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) November 2, 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 November 2, 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 Landos' Investigational New Drug application for LABP-104, a novel, oral, systemically delivered LANCL2 agonist, for the treatment of rheumatoid arthritis.

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 November 2, 2021
104	The cover page from Landos Biopharma, Inc.'s Form 8-K filed on November 3, 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 3rd day of November, 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 Rheumatoid Arthritis

Phase 1 trial is underway with topline results expected in the first half of 2022

Represents Landos' seventh IND cleared overall and the second IND cleared for LABP-104, a potentially first-in-class therapeutic candidate for systemic lupus erythematosus and rheumatoid arthritis

BLACKSBURG, Va., Nov. 02, 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 delivered LANCL2 agonist, for the treatment of rheumatoid arthritis (RA). The FDA has recently cleared an IND application for LABP-104 for the treatment of systemic lupus erythematosus (SLE). Landos has initiated a Phase 1 trial of LABP-104 for the treatment of RA and SLE in healthy volunteers and expects to report topline results in the first half of 2022.

"Our team continues to successfully and timely deliver on the goals we set out at the beginning of the year, notably to clear three INDs in 2021. The FDA clearance of the LABP-104 IND application in RA is Landos' seventh successful IND approval derived from our LANCE A.I. platform in less than four years," commented Josep Bassaganya-Riera, Chairman, President and Chief Executive Officer of Landos. "LABP-104 has reduced inflammatory cell infiltration and its LANCL2 mechanism showed significantly less risk for toxicities than biologic and JAK inhibitor treatments currently available. As RA patients are prone to relapse, we are inspired by the opportunity to develop a candidate that could potentially redefine the treatment paradigm as a therapy that helps maintain clinical remission and overall survival for these patients, while improving their quality of life."

Like omilancor, Landos's Phase 3-ready therapeutic candidate for UC, LABP-104 targets the anti-inflammatory receptor LANCL2, a novel mechanism for enhancing Treg function and decreasing TNF production. In a collagen-induced mouse model of arthritis, oral treatment with LABP-104 provided protection from severity of disease, including a significant reduction of redness and swelling in addition to overall paw size. Consistent with the validated actions of the LANCL2 pathway in other indications, with once-daily oral dosing, LABP-104 significantly reduced the numbers of Th17 and T follicular helper cells in the spleen while increasing the number of CD25high FOXP3+ Tregs.

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 for SLE and RA is available at clinicaltrials.gov (NCT05019950).

About Rheumatoid Arthritis (RA)

Rheumatoid arthritis (RA) is an autoimmune disease characterized by over-activation of the immune system and increased immune cell infiltration that results in chronic pain and loss of mobility due to excessive inflammation that swell joints and erode bone and cartilage. Current therapies in RA have limitations tied to safety and efficacy and are often accompanied by a high risk of severe side effects and co-morbidities. Furthermore, RA requires chronic treatment to maintain clinical remission. RA affects 1.3 million patients in the United States, with the number of new cases expected to increase as the elderly population grows. According to Global Data, in 2021, sales of prescription drugs to treat RA are estimated to total $20.9 billion. The US currently comprises approximately 74% of the total global prescription sales.

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. LABP-104 is currently in clinical development for systemic lupus erythematosus (SLE) and rheumatoid arthritis (RA). 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. Landos has initiated a Phase 1 trial of LABP-104 in healthy volunteers for the treatment of SLE and RA, with topline results expected the first half of 2022. In preclinical models of RA, LABP-104 has resulted in decreased tissue-damaging Th17 and Tfh cells with increased protective Tregs for RA. Landos owns 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’ seventh new clinical product candidate, LABP-104, is in an active Phase 1 trial for systemic lupus erythematosus and rheumatoid arthritis, 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.

Contacts:

Marek Ciszewski, J.D.
Landos Biopharma
562-373-5787
IR@LandosBiopharma.com

Michael K. Levitan (investors)
Solebury Trout
646-378-2920
mlevitan@soleburytrout.com

Hannah Gendel (media)
Solebury Trout
646-378-2943
hgendel@soleburytrout.com