LANDOS BIOPHARMA, INC.

FORM 8-K
(Current report filing)

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Address	1800 KRAFT DRIVE, SUITE 216 BLACKSBURG, VA, 24060
Telephone	540-818-2844
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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 15, 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 15, 2021, Landos Biopharma, Inc. issued the press release furnished herewith as Exhibit 99.1 to announce that it will present preclinical data of LABP-104, an oral, small-molecule LANCL2 agonist, in Systemic Lupus Erythematosus (SLE or Lupus) as an oral presentation on November 6, 2021 at the American College of Rheumatology Convergence 2021.

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 15, 2021
104	The cover page from Landos Biopharma, Inc.'s Form 8-K filed on September 17, 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 17th 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 Present Results of LABP-104 in Lupus at the American College of

Rheumatology Convergence 2021

Oral treatment with LABP-104 in preclinical models of Systemic Lupus Erythematosus (SLE) resulted in enhanced Treg function, decreased kidney inflammation and reduced interferon gamma signaling;

Phase 1 clinical trial anticipated to begin during Q4 2021.

BLACKSBURG, Va., September 15, 2021 — Landos Biopharma, Inc. (NASDAQ: LABP), 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, today announced that it will present preclinical data of LABP-104, an oral, small-molecule LANCL2 agonist, in Systemic Lupus Erythematosus (SLE or Lupus) as an oral presentation at the upcoming American College of Rheumatology (ACR) Convergence 2021. The meeting will be held virtually from November 3-10, 2021.

"These novel findings support the potential therapeutic efficacy of LABP-104 in SLE, along with the power of our LANCE platform to discover and validate novel targets at the intersection of immunity and metabolism. Altogether, they highlight the breadth and depth of our expansible inflammation and immunology pipeline," said Dr. Josep Bassaganya-Riera, Chairman, President and Chief Executive Officer of Landos. "Our Phase 2 trial with omilancor in ulcerative colitis illustrated the important immunoregulatory mechanisms of the Lanthionine Synthetase C-Like 2 (LANCL2) pathway including enhancing regulatory T cell (Treg) function. With these new data in lupus, we have further validation of LABP-104's therapeutic potential to activate this pathway's ability to intercept and possibly reverse the complex cascade of immunological events that lead to disease and pathology in lupus patients. We plan to pursue development of LABP-104 in lupus in addition to other debilitating autoimmune diseases with unmet clinical needs, where enhancement of Treg function plays an important therapeutic role."

Landos expects to enter Phase 1 clinical testing of LABP-104 as an oral therapeutic candidate for lupus during the fourth quarter of 2021, further expanding the company's deep inflammation and immunology pipeline.

ACR 2021 Presentation Details

Title: Therapeutic Efficacy of LABP-104, an Oral LANCL2 Agonist, for the Treatment of Systemic Lupus Erythematosus
Presentation ID: 1815680
Session: Abstracts: SLE – Animal Models
Date/Time: Saturday, November 6, 2021, from 11:15 to 11:30 a.m. EDT

Highlights Include:

- Oral treatment with LABP-104 protected against worsening from baseline in proteinuria grade in greater than 90% of mice, improved proteinuria grade in roughly 50% of mice and reduced anti-nuclear antibody levels by three-fold.
- Reduced overall histological score in the kidneys, including improvement in interstitial inflammation, glomerular proliferation and cellular crescents as well as significantly reduced effector IL-17+ and IL-21+ CD4+ T cells in the spleen while significantly increasing CD25+ FOXP3+ regulatory CD4+ T cells (Treg).

- Significantly reduced the production of interferon alpha in human peripheral blood mononuclear cells (PBMCs) from SLE patients in response to general, TLR7 and CpG oligonucleotide stimuli.

The presentation will be available under the "Publications" section of the Company's website at www.landosbiopharma.com concurrent with the live presentation on November 6, 2021.

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. As such, there is a high unmet medical need for an alternative 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. Landos expects to enter Phase 1 clinical testing in healthy volunteers in Q4 2021.

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 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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