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 23, 2023

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.)**
825 Industrial Road, Suite 400 **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 1.01 Entry into a Material Definitive Agreement.

Acquisition of Worldwide Rights in Proleukin® (aldesleukin)

On January 23, 2023, Iovance Biotherapeutics, Inc. (the "Company") and its newly formed, wholly owned subsidiary, Iovance Biotherapeutics UK Ltd ("Purchaser"), entered into an Option Agreement (the "Agreement") with Clinigen Holdings Limited, Clinigen Healthcare Limited, and Clinigen, Inc. (collectively, the "Sellers"), pursuant to which Purchaser will acquire the worldwide rights in Proleukin® (aldesleukin) (the "Product"), as well as the manufacturing, supply, commercialization and the generation of income from such rights and associated operations from the Sellers (the "Acquisition").

Material terms of the Agreement include an upfront payment of £167.7 million (or approximately $200 million), a £41.7 million (or approximately $50 million) milestone payment upon first approval of lifileucel in advanced melanoma, and deferred consideration based on double digit rates on global net sales (as defined therein) payable from the Company to Sellers following the completion of the transaction for the applicable deferred consideration term.

The Company is financing the Acquisition with existing cash. As of January 20, 2023, the Company's unaudited cash position is approximately $477.0 million, which includes net proceeds from its at-the market (ATM) equity financing facility of approximately $227.1 million raised during the fourth quarter of 2022 and early 2023.

Subject to the terms and conditions of the Agreement, the Sellers granted Purchaser a call option to purchase (x) all issued and outstanding shares of Clinigen SP Limited ("Target") (the "Shares"), (y) the business of the Target and the Sellers comprising the manufacturing, supply, commercialization and the generation of income from the Product rights and the undertaking of an active role in the development, maintenance and exploitation of those rights (the "Operations"), and (z) certain specified assets identified in the Agreement (the "Assets" and, together with the Shares and the Operations, the "Business") and Purchaser granted Sellers a put option to sell the Business.

The Agreement contains customary representations and warranties of a transaction of this type by each of the parties. These representations and warranties were made solely for the benefit of the parties to the Agreement and:

- should not be treated as categorical statements of fact, but rather as a way of allocating the risk to one of the parties if those statements prove to be inaccurate;
- may have been qualified by disclosures that were made to the other party in connection with the negotiation of the Agreement;
- may apply contractual standards of "materiality" that are different from "materiality" under applicable securities laws;
- were made only as of the date of the Merger Agreement or such other date or dates as may be specified in the Agreement; and
- information concerning the subject matter of such representations and warranties may change after the date of the Agreement, which subsequent information may or may not be fully reflected in public disclosures.

The Agreement is subject to customary termination provisions, and the Company would be required to pay to the Sellers a reverse termination fee (less certain transaction fees and expenses incurred by the Company) upon certain events as described in the Agreement.

The Company has provided the Sellers with a parent guarantee in favor of the Sellers, which guarantees that Purchaser will promptly fulfill all its obligations under the Agreement, subject to the conditions set forth in the Agreement.

The Acquisition is expected to close in the first quarter of 2023, subject to required regulatory approvals and clearances and other customary closing conditions.

The foregoing description of the Agreement does not purport to be complete and is qualified in its entirety by reference to the complete terms and conditions of the Agreement, a copy of which will be filed by amendment on Form 8-K/A to this Current Report or as an exhibit with the next periodic report.

In addition, the Company has agreed to non-binding terms related to a proposed secured line of credit of up to $100.0 million from Quogue Capital LLC (the "Line of Credit"). The Line of Credit provides for an interest rate equal to the Secured Overnight Financing Rate (SOFR) plus 8.50% with a floor of 12.5%, a 5-year maturity, a facility fee equal to $3,000,000, first priority security interest, and reimbursement for reasonable and documented fees and expenses. There will be no conversion features, nor any equity related thereto. The Line of Credit is non-binding, and it remains subject to the execution of a definitive agreement with customary provisions and customary closing conditions. Additional terms will be disclosed if and when the parties execute a definitive agreement. Wayne Rothbaum, a director of the Company, is the sole owner and managing member of Quogue Capital LLC. Mr. Rothbaum recused himself from the Company's Board of Directors (the "Board") deliberations related to the Line of Credit. All of disinterested directors present at the Board meeting reviewed the terms with outside counsel and the Company's financial advisor, and the disinterested directors and the Audit Committee of the Board will approve the definitive agreement, subject to their final review and approval of a binding agreement.

