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): May 6, 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** **(Address of Principal Executive Offices)**	**24060** **(Zip Code)**

(540) 218-2232
(Registrant's Telephone Number, Including Area Code)

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

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 (see General Instructions A.2. below):

☐ 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))

Securities registered pursuant to Section 12(b) of the Act.

Title of each class	Trading Symbol(s)	Name of 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 May 6, 2021, Landos Biopharma, Inc. (the "**Company**") issued a press release to announce the dosing of its first patient in a Phase 2 study of omilancor for moderate-to-severe Crohn's Disease.

In accordance with General Instruction B.2. of Form 8-K, the information in this Item 7.01 and Exhibit 99.1 hereto, 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 liability of that section, nor shall it be deemed incorporated by reference in any of the Company's filings under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any incorporation language in such a filing, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Description
99.1	Press Release, dated May 6, 2021, entitled "Landos Biopharma Announces First Patient Dosed in a Phase 2 Study of Omilancor for Moderate-to-Severe Crohn's Disease"
104	The cover page from Landos Biopharma, Inc.'s Form 8-K filed on May 7, 2021, formatted in Inline XBRL.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Landos Biopharma, Inc.

Dated: May 7, 2021

By: /s/ Josep Bassaganya-Riera
Josep Bassaganya-Riera
Chief Executive Officer

Exhibit 99.1

Landos Biopharma Announces First Patient Dosed in a Phase 2 Study of Omilancor for Moderate-to-Severe Crohn's Disease

Company's second omilancor program entering a Phase 2 study with plans to pursue at least five autoimmune indications

Topline results are expected in the second quarter of 2022

BLACKSBURG, VA., May 6, 2021 – Landos Biopharma (NASDAQ: LABP), a clinical-stage biopharmaceutical company focused on the discovery and development of therapeutics for patients with autoimmune diseases, today announced that the Company has dosed the first patient in a Phase 2 study of omilancor, Landos' novel, orally administered, gut-restricted LANCL2 agonist, for the treatment of moderate-to-severe Crohn's disease (CD).

"We are extremely proud of the momentum we have generated this year with the clinical advancement of omilancor, as this trial marks the second indication after ulcerative colitis which is Phase 3-ready," commented Josep Bassaganya-Riera, Chairman, President and Chief Executive Officer of Landos. "Initiating this Phase 2 trial is instrumental in supporting our efforts to showcase omilancor's ability to exert strong anti-inflammatory effects within the gastrointestinal tract through a novel mechanism of action. With no safe, convenient treatment maintenance options available for the over 100,000 patients worldwide living with moderate-to-severe CD, we believe omilancor, as an oral therapeutic designed to have higher tolerability and a gut-restricted PK profile, may provide a significantly improved therapeutic option."

This Phase 2 trial is a randomized, double-blind, placebo-controlled, parallel group, multicenter study designed to evaluate the proof of concept efficacy and safety of omilancor for the treatment of moderate-to-severe CD. Approximately 150 subjects will be randomized to receive either 1000 mg of omilancor or placebo. Treatment will be evaluated over a 12-week induction period followed by an 18-week maintenance period and 2-week post-treatment safety follow up. The co-primary endpoints will assess clinical remission at Week 12, defined by CDAI < 150, as well as the frequency and severity of AEs compared to placebo. The key secondary endpoints will evaluate the effects of omilancor on disease activity as measured by symptoms, colonoscopy, histology, and biomarkers as well as the health-related quality of life and pharmacokinetic parameters of this product candidate.

"There remains an unmet need for safer, more convenient and effective therapeutic alternatives to treat patients with CD," said Jean-Frederic Colombel, MD, Director, IBD Center at the Icahn School of Medicine at Mount Sinai and Landos Clinical Advisory Board member. "Oral treatment with omilancor has consistently demonstrated a benign and well-tolerated safety profile, a gut-restricted distribution without systemic immunosuppression, biologic-like efficacy signal and enhanced immunoregulatory mechanisms in UC patients. Based on these encouraging results, we believe omilancor could show similar levels of efficacy in CD patients with a well-tolerated safety profile and ultimately provide long-term benefit for millions of people living with IBD."

About Crohn's Disease (CD)

CD is a chronic, autoimmune, inflammatory bowel disease that causes inflammation, irritation and ulcers in any segment of the gastrointestinal tract. CD impacts the end of the small bowel and beginning of the colon most commonly, which in turn can lead to symptoms of abdominal pain, increased abdominal sounds, rectal pain and bleeding, bloody stools, diarrhea, fever, weight loss and malnutrition. There are four classes of CD and treatment depends on the level of severity. Current therapeutic options for severe disease, primarily biologics, have several limitations, which include but are not limited to safety risks for malignancies and infections, limited efficacy and lack of long-term maintenance options. There is an urgent need to establish a consensus for a first-line therapy for CD and improve upon the existing constraints in administration and efficacy.

About Omilancor (BT-11)

Omilancor is a novel, orally-active, gut-restricted small molecule investigational drug that targets the Lanthionine Synthetase C-Like 2 (LANCL2) pathway impacting the gastrointestinal tract. LANCL2 plays an important role in the immunoregulatory process. By activating the LANCL2 pathway and modulating the interactions between immunological and metabolic signals in immune cells, omilancor is designed to create a favorable regulatory microenvironment in the gut, decreasing the production of key inflammatory mediators and increasing anti-inflammatory markers in regulatory T cells (Treg) within the site of inflammation. The Company reported initial Phase 2 results of omilancor evaluating patients with ulcerative colitis in 2021 and expects to initiate a Phase 3 trial in the second half of 2021. Additionally, Landos initiated a Phase 2 trial of omilancor in patients with Crohn's disease in the first half of 2021.

About Landos Biopharma

Landos Biopharma is a clinical-stage biopharmaceutical company focused on the discovery and development of oral therapeutics for patients with autoimmune diseases that are the first to target new mechanisms of action, including the LANCL2, NLRX1 and PLXDC2 immunometabolic pathways. Landos Biopharma's core expertise is in the development of therapeutic candidates targeting novel pathways at the interface of immunity and metabolism. Lead asset omilancor is a novel, oral, gut-restricted small molecule therapeutic candidate for the treatment of ulcerative colitis, Crohn's disease and Eosinophilic Esophagitis that targets the LANCL2 pathway. NX-13 is a novel, oral, gut-restricted compound for the treatment of inflammatory bowel disease, which targets the NLRX1 pathway. Additional candidates are in development for the treatment of lupus nephritis, rheumatoid arthritis, multiple sclerosis, and diabetes. For more information, please visit www.landosbiopharma.com.

Cautionary Note on Forward-Looking Statements

Any 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 of the company's therapeutic candidates, the Company's anticipated milestones and future expectations and plans and prospects for the Company and other statements containing the words "subject to", "believe", "anticipate", "plan", "expect", "intend", "estimate", "project", "may", "will", "should", "would", "could", "can", the negatives thereof, variations thereon and similar expressions, or by 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. 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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