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): February 25, 2021

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 February 25, 2021, Iovance Biotherapeutics, Inc. (the "Company") issued a press release announcing its financial results for the fourth quarter and fiscal year ended December 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 February 25, 2021.

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: February 25, 2021

IOVANCE BIOTHERAPEUTICS, INC.

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

Exhibit 99.1

Iovance Biotherapeutics Reports Fourth Quarter and Full Year 2020 Financial Results and Corporate Updates

Advancing First-in-Class TIL Cell Therapy for Solid Tumors

SAN CARLOS, Calif., Feb 25, 2021 -- 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 fourth quarter and full year 2020 financial results and corporate updates.

Dr. Maria Fardis, Ph.D., President and Chief Executive Officer of Iovance, stated, "During 2020 we continued to advance our TIL cell therapies in metastatic melanoma, cervical, head and neck, and non-small cell lung cancers. We believe that the growing body of TIL clinical data across multiple late-stage indications in cancer, coupled with combination of TIL and checkpoint inhibitors in earlier stages of disease, validate the significant potential for TIL as a treatment option in multiple solid tumors and stages of cancer. In 2021, our top priority is to continue the dialogue with FDA regarding our potency assays to support a potential BLA submission for lifileucel. We are excited about many opportunities to further strengthen the Iovance leadership in development of TIL cell therapy, manufacturing, and potential commercialization."

Full Year 2020 Highlights and Recent Corporate Updates

Clinical:

- **TIL therapy, lifileucel, in melanoma:** as of a January 2021 corporate update, median duration of response has not been reached at 28.1 months of median study follow up in metastatic melanoma patients from Cohort 2 in the C-144-01 clinical study. Available care for Cohort 2 patients is chemotherapy, with an overall response rate of four to ten percent and overall survival of only seven to eight months.
- **TIL therapy, lifileucel, in cervical cancer**: The C-145-04 study of lifileucel, formerly LN-145, is intended to support a BLA submission for metastatic cervical cancer. Inclusion of both pivotal cohort 1 (post-chemotherapy) and cohort 2 (post-anti-PD-1/PDL-1) in the BLA may strengthen the potential label and reflect the expected upcoming treatment landscape in cervical cancer. Enrollment in both Cohorts 1 and 2 has been completed.
- **TIL therapy in non-small cell lung cancer (NSCLC)**: H. Lee Moffit Cancer Center presented data for Moffitt's TIL from a Phase 1 lung cancer trial at the American Association for Cancer Research (AACR) Virtual Annual Meeting I. Iovance initiated a 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). The company continues to investigate LN-145 in several additional NSCLC populations with unmet need across three cohorts in the IOV-COM-202 basket study, including a recently added chemotherapy-free regimen of LN-145 in combination with ipilimumab/nivolumab.
- **TIL therapy LN-145 in head and neck squamous cell carcinoma (HNSCC):** Initial data for TIL in combination with pembrolizumab in earlier lines of therapy were presented for the first time at the Society for Immunotherapy of Cancer (SITC) Annual Meeting. Patients from Cohort 2A in the IOV-COM-202 study 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 8.6 months of median study follow up (n=9). The company subsequently expanded enrollment in Cohort 2A to gather data in additional patients. In study C-145-03, target enrollment was achieved, and the study was closed to enrollment.

- **TIL clinical study enrollment updates:** To date, over 400 patients have been dosed with Iovance TIL products with more than a 90 percent manufacturing success rate. Recruitment continues in C-145-04 study in cervical cancer, the IOV-COM-202 study in solid tumors, the IOV-LUN-202 study in NSCLC and the IOV-CLL-01 study in CLL/SLL. The COVID-19 pandemic may impact the pace of enrollment and site activities in ongoing clinical studies, particularly in cohorts with earlier line patients. Recruitment may improve as the COVID-19 pandemic abates.

Regulatory:

- **Potency assays for lifileucel:** during a Type B meeting in the fourth quarter of 2020, Iovance and the U.S. Food and Drug Administration (FDA) did not reach agreement on the potency assays to define TIL. FDA and Iovance reached agreement on duration of follow up for the pivotal cohort for the planned BLA for lifileucel in metastatic melanoma. Additional work and dialogue with FDA continue regarding current and new potency assays in support of the BLA. The BLA submission is anticipated during 2021. Resolution of the potency assay for lifileucel in melanoma is also a key step towards BLA submission plans in cervical cancer.

Manufacturing:

- **Iovance Cell Therapy Center (*i*CTC)**: construction is advancing as planned at the Navy Yard in Philadelphia. Construction of the clean rooms were completed in late 2020 and activities in support of clinical manufacturing are expected to initiate in the coming weeks. Commercial manufacturing is on track for start in 2022.
- **Generation 3 (Gen 3) manufacturing**: a shorter 16-day third generation manufacturing process will be explored in a cohort of metastatic melanoma patients in the IOV-COM-202 study as well as a cohort of NSCLC patients in the IOV-LUN-202 study.

Corporate:

- Cash position of $635.0 million on December 31, 2020 is expected to be sufficient into 2023 to deliver on our pipeline programs.
- A strong organization of nearly 250 employees, of which 76 percent have more than a year of cell therapy experience, is in place to advance research, development, manufacturing, and commercial launch preparations.
- Iovance continues to expand its intellectual property portfolio and currently owns more than 20 granted or allowed U.S. and international patents for compositions and methods of treatment in a broad range of cancers relating to the Gen 2 manufacturing process. Iovance's portfolio also includes patent applications and granted patents directed towards Gen 3 manufacturing, selected TIL products, stable and transient genetic TIL modifications, and combinations of checkpoint inhibitors and TIL products.

