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 6, 2018

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. ☐

Item 2.02. Results of Operations and Financial Condition.

On November 6, 2018, the Company issued a press release announcing its financial results for the third quarter ended September 30, 2018 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 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 6, 2018.

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 6, 2018

IOVANCE BIOTHERAPEUTICS, INC.

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

Exhibit 99.1

Iovance Biotherapeutics Reports Third Quarter 2018 Financial Results and Provides Corporate Update

- Company to Host Conference Call at 4:30pm ET Today -

SAN CARLOS, CA – November 6, 2018 -- Iovance Biotherapeutics, Inc. (NASDAQ: IOVA), a biotechnology company developing novel cancer immunotherapies based on tumor-infiltrating lymphocyte (TIL) technology, today reported its third quarter 2018 financial results and provided a corporate update.

"We have made tremendous progress in the last several months. Following our recent end of Phase 2 meeting with the FDA, we released information about the meeting outcome and our US registration path, receipt of RMAT designation for metastatic melanoma, an abbreviated set of our latest clinical data, and conducted a successful round of financing. The company is now in a very strong financial position which will allow us to pursue our registration program to commercialize our TIL therapy," said Dr. Maria Fardis, Ph.D., MBA, president and chief executive officer of Iovance Biotherapeutics. "We intend to recruit a new cohort of patients in the C-144-01 study to support registration of lifileucel, build a commercial manufacturing facility as well as a commercial team to support our plans to bring lifileucel to patients, while we continue advancing our existing clinical programs and expand our TIL therapy into new indications."

Recent Achievements

Regulatory

- Iovance received the Regenerative Medicine Advanced Therapy (RMAT) designation for lifileucel, the company's adoptive cell therapy using its TIL technology for the treatment of patients with metastatic melanoma from the U.S. Food and Drug Administration (FDA).
- Iovance held an end of Phase 2 meeting with FDA during which the agency acknowledged that a single-arm cohort as part of the C-144-01 study could be supportive of initial registration and conduct of a randomized Phase 3 trial in the patient population being enrolled may not be feasible.

Clinical

- Enrollment in Cohort 2 of the global Phase 2 lifileucel metastatic melanoma study, C-144-01, reached the predefined sample size and was therefore closed.
    - As announced today, new data from Cohort 2 will be presented in a poster and as an oral presentation at the Society for Immunotherapy of Cancer (SITC) 33rd Annual Meeting in Washington, D.C. on November 10-12. The presentation will include 47 consecutively dosed patients with an objective response rate (ORR) of 38%, with a median duration of response (DOR) of 6.4 months and range of 1.3+ to 14+ months. The ORR includes one complete response and 17 partial responses, four of which are unconfirmed and pending patient's upcoming second assessments. Patients in the study had a mean of 3.3 prior systemic therapies and all the patients had received anti-PD-1 immunotherapy.

    - The most common treatment emergent adverse events observed in this cohort to date include chills, febrile neutropenia, anaemia, decreased platelet count, pyrexia, and hypophosphataemia. There were two grade 5 events reported.
    - Patient enrollment in a new cohort, Cohort 4, will be initiated in early 2019. This will be a single-arm cohort for registration in metastatic melanoma in a patient population that is post PD-1 blocking antibody and, if BRAF mutation positive, a BRAF inhibitor or BRAF inhibitor with MEK inhibitor. Iovance expects to fully enroll the necessary patients into this cohort by late 2019/early 2020. Cohort 4 is expected to enroll 80-100 patients. The primary endpoint for the study is ORR as determined by Blinded Independent Central Review (BIRC).

