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) October 28, 2021

Landos Biopharma, Inc.
(Exact name of Registrant as Specified in its Charter)

Delaware	**001-39971**	**81-5085535**
(State or Other Jurisdiction of Incorporation)	**(Commission file Number)**	**(IRS Employer Identification No.)**

1800 Kraft Drive, Suite 216, Blacksburg, Virginia	**24060**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's telephone number, including area code (540) 218-2232

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-2 under the Exchange Act (17 CFR 240.14a-2)

☐ 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))

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 $0.01 per share	**LABP**	**The Nasdaq Stock Market LLC**

Indicate by check mark whether the registrant is an emerging growth company 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 7.01 Regulation FD Disclosure.

On October 28, 2021, Landos Biopharma, Inc. issued the press release furnished herewith as Exhibit 99.1 to announce that the first subject has been dosed in a Phase 1 study of LABP-104, Landos' oral, small-molecule LANCL2 agonist, for the treatment of systemic lupus erythematosus.

The information in this Item 7.01 of this Current Report on Form 8-K (including Exhibit 99.1) is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1	Press Release of Landos Biopharma, Inc., dated October 28, 2021
104	The cover page from Landos Biopharma, Inc.'s Form 8-K filed on October 28, 2021, formatted in Inline XBRL.

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 on this 28th day of October, 2021.

LANDOS BIOPHARMA, INC.

By: */s/ Josep Bassaganya-Riera*
Name: Josep Bassaganya-Riera
Title: Chairman, President and Chief Executive Officer

Exhibit 99.1

Landos Biopharma Announces First Subject Dosed in a Phase 1 Study of LABP-104 for Systemic Lupus Erythematosus

October 28, 2021

Topline results are expected in the first half of 2022

A whole blood LABP-104 precision medicine signature will be assessed during the trial

BLACKSBURG, Va., Oct. 28, 2021 (GLOBE NEWSWIRE) — Landos Biopharma, Inc. (NASDAQ: LABP), a late-clinical-stage biopharmaceutical company utilizing its LANCE® Advanced A.I. platform to discover and develop novel therapeutics for patients with autoimmune diseases, today announced the Company has dosed the first subject in a Phase 1 study of LABP-104, a potentially first-in-class oral, small-molecule LANCL2 agonist, for the treatment of systemic lupus erythematosus (SLE).

“We are pleased to announce the initiation of the first clinical trial investigating LABP-104, marking Landos’ sixth novel clinical program addressing the unmet clinical needs of patients with autoimmune diseases,” said Dr. Josep Bassaganya-Riera, Chairman, President, and CEO of Landos. “Our LANCE platform coupled with our agile entrepreneurial culture continues to deliver high value shots on goal. There are approximately 1.5 million patients in the U.S. suffering from SLE with very limited therapeutic options. Leveraging our LANCE platform to develop a proprietary LABP-104 transcriptional response signature in blood holds promise to identify the SLE patients that may benefit the most from oral LABP-104 treatment. We are excited to advance LABP-104 as the first potential precision medicine-based therapeutic candidate for SLE into clinical testing.”

The Phase 1 trial is a randomized, placebo-controlled, double-blind, ascending dose, multi-cohort study designed to evaluate the safety, tolerability and pharmacokinetics of LABP-104 in healthy volunteers. A total of 56 healthy volunteers will be enrolled in two parts – a single ascending dose study (SAD) and then a multiple ascending dose study (MAD), during which the participants will be randomized to five cohorts receiving single oral doses of LABP-104 or placebo in the SAD and to three cohorts receiving three oral doses of LABP-104 or placebo once daily for seven days in the MAD. The primary endpoint will measure the safety and tolerability of LABP-104. Secondary endpoint will measure the pharmacokinetics of LABP-104. We expect to report topline results of the Phase 1 trial in the first half of 2022. Additional information about the Phase 1 LABP-104 trial is available at clinicaltrials.gov (NCT05019950).

By using the LANCE® Advanced A.I. platform, Landos has developed a 15-gene LABP-104 transcriptional response signature in whole blood that could be used as a companion diagnostic to better characterize the subsets of lupus patients that can benefit the most from oral treatment with LABP-104. This precision medicine signature will be further validated as an exploratory endpoint in Phase 1 and 2 SLE studies.