The foregoing description of the Line of Credit does not purport to be complete and is qualified in its entirety by reference to the complete terms and conditions of the Line of Credit, a copy of which will be filed by amendment on Form 8-K/A to this Current Report or as an exhibit with the next periodic report.

Item 8.01 Other Events.

On January 23, 2023, the Company issued a press release announcing the Acquisition and announcing certain other corporate and clinical updates. A copy 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 23, 2023.
104	Cover Page Interactive Data File (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: January 23, 2023

IOVANCE BIOTHERAPEUTICS, INC.

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

Exhibit 99.1

Iovance Biotherapeutics Provides Corporate, Clinical, and Regulatory Updates

Acquisition of Worldwide Rights to Proleukin® Provides Immediate and Ongoing Revenue and Secures IL-2 Supply for Clinical and Future Commercial TIL Therapy

Positive FDA Feedback on Phase 3 Confirmatory Study in Frontline Advanced (Metastatic or Unresectable) Melanoma

Positive Clinical Data in Anti-PD-1 Naïve Metastatic Non-Small Cell Lung Cancer (NSCLC)

Biologics License Application (BLA) Submission in Post-Anti-PD-1 Advanced Melanoma on Track to Complete in Q1 2023

Strengthened Cash Position to Fund Operating Plan Well into 2024

SAN CARLOS, Calif., January 23, 2023 – 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 provided corporate, clinical, and regulatory updates.

CORPORATE UPDATE

Acquisition of Proleukin®

Under a definitive agreement between Iovance and Clinigen Limited, Iovance will acquire worldwide rights to Proleukin® (aldesleukin), an interleukin-2 (IL-2) product used to promote T-cell activity following TIL infusion. Iovance expects the benefits of this transaction to include immediate and future revenue, securing the IL-2 supply chain and logistics surrounding TIL therapy administration, and lower cost of goods and clinical trial expenses for Proleukin® used with TIL therapies.

Terms of the agreement include an upfront payment of £166.7 million, a £41.7 million milestone payment upon first approval of lifileucel in advanced melanoma, and double-digit Proleukin® global sales royalties from Iovance to Clinigen. The transaction is expected to close in the first quarter of 2023, subject to required regulatory approvals and clearances and other customary closing conditions.

Iovance is financing the acquisition with existing cash. As of January 20, 2023, Iovance's unaudited cash position is approximately $477.0 million, which includes net proceeds from an at-the market (ATM) equity financing facility of approximately $227.1 million raised during the fourth quarter of 2022 and early 2023. In addition, Iovance has agreed to terms for a secured line of credit of up to $100 million from Quogue Capital. These proceeds are expected to fund the acquisition of Proleukin® and Iovance's operating plan well into 2024.

CLINICAL AND REGULATORY UPDATES

Lifileucel in Advanced Melanoma

TILVANCE-301 Phase 3 Confirmatory Trial: During the fourth quarter of 2022, Iovance reached agreement with the U.S. Food and Drug Administration (FDA) regarding the Phase 3 TILVANCE-301 trial of lifileucel in combination with pembrolizumab in frontline advanced melanoma. The TILVANCE-301 trial will randomize 670 patients and will investigate lifileucel in combination with pembrolizumab (experimental arm) compared with pembrolizumab monotherapy (control arm).

The FDA agreed to dual primary endpoints of objective response rate (ORR) to support accelerated approval and progression free survival (PFS) to support full approval of lifileucel in frontline advanced melanoma. The TILVANCE-301 confirmatory trial will also support full approval of lifileucel in post-anti-PD-1 advanced melanoma and is expected to be well underway at the time of potential BLA approval for lifileucel. Further details will be shared later in 2023.

Updated results from nearly 20 patients treated in Cohort 1A of the IOV-COM-202 trial of lifileucel in combination with pembrolizumab in frontline advanced melanoma remain consistent with previously reported data[1] demonstrating robust ORR by RECIST 1.1 and durability of response. Additional data will be shared later in 2023 and continue to support the opportunity for lifileucel in frontline advanced melanoma.