- Patient dosing continues in the C-145-04 study for cervical carcinoma. The company recently dosed its first patient in Europe. This study design is based on a Simon's two-stage design. The first stage has been completed and enrollment in the study continues with target enrollment of 47. Preliminary data for 15 patients yielded an ORR of 27% with an early look at the DOR ranging from 2.4 to 2.5+ months. Patients in the study had a median of five prior therapies. The safety findings from this study remain consistent with previous reports. The protocol for this study has been amended to limit the number of prior therapies to no more than three and to exclude patients who have been treated with prior immunotherapy. Iovance anticipates providing an update on this study at an upcoming medical meeting in 2019.
- In the C-145-03 study for head and neck cancer, to date, preliminary data for 13 patients has yielded an ORR of 31% with the DOR ranging from 2.8 to 7.6 months. The safety findings from this study is also consistent with previous reports. Patients in the study had a median of three prior therapies.
- For the study in NSCLC, IOV-LUN-201, in collaboration with MedImmune, the company amended the protocol to eliminate the TIL monotherapy cohort and patients will now be enrolled for treatment with LN-145 and durvalumab. There are currently nine sites active for this trial.
- The study in PD-1 naïve melanoma and head and neck patients with TIL in combination with pembrolizumab, and LN-145 as monotherapy in NSCLC patients (IOV-COM-202) is open to enrollment with two sites active.
- As of October 2018, Iovance has expanded to over 90 clinical sites for its five company-sponsored studies.

Manufacturing

- Iovance announced a new three-year Manufacturing Services Agreement with MaSTherCell S.A., a cell therapy-dedicated Contract Development and Manufacturing Organization (CDMO). MaSTherCell will manufacture TIL for Iovance's European late-stage clinical trials in its commercial-ready cGMP manufacturing suites and increases Iovance's capacity for manufacturing TIL in Europe.

Research

- Under a collaboration with Ohio State University, Iovance has developed a product candidate called peripheral blood lymphocytes (PBLs). A clinical program to administer PBLs in chronic lymphocytic leukemia (CLL) patients is expected to begin in 2019.
- Data from PD-1 selected TIL, one of the next generation TIL products at Iovance, will also be presented at SITC.

Corporate

- In October 2018, the company closed an underwritten public offering of 25,300,000 shares of its common stock at a public offering price of $9.97 per share, before underwriting discounts. The shares sold at closing included 3,300,000 shares issued upon the exercise in full by the underwriter of its option to purchase additional shares at the public offering price less the underwriting discount. The net proceeds from the offering, after deducting the underwriting discounts and commissions and other offering expenses payable by the company, were $236.6 million.

- Two U.S. patent applications covering therapeutic methods based upon Generation 2 manufacturing, which was developed at Iovance, were recently allowed.

Third Quarter 2018 Financial Results

Net loss for the third quarter ended September 30, 2018 was $33.8 million, or $0.36 per share, compared to a net loss of $22.1 million, or $0.35 per share for the same period ended September 30, 2017.

Research and development expenses were $27.9 million for the third quarter ended September 30, 2018, an increase of $11.3 million compared to $16.7 million for the third quarter ended September 30, 2017. The increase was primarily attributable to a $4.8 million increase in clinical trial costs due to; higher patient enrollment and an increase in the number of sites in the clinical trial of lifileucel for the treatment of metastatic melanoma, increased enrollment in the cervical and head and neck LN-145 clinical trials and the initiation of clinical trials in 2018 for new indications. Further, payroll and related expenses, including stock-based compensation expenses increased by $4.4 million due to a higher number of full time employees and dedicated consultants as the company expanded its internal research efforts and clinical development programs. In addition, research and alliance costs increased by $1.4 million for clinical trials run by Iovance's alliance partners and new research initiatives and $0.7 million for the expansion of manufacturing capacity at the company's Clinical Manufacturing Organizations (CMOs).

General and administrative expenses were $7.1 million for the third quarter ended September 30, 2018, an increase of $1.4 million compared to $5.7 million for the third quarter ended September 30, 2017. The increase was primarily attributable to a $1.5 million increase in stock-based compensation expenses due to an increase in the number of full time employees and higher stock prices during the quarter as compared to the same period in 2017.

Nine Months Ended September 30, 2018 Financial Results

Net loss for the nine months ended September 30, 2018 was $91.0 million, or $1.01 per share, compared to a net loss of $66.2 million, or $1.06 per share for the same period ended September 30, 2017.

Research and development expenses were $72.4 million for the nine months ended September 30, 2018, an increase of $21.5 million compared to $50.9 million for the same period ended September 30, 2017. The increase was primarily attributable to a $11.9 million increase in the company's clinical trial costs for ongoing and newly initiated studies and a $10.1 million increase in payroll and related expenses, including stock-based compensation expenses, for a higher number of full time employees and expenses for services performed by third parties in support of the company's clinical studies. Further, research and research alliance costs increased by $1.1 million as Iovance expanded its research efforts and the number of clinical development programs run by its collaborators. These increases were partially offset by a $1.5 million decrease in manufacturing costs due to higher costs in 2017 related to technical transfer activities.

