrent or metastatic disease, which constitutes almost all of the more advanced patients enrolled to date. The protocol may further be amended to enroll additional patients in order to support a BLA submission.

Research

- A poster entitled “Iovance Peripheral Blood Lymphocytes (PBL): A Potential Cell Therapy Strategy for the Treatment of Chronic Lymphocytic Leukemia” was presented at the 24th Congress of European Hematology Association in June 2019. The poster described the company’s nine-day manufacturing process and preclinical results for IOV-2001, PBL for chronic lymphocytic leukemia, created from 50 mL of blood.
- In July 2019, the company entered into a clinical trial agreement with the University of Montreal Health Centre (CHUM), under which CHUM will conduct a clinical study that it has designed using PD-1 positive selected TIL. The PD-1 positive TIL to be used in the study will be manufactured by a GMP cell processing facility within the University of Montreal network using a process developed by CHUM. Iovance also has an option to negotiate an exclusive license to the technology from CHUM. Iovance is expanding its footprint in Canada with this collaboration.

Corporate

- In May 2019, the company entered into a long-term lease agreement to build an approximately 136,000 square foot commercial-scale production facility in Philadelphia for commercial and clinical production of autologous TIL products. The company and its partners began construction of the facility in June 2019.
- Friedrich Graf Finckenstein, M.D., joined the company as chief medical officer.
- Athena Countouriotis, M.D., was appointed to the company’s board of directors.
- The company currently owns seven recently granted or allowed U.S. patents for compositions and methods of treatment in a broad range of cancers relating to its Gen 2 manufacturing process, including U.S. Patent Nos. 10,166,257, 10,130,659, and 10,272,113. The company’s owned and licensed intellectual property portfolio also includes patent applications relating to TIL, marrow infiltrating lymphocyte, and PBL therapies; methods of manufacturing; the use of costimulatory molecules in TIL therapy and manufacturing; stable and transient genetically-modified TIL therapies; and methods of treating patient subpopulations.

Second Quarter 2019 Financial Results

Net loss for the second quarter ended June 30, 2019, was \$47.6 million, or \$0.38 per share, compared to net loss of \$30.7 million, or \$0.34 per share for the second quarter ended June 30, 2018.

Research and development expenses were \$39.3 million for the second quarter of 2019, an increase of \$14.7 million compared to \$24.6 million for the second quarter of 2018. The increase in research and development expenses was primarily attributable to costs associated with the transfer of the manufacturing process to additional facilities to increase our manufacturing capacity, an increase in total patients in our clinical studies which in turn resulted in higher study costs, and an increase in research and development employees.

General and administrative expenses were \$10.9 million for the second quarter of 2019, an increase of \$4.1 million compared to \$6.8 million for the second quarter of 2018. The increase was primarily attributable to new general and administrative employees and higher stock-based compensation, legal expenses related to the intellectual property portfolio and real estate and external market research costs as we prepare for commercialization.

Six Months Ended June 30, 2019 Financial Results

Net loss for the six months ended June 30, 2019, was \$84.5 million, or \$0.68 per share, compared to net loss of \$57.2 million, or \$0.65 per share for the same period ended June 30, 2018.

Research and development expenses were \$70.2 million for the six months ended June 30, 2019, an increase of \$25.7 million compared to \$44.5 million for the same period ended June 30, 2018. The increase in research and development expenses was primarily attributable to costs associated with the transfer of the manufacturing process to additional facilities to increase our manufacturing capacity, higher costs for drugs used in the clinical studies, an increase in total patients in our clinical studies which in turn resulted in higher study costs, and an increase in the number of research and development employees.

General and administrative expenses were \$19.9 million for the six months ended June 30, 2019, an increase of \$6.1 million compared to \$13.8 million for the same period ended June 30, 2018. The increase was primarily attributable to the addition of general and administrative employees and higher stock-based compensation, legal expenses related to intellectual property, and external market research expenses.

Cash, Cash Equivalents, Short-Term Investments and Restricted Cash

At June 30, 2019, the company held \$409.6 million in cash, cash equivalents, short-term investments and restricted cash as compared to \$440.0 million at March 31, 2019. During the second quarter the company used \$33.8 million for operating activities. The company anticipates that the year-end balance of cash, cash equivalents, short-term investments and restricted cash may be between \$310 and \$320 million.

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 7574927. A live and archived webcast can be accessed in the Investors section of the company's website at www.iovance.com.

About Iovance Biotherapeutics, Inc.

Iovance Biotherapeutics intends to commercialize autologous cell therapy products for solid tumors and blood cancers. Tumor infiltrating lymphocyte (TIL) therapy uses a patient's own cancer-fighting immune cells to attack solid tumors. TIL are extracted from tumor cells, and once expanded through a proprietary process are infused back into the patient. After infusion, TIL enter tumor tissue, where they recognize, attack, and destroy the tumor. The company is currently conducting pivotal studies in patients with metastatic melanoma and advanced cervical cancer. In addition, the company's TIL therapies are being investigated for the treatment of patients with locally advanced, recurrent or metastatic cancers including head and neck and non-small cell lung cancer. Iovance has also developed a T cell therapy for blood cancers called peripheral blood lymphocyte (PBL) and intends to bring that product to clinic to investigate utility of PBL in chronic lymphocytic leukemia. 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," "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 equivalent, and short term investment positions; 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 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; the 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; 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, safety, manufacturing and control requirements; the Company's interpretation of communications with 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; 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.

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

	<u>June 30,</u> <u>2019</u>	<u>December 31,</u> <u>2018</u>
Cash, cash equivalents, and short-term investments	\$ 404,153	\$ 468,523
Restricted cash	\$ 5,450	\$ -
Total assets	\$ 435,924	\$ 480,821
Stockholders' equity	\$ 397,422	\$ 466,193

IOVANCE BIOTECHNOLOGIES, INC.
Condensed Statements of Operations
(unaudited, in thousands, except per share information)

	<u>For the Three Months Ended</u> <u>June 30,</u>		<u>For the Six Months Ended</u> <u>June 30,</u>	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
Revenues	\$ -	\$ -	\$ -	\$ -
Costs and expenses*				
Research and development	39,298	24,551	70,203	44,463
General and administrative	10,867	6,827	19,948	13,792
Total costs and expenses	<u>50,165</u>	<u>31,378</u>	<u>90,151</u>	<u>58,255</u>
Loss from operations	(50,165)	(31,378)	(90,151)	(58,255)
Other income				
Interest income, net	2,614	718	5,650	1,080
Net Loss	<u>\$ (47,551)</u>	<u>\$ (30,660)</u>	<u>\$ (84,501)</u>	<u>\$ (57,175)</u>
Net Loss Per Common Share, Basic and Diluted	<u>\$ (0.38)</u>	<u>\$ (0.34)</u>	<u>\$ (0.68)</u>	<u>\$ (0.65)</u>
Weighted-Average Common Shares Outstanding, Basic and Diluted	<u>123,567</u>	<u>90,236</u>	<u>123,491</u>	<u>87,310</u>
* Includes stock-based compensation as follows				
Research and development	\$ 2,720	\$ 2,381	\$ 5,421	\$ 4,381
General and administrative	3,706	2,841	6,851	4,945
	<u>\$ 6,426</u>	<u>\$ 5,222</u>	<u>\$ 12,272</u>	<u>\$ 9,326</u>