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): November 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 value	IOVA	The Nasdaq Stock Market, LLC

Item 2.02. Results of Operations and Financial Condition.

On November 5, 2020, Iovance Biotherapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 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 November 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: November 5, 2020

IOVANCE BIOTHERAPEUTICS, INC.

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

Exhibit 99.1

Iovance Biotherapeutics Reports Third Quarter and Year-to-Date 2020 Financial Results and Corporate Updates

Registration-Directed Study Initiated in Non-Small Cell Lung Cancer

SAN CARLOS, Calif., Nov 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 third quarter 2020 financial results and provided a corporate update.

"Subsequent to meeting with FDA, we have moved the BLA submission date for lifileucel to 2021 in order to reach agreement on the required potency assays to fully define TIL," said Maria Fardis, PhD, President and CEO of Iovance. "In additional indications, we look forward to starting our registration-directed study in non-small cell lung cancer, and to presenting initial clinical data of TIL in combination with anti-PD-1 therapy in head and neck cancer. Our financial strength also allows us to advance our clinical programs and continue our operating plans. Overall, I believe that Iovance is well-positioned to be the leader in development, manufacturing and commercialization of TIL cell therapy for cancer."

Third Quarter 2020 and Recent Corporate Updates

Clinical:

- **TIL therapy, lifileucel, in Melanoma:** Iovance and the U.S. Food and Drug Administration (FDA) reached agreement on duration of follow up for pivotal data for the biologics license application (BLA) for lifileucel in metastatic melanoma. Additional work is underway on current and new potency assays in support of the BLA. Dialogue with FDA about the assays is expected to continue with BLA submission anticipated to occur in 2021.
- **TIL therapy, lifileucel, in Cervical cancer**: the last patient was dosed in the pivotal Cohort 1 of the C-145-04 study of lifileucel, formerly LN-145, for metastatic cervical cancer.
- **TIL therapy in non-small cell lung cancer (NSCLC)**: the protocol was finalized for 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). Cohorts 1 and 3 have patients with TPS score of less than one percent, and Cohort 2 will enroll patients with TPS score of greater than or equal to one percent.
- **TIL therapy LN-145 in head and neck squamous cell carcinoma (HNSCC):** In the abstract for the upcoming Society for Immunotherapy of Cancer (SITC) Annual Meeting, patients with HNSCC who received LN-145 in combination with pembrolizumab showed an overall response rate (ORR) of 44% and median duration of response had not been reached at 6.9 months of median study follow up (n=9). Updated data will be presented at SITC.
- **Iovance development program**: To date, over 400 patients have been dosed with Iovance TIL products with more than 90 percent manufacturing success rate.

Manufacturing:

- Construction of the Iovance Cell Therapy Center (*i*CTC) is advancing as planned at the Navy Yard in Philadelphia. Clean rooms are expected to be completed in late 2020 with clinical activities to initiate in early 2021. Commercial manufacturing is on track for 2022.

Corporate:

- Cash position of $719.7 million at September 30 is sufficient for Iovance to execute commercial launch and pipeline programs, including the IOV-LUN-202 study in NSCLC.
- A strong organization of over 200 employees is in place across multiple locations to advance research, development, manufacturing and commercial launch preparations.
- Iovance has been granted or allowed a total of 20 U.S. patents for compositions and methods of treatment in using Iovance TIL in a broad range of cancers related to its 22-day second generation (Gen 2) manufacturing process.

Upcoming Data in Head and Neck Cancer at SITC Annual Meeting (November 9-14, 2020):

- **Poster Presentation (Abstract #353):** Safety and efficacy of tumor infiltrating lymphocytes (TIL; LN-145) in combination with pembrolizumab for advanced, recurrent or metastatic HNSCC
- **Authors**: A Jimeno, et al.
- **Presentation Times**: Wednesday, Nov. 11, from 5:15-5:45 p.m. EST and Friday, Nov. 13, from 4:40-5:10 p.m. EST.
- **Location**: Virtual Poster Hall

Third Quarter and September Year-to-Date Financial Results

Iovance held $719.7 million in cash, cash equivalents, short-term investments and restricted cash at September 30, 2020 compared to $312.5 million at December 31, 2019. The current cash position includes net proceeds of $567.0 million from a common stock public offering in June 2020. The company anticipates that the year-end balance of cash, cash equivalents, short-term investments and restricted cash may be over $630 million.

Net loss for the third quarter ended September 30, 2020, was $58.6 million, or $0.40 per share, compared to a net loss of $49.5 million, or $0.40 per share, for the third quarter ended September 30, 2019. Net loss for the nine months ended September 30, 2020, was $191.2 million, or $1.41 per share, compared to a net loss of $134.0 million, or $1.08 per share, for the same period ended September 30, 2019.

Research and development expenses were $43.1 million for the third quarter ended September 30, 2020, an increase of $1.5 million compared to $41.6 million for the third quarter ended September 30, 2019. Research and development expenses were $149.3 million for the nine months ended September 30, 2020, an increase of $37.5 million compared to $111.8 million for the same period ended September 30, 2019.

The increase in research and development expenses in the third quarter 2020 over the prior year period was primarily attributable to growth of the internal research and development team and higher stock-based compensation, partially offset by a decrease in manufacturing costs. The increase in research and development expenses in the first nine months of 2020 over the prior year period was primarily attributable to higher patient enrollment in clinical trials, licensing fees and growth of the internal research and development team.

