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 5, 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 August 5, 2021, Iovance Biotherapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended June 30, 2021 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 5, 2021.
104	Cover Page Interactive Data File - the cover page interactive date file does not appear in the Interactive Date File because its XBRL tags are embedded within the Inline XBRL document.

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 5, 2021

IOVANCE BIOTHERAPEUTICS, INC.

By: /s/ Frederick G. Vogt
Frederick G. Vogt, Interim CEO & General Counsel

Exhibit 99.1

Iovance Biotherapeutics Reports Second Quarter and First Half 2021 Financial Results and Corporate Updates

Expanding Leadership for TIL Cell Therapy in Solid Tumors

SAN CARLOS, Calif., August 5, 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 second quarter 2021 financial results and corporate updates.

Frederick Vogt, Ph.D., J.D., Interim President and Chief Executive Officer of Iovance, stated, "During the first half of 2021 we advanced our TIL pipeline and presented clinical data across multiple solid tumor indications and treatment settings, including single-agent TIL in metastatic non-small cell lung cancer and melanoma, as well as initial clinical data for TIL in combination with pembrolizumab in early line melanoma. Our top priority remains our ongoing work to address FDA feedback regarding the potency assays for lifileucel to support our planned BLA submission. We are increasingly confident in the broad potential for TIL as the next class of paradigm-shifting therapy for cancer patients with significant unmet need."

Second Quarter 2021 Highlights and Recent Corporate Updates

Regulatory

- **Potency assays for lifileucel:** Following FDA feedback regarding the potency assays for lifileucel, Iovance will continue ongoing work developing and validating its potency assays and plans to submit additional assay data and anticipates meeting with the FDA before the end of 2021. The company's biologics license application (BLA) submission for lifileucel is now expected to occur during the first half of 2022. Resolution of the potency assay for lifileucel in melanoma is also a key step towards our regulatory plans in other indications.

Clinical

- **TIL therapy in melanoma:**
  - **Metastatic melanoma**: follow up data from Cohort 2 in the C-144-01 study of lifileucel in advanced melanoma were presented at the American Society for Clinical Oncology (ASCO) 2021 Annual Meeting. As of the April 2021 data cutoff for the presentation, the overall response rate (ORR) was 36.4% (4.5% complete response rate and 31.8% partial response rate) and median duration of response (DOR) was not reached at 33.1 months of median study follow up as assessed by investigators (n=66). Detailed Cohort 2 data were also published in a manuscript in the Journal of Clinical Oncology, an ASCO journal.
  - **Anti-PD-1 naïve melanoma**: initial clinical data for lifileucel in combination with pembrolizumab were presented in a poster at ASCO 2021. The ORR was 86% and the complete response rate was 43% at a median follow up of 8.2 months in anti-PD-1 naïve melanoma patients in Cohort 1A in the IOV-COM-202 basket study (n=7).

- **TIL therapy in non-small cell lung cancer (NSCLC)**:

    - **LN-145 clinical data in metastatic NSCLC (mNSCLC)**: clinical data for LN-145 showed a 21.4% ORR and 64.3% disease control rate in mNSCLC patients from Cohort 3B in the IOV-COM-202 study (n=28), including two responders with PD-L1 negative tumors. All Cohort 3B patients had received one or more prior systemic therapies, including anti-PD-1 therapy, and all responders also received prior chemotherapy. Detailed results are anticipated at a medical meeting in 2021.

    - **LN-145 in second-line mNSCLC:** the first patient was dosed and more than 15 U.S. clinical sites have been activated in the registration-supporting IOV-LUN-202 study of LN-145 in patients with mNSCLC.

Research

- Iovance is committed to advancing the next generation of TIL and related therapies and technologies. Late preclinical programs in IND-enabling studies include a novel IL-2 analog (IOV-3001) as well as a genetically modified TIL (IOV-4001). IOV-4001 leverages TALEN technology licensed from Cellectis S.A. to genetically knock out PD-1 in TIL cells.

Manufacturing

- **TIL manufacturing success:** To date, nearly 500 patients have been dosed with Iovance TIL products with more than a 90 percent manufacturing success rate.
- **Iovance Cell Therapy Center (*i*CTC)**: the investigational new drug (IND) application amendment has been cleared and clinical manufacturing of TIL is expected to commence at the *i*CTC in the near future. Commercial manufacturing remains on track to commence with a potential regulatory approval.

