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): June 14, 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 June 14, 2021, Landos Biopharma, Inc. (the "**Company**") issued a press release to announce the positive outcome of its end of Phase 2 meeting with the U.S. Food and Drug Administration for omilancor. A copy of the press release is furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K.

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

Exhibit Number	Exhibit Description
99.1	Press Release, dated June 14, 2021.
104	The cover page from Landos Biopharma, Inc.'s Form 8-K filed on June 14, 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: June 14, 2021

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

Exhibit 99.1

Landos Biopharma Announces Positive Outcome of End-of-Phase 2 Meeting with the FDA for Omilancor in Mild-to-Moderate Active Ulcerative Colitis (UC) Patients

The FDA clears the path to initiate the PACIFY I and II global registration studies in Mild-to-Moderate Active UC patients representing the potential for a broad product label for Omilancor

BLACKSBURG, Va., June 14, 2021 (GLOBE NEWSWIRE) — Landos Biopharma, Inc. (NASDAQ: LABP), a late-clinical-stage biopharmaceutical company utilizing its LANCE Advanced Artificial Intelligence (A.I.) platform to discover and develop novel oral therapeutics for patients with autoimmune and inflammatory diseases, today announced the successful outcome of an End-of-Phase 2 (EOP2) meeting with the U.S. Food and Drug Administration (FDA) for omilancor, its lead candidate in late-stage clinical development for the treatment of mild-to-moderate active ulcerative colitis (UC) patients. Landos and the FDA agreed on key elements necessary for regulatory approval, clearing a path forward for a global pivotal Phase 3 program with omilancor in patients with mild-to-moderate active UC.

The global pivotal PACIFY program will include two global pivotal Phase 3 clinical trials (PACIFY I and PACIFY II) and evaluate a single dose of omilancor versus placebo, with primary endpoints of clinical remission at weeks 12 and 52 to support label claims of induction and maintenance of clinical remission measured using the 3-component Mayo score. Landos is working to finalize the details of the Phase 3 protocols based on feedback and guidance from the FDA.

“We are pleased with the results of our End-of-Phase 2 meeting with the FDA and are excited to be able to progress omilancor into Phase 3 development as a potentially improved treatment option for a broad population of patients with mild-to-moderate active UC worldwide,” said Josep Bassaganya-Riera, Chairman, President and Chief Executive Officer of Landos. “Our Phase 2 results indicated omilancor was well-tolerated with strong efficacy signals, which we believe support its potential as a pre- and post-biologic broad-spectrum therapy for UC patients, and provided us with invaluable insights for the design of our Phase 3 PACIFY trials. We are appreciative of the support and guidance from the FDA and are working to initiate the Phase 3 global program in the U.S., Europe and Asia, to support regulatory approvals in the U.S., European and Asian markets.”

The Phase 3 design was supported by nonclinical and clinical safety and efficacy data, including encouraging results from a Phase 2 study that evaluated omilancor in 198 patients with mild-to-moderate active UC and which demonstrated statistically significant immunological and biomarker results that mirror activation of the novel LANCL2 mechanism by omilancor in the gut. Phase 1 and Phase 2 clinical data demonstrated that omilancor was well tolerated at all doses evaluated, with no dose-limiting toxicities.

About Ulcerative Colitis (UC)

UC is a chronic, autoimmune, inflammatory bowel disease that causes inflammation, irritation, and ulcers in the lining of the large intestine (colon) and rectum. Symptoms include abdominal pain, rectal pain and bleeding, bloody stools, diarrhea, fever, weight loss, and malnutrition. Having UC puts a patient at increased risk of developing colon cancer. Diagnosis typically occurs in early adulthood and the disease requires maintenance treatment for the remainder of the patient's life. UC is estimated to affect over 900,000 patients in the United States and over 1 million patients throughout the rest of the world. With 70% of addressable patients experiencing a second flare within one year and 30% of patients in remission failing to stay in remission for more than one year, there is an unmet medical need in UC for safer and more efficacious therapeutics.

About Omilancor

Discovered using Landos proprietary LANCE Advanced A.I. platform, omilancor is a novel, oral, 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. Landos reported initial Phase 2 results of omilancor evaluating patients with ulcerative colitis in 2021 and expects to initiate a global pivotal Phase 3 program (PACIFY I and PACIFY II trials) in patients with mild-to-moderately active UC. 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 is a clinical-stage biopharmaceutical company utilizing its LANCE Advanced A.I. platform to discover and develop novel oral therapeutics for patients with autoimmune diseases. LANCE has discovered new mechanisms of action, including the LANCL2, NLRX1 and PLXDC2 immunometabolic pathways. Landos has 17 active development programs targeting these novel pathways at the interface of immunity and metabolism. Lead asset omilancor is a novel gut-restricted small molecule drug candidate for the treatment of ulcerative colitis, Crohn's disease and Eosinophilic Esophagitis that targets the LANCL2 pathway. NX-13 is a novel, gut-restricted small molecule drug candidate for the treatment of inflammatory bowel disease, that 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 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 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. Risks regarding our business are described in detail in our Securities and Exchange Commission ("SEC") filings, including in our 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 we make 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:

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

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