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): August 3, 2022

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.)**

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

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

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 Securities Exchange Act of 1934:

Title of each class	Trading symbol	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 August 3, 2022, Landos Biopharma, Inc. issued a press release to announce results from its Phase 1b clinical trial of NX-13 for the treatment of ulcerative colitis. 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 August 3, 2022.
104	The cover page from Landos Biopharma, Inc.'s Form 8-K filed on August 3, 2022, 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: August 3, 2022

/s/ Gregory Oakes
Gregory Oakes
Chief Executive Officer

Exhibit 99.1

Landos Biopharma Reports Positive Top-Line Results From NX-13 Phase 1b Trial

NX-13 Demonstrated Favorable Safety and Tolerability Profile Across Range of Once-Daily Doses

Results Indicate Promising Early Signals Regarding the Efficacy of NX-13

Phase 2 Proof of Concept Clinical Trial in Ulcerative Colitis Planned

NEW YORK, August 3, 2022— Landos Biopharma, Inc. (NASDAQ: LABP), a clinical-stage biopharmaceutical company developing novel, oral medicines for patients with autoimmune diseases, today announced positive top-line results from its Phase 1b clinical trial of NX-13, a novel, oral, NLRX1 agonist in development for the treatment of ulcerative colitis (UC) as a once-daily oral therapy. The data showed that NX-13 was well tolerated following evaluation of multiple doses over four weeks compared with a placebo.

Based on these results, the Company plans to initiate a Phase 2 clinical trial to evaluate the safety, efficacy, and optimal dosing of NX-13 in UC patients.

"We are pleased to announce the successful completion of our Phase 1b trial of NX-13, which marks an important milestone for Landos," said Gregory Oakes, President and CEO of Landos. "NX-13 showed a favorable safety and tolerability profile in UC patients across a range of doses. While the study was shorter in duration than standard induction trials and not powered for efficacy, there was an indication of promising signals of clinical improvement as soon as two weeks in patients' symptoms and four weeks by endoscopy in exploratory endpoints. This early signal, as well as the data from a long-term toxicology study, support the potential of NX-13 as an important new treatment for UC. Landos is eager to advance the learnings from this Phase 1b trial through further analysis of its clinical, pharmacokinetic, and pharmacodynamic data and an appropriately designed proof of concept trial. To this end, Landos plans to advance this product candidate into a Phase 2 clinical trial."

The Phase 1b study was a randomized, double-blind, placebo-controlled study to evaluate safety and pharmacokinetics of NX-13 at multiple dose levels, which was orally administered once-daily over four weeks. 38 adult patients with active UC with a total Mayo score between four and ten were enrolled in the study. Dose arms of 250mg immediate release (IR), 500mg IR, and 500mg modified release (MR) were tested, with each arm containing 11 participants. Five participants received a placebo.

Across the four cohorts, no serious adverse events (SAEs) were reported, consistent with earlier studies in healthy volunteers and preclinical models.

"The continued development of NX-13 is one of several important initiatives underway at Landos," continued Mr. Oakes. "Since joining the Company in June, I have been working closely with the Board of Directors to review the business and finalize the development of a focused plan to advance the pipeline and optimize successful outcomes for our three clinical-stage programs. There is positive momentum underway at Landos, and we are optimistic about the potential for NX-13 for patients suffering from UC. We look forward to providing a comprehensive update on our clinical development plans later this year."

About NX-13

NX-13 is a novel, gut-restricted, orally active, small molecule therapeutic candidate for the treatment of UC. NX-13 targets NLRX1, a mitochondria-associated receptor with the ability to modulate immune responses. By activating the NLRX1 pathway, NX-13 is designed to increase oxidative phosphorylation in immune cells, reduce differentiation of effector CD4-positive T cells, and decrease production of inflammatory cytokines in the gastrointestinal tract.

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. We believe we were the first to identify and target LANCL2, NLRX1 and PLXDC2, which are immunometabolic pathways or targets. We have identified seven novel immunometabolic pathways or targets based on predictions of immunometabolic function using a proprietary advanced artificial intelligence-based integrated computational and experimental precision medicine platform. Our near-term focus is on our clinical-stage programs including omilancor for the treatment of UC, NX-13 for the treatment of UC, and LABP-104 for the potential treatment of systemic lupus erythematosus and rheumatoid arthritis.

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, including NX-13, 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 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.

Contacts

Tanner Kaufman / Kara Sperry
Joele Frank, Wilkinson Brimmer Katcher
212-355-4449