Lifileucel in Anti-PD-1 Naïve Metastatic Non-Small Cell Lung Cancer (NSCLC)

IOV-COM-202 Cohort 3A: Confirmed ORR by RECIST 1.1 of 47% (n=8/17) was observed in patients treated with a combination of TIL therapy (LN-145) and pembrolizumab in Cohort 3A of the IOV-COM-202 trial. Responses were observed regardless of PD-L1 status. Safety was consistent with other studies of Iovance TIL therapies in combination with pembrolizumab. Study enrollment remains ongoing.

ORR by Clinical Subset: Cohort 3A comprises three distinct clinical subsets of anti-PD-1 naïve metastatic NSCLC: 1) treatment-naïve, 2) post-chemotherapy, and 3) *EGFR*-mutant after prior treatment with tyrosine kinase inhibitors (TKI). Response rates were highest in patients who were treatment-naïve (80% ORR; n=4/5) and post-chemotherapy anti-PD-1 naïve (43% ORR, n=3/7) compared with *EGFR*-mutant after prior treatment with TKI (20% ORR, n=1/5). Two patients achieved complete responses and remain on study (post-chemotherapy anti-PD-1 naive, n=1 and *EGFR*-mutant after prior treatment with TKI, n=1). The observed differences in ORR between the patient subsets are informing the design of a subsequent potential registration study. Detailed clinical results will be shared at a future medical meeting.

Regulatory Strategy: Iovance plans to meet with FDA in 2023 to discuss Cohort 3A results and a potential registration trial of lifileucel in frontline advanced NSCLC patients who are *EGFR* wild-type. The proposed design will be a frontline maintenance study of standard-of-care pembrolizumab and limited duration chemotherapy followed by treatment consisting of TIL therapy in combination with pembrolizumab compared with pembrolizumab monotherapy in responding patients. This design takes advantage of the findings of Cohort 3A and has the potential to offer frontline advanced NSCLC patients improved responses and PFS compared with single agent maintenance pembrolizumab.

BLA Submission

The rolling BLA submission for lifileucel in post-anti-PD-1 advanced melanoma commenced in August 2022 and is on track to complete during the first quarter of 2023.

Investor Webcast

Iovance will host a webcast on Monday, January 23, 2023, at 8:30 a.m. ET to discuss these corporate, clinical and regulatory updates. To participate in the webcast, please register at https://register.vevent.com/register/BIb01d5a16742c4d99b3dfe1b02bad8147. The live webcast and replay can be accessed in the Investors section of the company's website at ir.iovance.com.

About Iovance Biotherapeutics, Inc.

Iovance Biotherapeutics aims to be the global leader in innovating, developing and delivering tumor infiltrating lymphocyte (TIL) therapies for patients with cancer. We are pioneering a transformational approach to cure cancer by harnessing the human immune system's ability to recognize and destroy diverse cancer cells in each patient. Our lead late-stage TIL product candidate, lifileucel for metastatic melanoma, has the potential to become the first approved one-time cell therapy for a solid tumor cancer. The Iovance TIL platform has demonstrated promising clinical data across multiple solid tumors. We are committed to continuous innovation in cell therapy, including gene-edited cell therapy, that may extend and improve life for patients with cancer. 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; whether clinical trial results from our pivotal studies and cohorts, and meetings with the FDA, may support registration studies and subsequent approvals by the FDA; 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 changing landscape of care for cervical cancer patients may impact our clinical trials in this indication; 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 (including from the recent pre-BLA meeting with the FDA); the risk that the rolling BLA submission for lifileucel in metastatic melanoma may take longer than expected; 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.

CONTACTS

Iovance Biotherapeutics, Inc.
Sara Pellegrino, IRC
SVP, Investor Relations & Corporate Communications
650-260-7120 ext. 264
Sara.Pellegrino@iovance.com

Jen Saunders
Director, Investor Relations & Public Relations
267-485-3119
Jen.Saunders@iovance.com

[1] Iovance Biotherapeutics Announces Regulatory and Clinical Updates for Lifileucel in Melanoma, April 5, 2022.