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 21, 2023

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.)**

P.O. Box 11239 **Blacksburg, Virginia** **(Address of Principal Executive Offices)**	**24062** **(Zip Code)**

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

(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:

☐ 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 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 21, 2023, Landos Biopharma, Inc. (the "Company") issued a press release announcing a peer-reviewed publication describing the safety, tolerability, pharmacokinetic and clinical efficacy results for the NX-13 Phase 1b trial in patients with ulcerative colitis (UC) in the *Journal of Crohn's and Colitis*. A copy of this press release is furnished as Exhibit 99.1 hereto.

The information in this Item 7.01 and Exhibit 99.1 hereto are 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 November 21, 2023.
104	The cover page from Landos Biopharma, Inc.'s Form 8-K filed on November 21, 2023, 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.

Landos Biopharma, Inc.

Date: November 21, 2023

By: /s/ Gregory Oakes

Gregory Oakes

President and Chief Executive Officer

Landos Biopharma Publishes Results of NX-13 Phase 1b Study in Ulcerative Colitis in *Journal of Crohn's and Colitis*

NX-13, a Novel, Oral, NLRX1 Agonist, was Observed to be Well Tolerated and Demonstrated Early Signs of Rapid Symptomatic Relief and Endoscopic Improvement in Patients with Ulcerative Colitis

NEXUS Phase 2 Proof-of-Concept Study is Ongoing, with Top-Line Readout Expected in Q4 2024

NEW YORK, November 21, 2023 –– Landos Biopharma, Inc. (NASDAQ: LABP), a clinical-stage biopharmaceutical company developing novel, oral medicines for patients with autoimmune diseases, today announced a peer-reviewed publication describing the safety, tolerability, pharmacokinetic and clinical efficacy results for the NX-13 Phase 1b trial in patients with ulcerative colitis (UC) in the *Journal of Crohn's and Colitis*.

"We are delighted to have our Phase 1b results of NX-13 in UC published in the Journal of Crohn's and Colitis," said Dr. Fabio Cataldi, Executive Vice-President & Chief Medical Officer at Landos. "The publication highlights the promising data that are the foundation for our ongoing NEXUS Phase 2 trial, which is on track for top-line readout in the fourth quarter of 2024."

The publication, titled "The Safety, Tolerability, Pharmacokinetics and Clinical Efficacy of the NLRX1 agonist NX-13 in Active Ulcerative Colitis: Results of a Phase 1b Study", reports the results of the Phase 1b trial which included 38 patients randomized to placebo (n=5), 250mg immediate release (IR) of NX-13 (n=11), 500mg IR of NX-13 (n=11) or 500mg delayed release NX-13 (n=11). NX-13 was found to be well tolerated in all patients studied. No deaths or severe adverse events were reported and all adverse events were mild to moderate.

The majority of patients treated with NX-13 for four weeks showed consistent and rapid clinical improvement in total Mayo score and in symptoms relief (as measured by rectal bleeding and stool frequency). Additionally, the endoscopic improvement observed correlated closely with symptoms improvement.

"Despite advances in UC treatments, the need for new and novel therapies such as NX-13 remains highly important for patients," commented Bram Verstockt, M.D., Ph.D., and lead author. "The early signs of efficacy, along with a favorable safety profile, highlighted in this publication are encouraging. I am excited about the potential of NX-13 and immunometabolism in breaking the inflammatory cycle in UC, which remains a significant unmet need in effectively treating patients."

NX-13 is currently being evaluated in the NEXUS trial, a randomized, multicenter, double-blind, placebo-controlled, multiple dose, statistically powered, Phase 2 proof-of-concept study (NCT05785715) with top-line results expected in the fourth quarter of 2024.

About Landos Biopharma

Landos Biopharma is a clinical stage biopharmaceutical company focused on the development of first-in-class, oral therapeutics for patients with autoimmune disease. Our mission is to create safer and more effective treatments that address the therapeutic gap in the current treatment paradigm.

We have a portfolio of novel targets anchoring two libraries of immunometabolic modulation pathways, including four potentially first-in-class, once-daily, oral therapies targeting eight indications in the immunology space.

We are currently focused on advancing the clinical development of NX-13 in UC. We initiated the NEXUS Phase 2 proof-of-concept trial in April 2023 and expect to report top-line results in the fourth quarter of 2024.

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 and other statements containing the words “anticipate”, “plan”, “expect”, “may”, “will”, “could”, “believe”, “look forward”, “potential”, 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 current and future clinical trials, including the ongoing Phase 2 trial of NX-13, 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, our anticipated cash runway 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. 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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