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 11, 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 11, 2021, Landos Biopharma, Inc. issued the press release furnished herewith as Exhibit 99.1 to announce that the U.S. Food and Drug Administration has cleared the Landos Investigational New Drug application for LABP-104, a novel, oral, systemically distributed LANCL2 agonist, for the treatment of systemic lupus erythematosus. Landos plans to initiate a Phase 1 trial in healthy volunteers before year-end and report topline results in the first half of 2022.

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 11, 2021
104	The cover page from Landos Biopharma, Inc.'s Form 8-K filed on October 12, 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 12th 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 FDA Clearance of its IND for LABP-104 for the Treatment of Systemic Lupus Erythematosus

October 11, 2021

Phase 1 trial initiation expected before yearend with topline results in 1H 2022

BLACKSBURG, Va., Oct. 11, 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 that the U.S. Food and Drug Administration (FDA) has cleared the Company's Investigational New Drug (IND) application for LABP-104, a novel, oral, systemically distributed LANCL2 agonist, for the treatment of systemic lupus erythematosus (SLE). Landos plans to initiate a Phase 1 trial in healthy volunteers before yearend and report topline results in the first half of 2022.

"Building on our early success with omilancor in gastrointestinal and topical indications, our LANCE platform continues to deliver novel oral, small-molecule therapeutics for patients with autoimmune diseases. The FDA clearance of the LABP-104 IND application in SLE is Landos' sixth successful IND approval in less than four years and demonstrates our commitment to developing safer and more effective first-in-class therapeutics for these patients," commented Josep Bassaganya-Riera, Chairman, President and Chief Executive Officer of Landos. "SLE is an often misdiagnosed and potentially terminal disease, primarily impacting women of child-bearing age, characterized by multiple organ failures when the immune system turns on itself. There is no cure for SLE and, given that current treatment regimens rely on potent immunosuppressants that pose debilitating side effects, we are highly motivated to leverage our deep understanding of the LANCL2 pathway to develop LABP-104 as a differentiated, oral, once-daily therapeutic option for these patients."

LABP-104 activates the LANCL2 pathway to restore the immune system to homeostasis through the enhancement of regulatory T cell (Treg) function and increasing mitochondrial metabolism. In preclinical and translational studies, LABP-104 reduced interferon gamma signaling in human SLE patient peripheral blood mononuclear cells (PBMCs) in response to TLR7 and DNA antigens. Additionally, oral treatment with LABP-104 prevented the worsening of proteinuria and reduced anti-nuclear antibody levels by three-fold. Overall, oral LABP-104 treatment demonstrated reduced kidney tissue damage and statistically significant therapeutic efficacy in mouse models of lupus. Mechanistically, the clinical and histological improvements significantly reduced effector, tissue-damaging IL-17- and IL-21-producing CD4+ T cells in the spleen while significantly increasing protective Tregs.

The planned 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 7 days in the MAD. The primary endpoint will measure the safety and tolerability of LABP-104. The secondary endpoint will measure the pharmacokinetics of the once-daily oral therapeutic.

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, 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.

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. Landos has another novel, oral, gut-restricted small-molecule drug candidate, NX-13, that is being investigated in an active Phase 1b trial in ulcerative colitis. NX-13 targets the NLRX1 pathway. Landos’ sixth new product candidate, LABP-104, has received FDA clearance for its IND in systemic lupus erythematosus (SLE). Additional product candidates in Landos’ 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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