Corporate

- Cash position of $708.7 million on June 30, 2021 is expected to be sufficient well into 2023.
- A strong organization of nearly 270 employees with an average of more than 3.5 years 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 25 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 Gen 2 patent rights are expected to provide exclusivity through 2038. Iovance's portfolio also includes patent applications and granted patents directed towards Gen 3 manufacturing, selected TIL products, stable and transient genetic TIL modifications, tumor digest and fragment compositions and methods (including cryopreservation), and combinations of checkpoint inhibitors and TIL products.

Second Quarter and First Half 2021 Financial Results

Iovance held $708.7 million in cash, cash equivalents, investments and restricted cash at June 30, 2021 compared to $635.0 million at December 31, 2020. The cash position as of the second quarter is expected to be sufficient for more than two years based on the current operating plan.

Jean-Marc Bellemin, Chief Financial Officer, stated, “Our balance sheet remains strong to advance our operating plan, including launch preparations and pipeline development, with no immediate need to raise additional capital.”

Net loss for the second quarter ended June 30, 2021, was $81.4 million, or $0.53 per share, compared to a net loss of $63.0 million, or $0.47 per share, for the second quarter ended June 30, 2020. Net loss for the six months ended June 30, 2020, was $156.8 million, or $1.04 per share, compared to a net loss of $132.6 million, or $1.02 per share, for the same period ended June 30, 2020.

Research and development expenses were $62.1 million for the second quarter ended June 30, 2021, an increase of $12.8 million compared to $49.3 million for the second quarter ended June 30, 2020. Research and development expenses were $118.1 million for the six months ended June 30, 2021, an increase of $11.8 million compared to $106.2 million for the same period ended June 30, 2020.

The increase in research and development expenses in the second quarter 2021 over the prior year period was primarily attributable to an increase in costs associated with growth of the internal research and development team and increases in manufacturing and iCTC facility related costs. The increase in research and development expenses in the first half of 2021 over the prior year period was primarily attributable to growth of the internal research and development team, an increase in iCTC facility related costs, which were partially offset by lower manufacturing and clinical costs following the completion of enrollment in the pivotal cohorts for melanoma and cervical cancer.

General and administrative expenses were $19.3 million for the second quarter ended June 30, 2021, an increase of $5.0 million compared to $14.4 million for the second quarter ended June 30, 2020. General and administrative expenses were $38.9 million for the six months ended June 30, 2021, an increase of $10.7 million compared to $28.2 million for the same period ended June 30, 2020.

The increases in general and administrative expenses in the second quarter and first half of 2021 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 second quarter 2021 financial results and corporate updates. The conference call dial-in numbers are 1-(844) 646-4465 (domestic) or 1-(615) 247-0257 (international) and the access code is 1489438. 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 or cohorts may not be reflected in the final analyses of our ongoing clinical trials or subgroups within these trials or in other prior trials or cohorts; 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 forecasts and increase our estimated capital requirements; and other factors, including general economic conditions and regulatory developments, not within our control.

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

	June 30, 2021	December 31, 2020
	(Unaudited)	
Cash, cash equivalents, and investments	$ 702,656	$ 629,437
Restricted cash	$ 6,084	$ 5,525
Total assets	$ 852,790	$ 768,458
Stockholders' equity	$ 744,413	$ 656,498

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2021	2020	2021	2020
Revenues	$ -	$ -	$ -	$ -
Costs and expenses*				
Research and development	62,119	49,274	118,068	106,226
General and administrative	19,307	14,353	38,928	28,211
Total costs and expenses	81,426	63,627	156,996	134,437
Loss from operations	(81,426)	(63,627)	(156,996)	(134,437)
Other income				
Interest income, net	75	609	196	1,824
Net Loss	$ (81,351)	$ (63,018)	$ (156,800)	$ (132,613)
Net Loss Per Share of Common Stock, Basic and Diluted	$ (0.53)	$ (0.47)	$ (1.04)	$ (1.02)
Weighted-Average Shares of Common Stock Outstanding, Basic and Diluted	153,751	133,162	150,571	129,848
*** Includes stock-based compensation as follows**				
Research and development	$ 8,585	$ 5,465	$ 17,787	$ 9,783
General and administrative	5,829	5,072	13,568	10,166
	$ 14,414	$ 10,537	$ 31,355	$ 19,949

CONTACTS

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