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): January 10, 2022

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 8.01. Other Events.

On January 10, 2022, Iovance Biotherapeutics, Inc. (the "Company") issued a press release. The full text of the press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release of Iovance Biotherapeutics, Inc., dated January 10, 2022.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

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: January 10, 2022

IOVANCE BIOTHERAPEUTICS, INC.

By: /s/ FREDERICK G. VOGT
Frederick G. Vogt, Interim Chief Executive Officer

Exhibit 99.1

Iovance Biotherapeutics Announces Raj K. Puri, M.D., Ph.D. to Join Leadership Team

SAN CARLOS, Calif., January 10, 2022 -- Iovance Biotherapeutics, Inc. (NASDAQ: IOVA), a late-stage biotechnology company developing novel T cell-based cancer immunotherapies, today announced that Raj K. Puri, M.D., Ph.D., will join the Company as Executive Vice President, Regulatory Strategy and Translational Medicine. Dr. Puri will begin his employment with the Company toward the end of the first quarter of 2022.

For more than 19 years, Dr. Puri has served as the director of the Division of Cellular and Gene Therapies (DCGT) in the Office of Tissues and Advanced Therapies at the United States Food and Drug Administration (FDA) in its Center for Biologics Evaluation and Research. He is also a Chief of Tumor Vaccines and Biotechnology Branch within DCGT. During his more than 33 years working at the FDA, Dr. Puri held various positions as a reviewer and laboratory chief prior to his service as a division director. Dr. Puri has experience with the evaluation and regulation of advanced therapies including cell and gene therapy, cancer vaccines, and cellular immunotherapy. As a principal investigator and throughout his career, Dr. Puri has led research in the field of cancer therapies, including agents such as immunotoxins, cancer vaccines, and T cells including chimeric antigen receptor-modified T cells and tumor infiltrating lymphocytes.

Dr. Puri trained at the National Cancer Institute's Surgery Branch, where he worked in the laboratory of Dr. Steven Rosenberg on adoptive immunotherapy approaches for cancer, and at the Mayo Clinic, Rochester, Minnesota where he worked on progesterone hormone receptors. He received his M.D. from the University of Juarez Medical School Institute of Biosciences and his Ph.D. in Medical Sciences from the Central Drug Research Institute, Lucknow.

"We are excited that Raj has chosen to join Iovance and contribute to our mission of developing and offering patients access to novel therapies," said Frederick G. Vogt, Ph.D., J.D., Iovance's Interim Chief Executive Officer and President. "Raj's deep regulatory and translational medicine experience will be invaluable for our clinical and preclinical programs."

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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