General and administrative expenses were $15.9 million for the third quarter ended September 30, 2020, an increase of $5.9 million compared to $10.0 million for the third quarter ended September 30, 2019. General and administrative expenses were $44.1 million for the nine months ended September 30, 2020, an increase of $14.2 million compared to $30.0 million for the same period ended September 30, 2019.

The increases in general and administrative expenses in the third quarter and first nine months of 2020 compared to the prior year periods were 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 third quarter and year-to-date 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 1190777. 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 ("Iovance" or the "Company") 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 (the "PSLRA"). All such written or oral statements made in this press release, filings with the Securities and Exchange Commission ("SEC"), reports to stockholders and in meetings with investors and analysts, 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. These forward-looking statements include, but are not limited to, statements regarding 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 strength of the Company's product pipeline; and the guidance provided for the Company's future cash, cash equivalents, short-term investments, restricted cash balances and forecasted operating expenses, including our statements regarding the sufficiency of our cash reserves to execute commercial launch and pipeline programs, which assumes no material change in liabilities. These statements involve risks, uncertainties and other factors 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, including, without limitation, the following substantial known and unknown risks and uncertainties inherent in the Company's business: 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 U.S. Food and Drug Administration ("FDA") availability due to competing priorities; our ability to achieve long-term profitability and successfully commercialize our products alone or with third parties, as well as our history of operating losses and our expectations that we will continue to incur significant operating losses; our limited operating history in our current line of business, which makes it difficult to evaluate our prospects, our business plan or the likelihood of our successfully implementing such business plan; risks related to the timing of and our ability to successfully develop, submit, obtain and maintain FDA or other regulatory authority approval of, or other action with respect to, our product candidates (including with respect to lifileucel for the treatment of metastatic melanoma, for which we currently expect to submit a biologics licensing application ("BLA") to the FDA during 2021), and our ability to successfully commercialize any product candidates for which we obtain FDA approval; our limited history in conducting clinical trials, on which our future profitability is substantially dependent, and our need to rely on third parties, including contract research organizations, contract manufacturing organizations and consultants, in connection with the conduct, supervision and monitoring of our clinical trials for our product candidates; preliminary and interim clinical results, which may include efficacy and safety results, from ongoing Phase 2 studies may not be reflected in the final analyses of our ongoing clinical trials or subgroups within these trials; the risk that a slower rate of enrollment may delay the Company's clinical trial timelines or otherwise adversely impact our clinical development activities; the risk that 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 risk that the results obtained in our ongoing clinical trials may not be indicative of results obtained in future clinical trials or that data within these trials may not be supportive of product approval, including that later developments with the FDA may be inconsistent with already completed FDA meetings; the risk that the FDA may not agree with our approach to expand our cervical cancer trial to include Cohort 2 of the C-145-04 trial; the risk that 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 risk that regulatory authorities may potentially delay the timing of FDA or other regulatory approval of, or other action with respect to, our product candidates, or 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 the Company's interpretation of the results of its clinical trials or communications with the FDA may differ from the interpretation of such results or communications by the FDA; our ability to obtain and maintain intellectual property rights related to our product pipeline; our ability to successfully implement our research and development programs and collaborations; the acceptance by the market of our product candidates and their potential reimbursement by payors, if approved; our ability to obtain tax incentives and credits and the risk that our existing net operating loss carryforwards and research tax credits may expire or otherwise be limited in use; the success of our manufacturing, license or development agreements; risks related to the Company's ability to maintain and benefit from accelerated FDA review designations, including breakthrough therapy designation or regenerative medicine advanced therapy designation, 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 which 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; our dependence on additional financing to fund our operations and complete the development and commercialization of our product candidates, and the risks that raising such additional capital may restrict our operations or require us to relinquish rights to our technologies or product candidates; 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 the Company's control.

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

	September 30, 2020 (unaudited)	December 31, 2019
Cash, cash equivalents, and short-term investments	$ 714,148	$ 307,081
Restricted cash	$ 5,525	$ 5,450
Total assets	$ 782,294	$ 344,655
Stockholders' equity	$ 711,841	$ 298,971

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenues	$ -	$ -	$ -	$ -
Costs and expenses*				
Research and development	43,050	41,582	149,276	111,785
General and administrative	15,916	10,029	44,127	29,977
Total costs and expenses	58,966	51,611	193,403	141,762
Loss from operations	(58,966)	(51,611)	(193,403)	(141,762)
Other income				
Interest income, net	395	2,124	2,219	7,774
Net Loss	$ (58,571)	$ (49,487)	$ (191,184)	$ (133,988)
Net Loss Per Share of Common Stock, Basic and Diluted	$ (0.40)	$ (0.40)	$ (1.41)	$ (1.08)
Weighted-Average Shares of Common Stock Outstanding, Basic and Diluted	146,492	124,035	135,457	123,674
*** Includes stock-based compensation as follows**				
Research and development	$ 5,282	$ 3,346	$ 15,065	$ 8,767
General and administrative	5,424	3,252	15,590	10,103
	$ 10,706	$ 6,598	$ 30,655	$ 18,870