Fourth Quarter and Full Year 2020 Financial Results

Iovance held $635.0 million in cash, cash equivalents, short-term investments and restricted cash at December 31, 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 will be sufficient into 2023.

Jean-Marc Bellemin, Chief Financial Officer, stated, “I am confident that Iovance is in a strong position to continue to execute our operating plan and advance our portfolio in 2021. Our healthy balance sheet will help us deliver on our commitments, both to patients and to our shareholders.”

Net loss for the fourth quarter ended December 31, 2020, was $68.4 million, or $0.47 per share, compared to a net loss of $63.6 million, or $0.50 per share, for the fourth quarter ended December 31, 2019. Net loss for full year ended December 31, 2020, was $259.6 million, or $1.88 per share, compared to a net loss of $197.6 million, or $1.59 per share, for the full year ended December 31, 2019.

Research and development expenses were $52.4 million for the fourth quarter ended December 31, 2020, a decrease of $1.8 million compared to $54.2 million for the fourth quarter ended December 31, 2019. Research and development expenses were $201.7 million for the 12 months ended December 31, 2020, an increase of $35.7 million compared to $166.0 million for the full year ended December 31, 2019.

The decrease in research and development expenses in the fourth quarter 2020 over the prior year period was primarily attributable to a decrease in manufacturing and clinical costs following the completion of enrollment in the pivotal cohorts for melanoma and cervical cancer. The increase in research and development expenses in the full year 2020 over the prior full year period was primarily attributable to higher clinical costs, licensing fees and growth of the internal research and development team.

General and administrative expenses were $16.1 million for the fourth quarter ended December 31, 2020, an increase of $5.2 million compared to $10.9 million for the fourth quarter ended December 31, 2019. General and administrative expenses were $60.2 million for the full year ended December 31, 2020, an increase of $19.3 million compared to $40.9 million for the same period ended December 31, 2019.

The increases in general and administrative expenses in the fourth quarter and full year 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 fourth 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 9075827. 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. Upon infusion, TIL reach tumor tissue, where they attack cancer cells. The company has completed dosing in pivotal programs in patients with metastatic melanoma and cervical cancer. In addition, the company's TIL therapy is being investigated in a registration-supporting study for the treatment of patients with locally advanced, recurrent or metastatic non-small cell lung cancer. Clinical studies are also underway to evaluate TIL in earlier stage cancers in combination with currently approved treatments, and to investigate Iovance peripheral blood lymphocyte (PBL) T cell therapy for blood cancers. 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, 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. Forward-looking statements are based on assumptions and assessments made in light of management's experience and perception of historical trends, current conditions, expected future developments and other factors believed to be appropriate. Forward-looking statements in this press release are made as of the date of this press release, and we undertake no duty to update or revise any such statements, whether as a result of new information, future events or otherwise. Forward-looking statements are not guarantees of future performance and are subject to risks, uncertainties and other factors, many of which are outside of our control, 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. Important factors that could cause actual results, developments and business decisions to differ materially from forward-looking statements are described in the sections titled "Risk Factors" in our filings with the Securities and Exchange Commission, including our most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q, and include, but are not limited to, the following substantial known and unknown risks and uncertainties inherent in our business: the effects of the COVID-19 pandemic; risks related to the timing of and our ability to successfully develop, submit, obtain and maintain U.S. Food and Drug Administration ("FDA") or other regulatory authority approval of, or other action with respect to, our product candidates, and our ability to successfully commercialize any product candidates for which we obtain FDA approval; preliminary and interim clinical results, which may include efficacy and safety results, from ongoing clinical trials may not be reflected in the final analyses of our ongoing clinical trials or subgroups within these trials; the risk that enrollment may need to be adjusted for our 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 our cervical cancer trial may have an adverse effect on the results reported to date; the risk 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 our interpretation of the results of our clinical trials or communications with the FDA may differ from the interpretation of such results or communications by the FDA; the acceptance by the market of our product candidates and their potential reimbursement by payors, if approved; our ability or inability to manufacture our therapies using third party manufacturers or our own facility may adversely affect our potential commercial launch; the results of clinical trials with collaborators using different manufacturing processes may not be reflected in our sponsored trials; 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 our control.

CONTACTS

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IOVANCE BIOTHERAPEUTICS, INC.
Selected Consolidated Balance Sheet Data
(In thousands)

	December 31, 2020	December 31, 2019
Cash, cash equivalents, short-term investments, and restricted cash	$ 634,962	$ 312,531
Total assets	$ 768,458	$ 344,655
Stockholders' equity	$ 656,420	$ 298,971

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

	For the Three Months Ended December 31,		For the Years Ended December 31,	
	2020	2019	2020	2019
Revenues	$ -	$ -	$ -	$ -
Costs and expenses*				
Research and development	52,451	54,238	201,727	166,023
General and administrative	16,083	10,872	60,210	40,849
Total costs and expenses	68,534	65,110	261,937	206,872
Loss from operations	(68,534)	(65,110)	(261,937)	(206,872)
Other income				
Interest income, net	137	1,542	2,356	9,316
Net Loss	$ (68,397)	$ (63,568)	$ (259,581)	$ (197,556)
Net Loss Per Common Share, Basic and Diluted	$ (0.47)	$ (0.50)	$ (1.88)	$ (1.59)
Weighted-Average Common Shares Outstanding, Basic and Diluted	146,738	126,273	138,301	124,336
*** Includes stock-based compensation as follows**				
Research and development	$ 4,662	$ 2,629	$ 19,727	$ 11,936
General and administrative	5,570	2,778	21,160	12,881
	$ 10,232	$ 5,407	$ 40,887	$ 24,277