General and administrative expenses were $20.9 million for the nine months ended September 30, 2018, an increase of $5.0 million compared to $15.9 million for the same period ended September 30, 2017. The increase was primarily attributable to a $4.3 million increase in payroll and related expenses, including stock-based compensation expenses, due to a higher number of full time employees and higher stock prices during 2018 and a $0.6 million increase in professional service and legal expenses.

At September 30, 2018, the company held $260 million in cash, cash equivalents, and short-term investments compared to $276.1 million at June 30, 2018. During the third quarter the company used $28.2 million for operating-related activities and received $12.1 million of proceeds from the exercise of warrants and stock options. In October 2018 the company received $236.6 in net proceeds from the issuance of common stock. The company anticipates that the year-end balance of cash, cash equivalents and short-term investments may be between $460 to $465 million.

Webcast and Conference Call
Iovance will host a conference call today at 4:30 p.m. ET to discuss these third quarter 2018 results and 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 8718039. The live webcast can be accessed under "News & Events" in the "Investors" section of the company's website at http://www.iovance.com/ or you may use the link: https://edge.media-server.com/m6/p/bdn8vp67.

A replay of the call will be available from November 6, 2018 at 7:30 p.m. ET to November 13, 2018 at 8:30 p.m. ET. To access the replay, please dial 1-855-859-2056 (domestic) or 1-404-537-3406 (international) and reference the access code 8718039. The archived webcast will be available for thirty days in the Investors section of Iovance Biotherapeutics' website at http://www.iovance.com/.

About Iovance Biotherapeutics, Inc.
Iovance Biotherapeutics, Inc. is a clinical-stage biotechnology company focused on the development of cancer immunotherapy products for the treatment of various cancers. The company's lead product candidate is an adoptive cell therapy using TIL technology being investigated for the treatment of patients with metastatic melanoma, recurrent and/or metastatic squamous cell carcinoma of the head and neck, recurrent, metastatic or persistent cervical cancer and locally advanced or metastatic non-small cell lung cancer. For more information, please visit http://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 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 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 described above may not be reflected in the final analyses of these trials including new cohorts within these trials; the results obtained in the Company's ongoing clinical trials, such as the studies and trials referred to in this release, may not be indicative of results obtained in future clinical trials or supportive of product approval; regulatory authorities may potentially delay the timing of FDA or other regulatory authority 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 may not be able to obtain or maintain FDA or other regulatory authority approval of its product candidates; 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; the ability of the Company to manufacture its therapies using third party manufacturers; the ability of the Company to obtain and maintain intellectual property rights relating to its product pipeline; and the acceptance by the market of the Company's product candidates and their potential reimbursement by payors, if approved. 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)

	September 30, 2018	December 31, 2017
Cash and cash equivalents	$ 80,738	$ 145,373
Short-term investments	$ 179,262	$ -
Total assets	$ 270,834	$ 155,373
Stockholders' equity	$ 254,160	$ 145,481

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenues	$ -	$ -	$ -	$ -
Costs and expenses*				
Research and development	27,947	16,679	72,410	50,919
General and administrative	7,113	5,664	20,905	15,887
Total costs and expenses	35,060	22,343	93,315	66,806
Loss from operations	(35,060)	(22,343)	(93,315)	(66,806)
Other income				
Interest income, net	1,230	194	2,310	596
Net Loss	$ (33,830)	$ (22,149)	$ (91,005)	$ (66,210)
Net Loss Per Common Share, Basic and Diluted	$ (0.36)	$ (0.35)	$ (1.01)	$ (1.06)
Weighted-Average Common Shares Outstanding, Basic and Diluted	95,077	63,332	89,927	62,697
*** Includes stock-based compensation as follows**				
Research and development	$ 2,255	$ 881	$ 6,636	$ 3,873
General and administrative	3,261	1,738	8,206	5,335
	$ 5,516	$ 2,619	$ 14,842	$ 9,208

(1) Certain amounts within the statement of operations for the three and nine months ended September 30, 2017 have been reclassified to conform with the current period presentation. These reclassifications had no impact on the Company's previously reported financial position, or cash flows for any of the periods presented.