About Systemic Lupus Erythematosus (SLE)

Systemic lupus erythematosus (SLE) is the most common type of the autoimmune disease lupus. In SLE, the immune system attacks its own tissues, causing widespread inflammation and tissue damage. SLE can affect multiple organs and systems including skin, joints, kidneys, brain, blood cells, lungs and heart. SLE is commonly treated with corticosteroids and antimalarials that aim to lower the interferon alpha response, which elicit strong antiviral activities in target cells. However, current therapeutic options for SLE can cause serious side effects, including the potential for cardiovascular damage, increased risk of infections, sepsis and pneumonia. Newly-FDA-approved therapies for SLE are infusions into a vein in the arm that can cause upper respiratory tract infections, bronchitis, infusion-related reactions and herpes zoster (shingles). As such, there is a high unmet medical need for an alternative oral frontline therapy for the estimated 1.5 million SLE patients in the US and approximately 5 million patients globally, with an estimated market value of approximately $1.6 billion by 2028 and a growth rate of 5.6%.

About LABP-104

LABP-104 is an oral, once-daily, systemically-distributed, small-molecule therapeutic candidate which activates LANCL2, a surface-membrane-associated receptor that is responsible for modulating key cellular and molecular changes tied to autoimmune diseases. By activating the LANCL2 pathway, LABP-104 increases the anti-inflammatory capacity and stability of regulatory CD4+ T cells while also supporting the metabolic demands of autophagy in phagocytes. To date, treatment with LABP-104 has reduced the production of interferon alpha in human PBMCs from SLE patients and provided protection from clinical disease and tissue pathology in mouse models of lupus. We own an issued patent on LABP-104 in the U.S., a number of foreign patent applications, and an international patent application available for filing in additional foreign countries and regions through the Patent Cooperation Treaty.

About Landos Biopharma

Landos Biopharma is a late-clinical-stage biopharmaceutical company utilizing its LANCE® Advanced A.I. platform to discover and develop novel therapeutics for patients with autoimmune diseases. Using the LANCE® platform, the Company has discovered new mechanisms of action, including the LANCL2, NLRX1 and PLXDC2 immunometabolic pathways. Landos Biopharma has 17 active development programs targeting these novel pathways at the interface of immunity and metabolism. Its lead product candidate, omilancor targets the LANCL2 pathway and is a novel oral, gut-restricted, small-molecule potentially first-in-class therapeutic currently being prepared for global pivotal Phase 3 trials for the treatment of ulcerative colitis, in two active Phase 2 trials in Crohn’s disease, and is anticipated to initiate Phase 1 studies in eosinophilic esophagitis in 2022. Omilancor is also being studied in a topical formulation for psoriasis and atopic dermatitis. NX-13 is a novel, oral, gut-restricted small-molecule drug candidate that targets the NLRX1 pathway and is currently in an active Phase 1b trial in ulcerative colitis. NX-13 targets the NLRX1 pathway. Landos’ sixth new clinical product candidate, LABP-104, is in an active Phase 1 trial for systemic lupus erythematosus guided by a proprietary 15-gene precision medicine companion diagnostic developed by its LANCE® advanced A.I. platform. Additional product candidates in Landos’ expansible inflammation and immunology pipeline are in preclinical and IND-enabling stages of development. For more information, please visit www.landosbiopharma.com.

Cautionary Note on Forward-Looking Statements

Statements in this press release about future expectations, plans and prospects for Landos Biopharma, Inc. (the "Company"), including statements about the Company's strategy, clinical development and regulatory plans for its product candidates, the Company's anticipated milestones and future expectations and plans and prospects for the Company and other statements containing the words "anticipate", "plan", "expect", "may", "will", "could", the negatives thereof, variations thereon and similar expressions, or any discussions of strategy constitute forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the uncertainties inherent in the initiation and enrollment of future clinical trials, expectations of expanding ongoing clinical trials, availability and timing of data from ongoing clinical trials, expectations for regulatory approvals, other matters that could affect the availability or commercial potential of the Company's product candidates and other similar risks. Risks regarding the Company's business are described in detail in its Securities and Exchange Commission ("SEC") filings, including in its Annual Reports on Form 10-K and Quarterly Reports on Form 10-Q, which are available on the SEC's website at www.sec.gov. Additional information will be made available in other filings that the Company makes from time to time with the SEC. Such risks may be amplified by the impacts of the COVID-19 pandemic. In addition, the forward-looking statements included in this press release represent the Company's views only as of the date hereof. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so, except as may be required by law. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date hereof.

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