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) September 20, 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 September 20, 2021, Landos Biopharma, Inc. issued the press release furnished herewith as Exhibit 99.1 to announce its research collaboration with the Icahn School of Medicine at Mount Sinai to conduct a Phase 2 trial of omilancor, Landos' novel, orally administered, gut-restricted LANCL2 agonist, in patients with moderate-to-severe Crohn's disease.

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 September 20, 2021
104	The cover page from Landos Biopharma, Inc.'s Form 8-K filed on September 22, 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 22nd day of September, 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 to Collaborate on a Phase 2 Study of Omilancor in Crohn's Disease with the

Icahn School of Medicine at Mount Sinai

Second Phase 2 trial of omilancor in Crohn's disease (CD), expected to initiate in 2021

Awarded a $3 million NIH R01 grant from the U.S. National Institute of Diabetes and Digestive and Kidney Diseases to fund this study

BLACKSBURG, Va., September 20, 2021 — Landos Biopharma, Inc. (NASDAQ: LABP), a late-clinical-stage biopharmaceutical company utilizing its LANCE® Advanced A.I. platform to develop novel oral small-molecule therapeutics for patients with autoimmune diseases, today announced a research collaboration with the Icahn School of Medicine at Mount Sinai to conduct a Phase 2 trial of omilancor, Landos' novel, orally administered, gut-restricted LANCL2 agonist, in patients with moderate-to-severe Crohn's disease (CD).

"Entering this partnership with the Icahn School of Medicine at Mount Sinai highlights our ability to pursue innovative clinical and translational studies that build on our pioneering immunometabolism franchise in autoimmune diseases," said Dr. Josep Bassaganya-Riera, Chairman, President, and CEO of Landos. "We are excited to expand the investigation of our Phase-3 ready product candidate, omilancor, in this mechanistic Phase 2 study in CD to further validate how activation of the LANCL2 pathway by omilancor enhances regulatory T cell (Treg) function in the gastrointestinal tract. Rescuing Treg function in biologic failure patients is a critical step for inducing durable remission given the impaired regulatory compartment in this hard to treat patient population. We thank the U.S. National Institutes of Health (NIH) for recognizing the promise of omilancor as a potential oral treatment for inflammatory bowel disease (IBD) and the value of its novel LANCL2 mechanism of action with this competitive grant that provides further independent validation and de-risking for omilancor and our broader inflammation and immunology pipeline."

This Phase 2 trial is a randomized, double-blind study designed to evaluate the efficacy, safety and mechanisms of omilancor in patients with moderate-to-severe CD. Approximately 40 patients will be randomized to receive either 880 mg of omilancor or adalimumab (Humira), the standard of care, once daily for 12 weeks. Over the course of the induction period, patients will be monitored at baseline, 2, 6 and 12 weeks for an assessment of symptoms, disease-associated biomarkers and patient-reported outcomes. Intestinal biopsy specimens, stool and peripheral blood will be comprehensively analyzed at the Laboratory of Mucosal Immunology at Mount Sinai Hospital. This trial is funded by a $3 million grant awarded to Landos by the National Institute of Diabetes and Digestive and Kidney Diseases at the NIH.

"Patients with CD need safer and more effective oral therapeutic options, especially those who have previously failed on biologics," said Jean-Frederic Colombel, MD, Director, Susan and Leonard Feinstein IBD Clinical Center at the Icahn School of Medicine at Mount Sinai in New York City. Dr. Colombel is also a member of the Landos Clinical Advisory Board and a paid consultant. "By looking at the underlying cellular and molecular multi-pronged mechanisms of omilancor in CD patients that failed biologics we can better understand how it provides clinical benefit. Based on the promise of previous early studies, I am excited by its potential to fill a clear treatment gap for patients with moderate to severe CD."

“We are excited to launch immunometabolism studies in IBD as part of this mechanistic Phase 2 study” said Saurabh Mehandru, MD, Associate Professor and Principal Investigator of the Laboratory of Mucosal Immunology at Mount Sinai Hospital where the mechanistic studies will be performed. “Immunometabolism is a relatively novel frontier in IBD pioneered by the Landos team. Through these studies, we aim to learn more about the metabolic underpinnings of cellular immune responses in IBD and their targeting with omilancor and LANCL2 engagement. Further, by studying patients longitudinally, we may be able to determine early predictors of therapeutic response to omilancor which could pave the way to better patient stratification in future. Therefore, I am very excited at the prospect of this well-designed, mechanism-focused study in patients with CD.”

Prescription therapeutics used to treat CD in the United States generated approximately $10.7 billion in sales in 2020 and are anticipated to grow at over 4.1% per annum over the coming years. Humira comprises nearly 33% of the market, with an estimated sales forecast of $2.3 billion by patient growth.

About Crohn’s Disease (CD)

CD is a chronic, autoimmune disease of the gastrointestinal tract 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. Current therapeutic options for severe CD are limited primarily to biologics, which have limitations, including but not limited to safety risks for malignancies, infections or even death, limited efficacy and lack of long-term maintenance options. There is an unmet clinical need for novel first-in-class therapeutics for CD and improvement upon the existing constraints in administration, tolerability and efficacy.

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 enhancing regulatory T cells (Treg) function within the site of inflammation. Landos reported continued positive Phase 2 results of omilancor evaluating patients with ulcerative colitis (UC) in 2021 and following a positive End-of-Phase 2 meeting has initiated site feasibility studies for its global pivotal Phase 3 clinical 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 150 patients with Crohn’s disease in the first half of 2021 with topline results expected in the first half of 2022 and anticipates initiation of Phase 1 studies in eosinophilic esophagitis. Omilancor is also being studied in a topical formulation for psoriasis and atopic dermatitis.

About Landos Biopharma

Landos Biopharma is a late-clinical-stage biopharmaceutical company utilizing its LANCE® Advanced A.I. platform to discover and develop novel oral 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 an active Phase 2 trial 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. Additional product candidates are in development for the treatment of lupus nephritis, rheumatoid arthritis, multiple sclerosis, Alzheimer's disease, non-alcoholic steatohepatitis (NASH), asthma, chronic obstructive pulmonary disease (COPD), diabetes, and diabetic nephropathy. 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 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:

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