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 14, 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 September 14, 2023, Landos Biopharma, Inc. (the "Company") issued a press release announcing its strategic collaboration agreement to investigate the effect of NX-13 on epithelial cells with the Inflammatory Bowel Disease (IBD) Team at KU Leuven and University Hospitals Leuven (KU Leuven) in Leuven, Belgium. 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 No.	Description
99.1	Press Release, dated September 14, 2023.
104	Cover page Interactive Data File (embedded within the Inline XBRL document).

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: September 14, 2023

By: /s/ Gregory Oakes
Gregory Oakes
Chief Executive Officer

Exhibit 99.1

Landos Biopharma Announces Strategic Research Collaboration with KU Leuven and University Hospitals Leuven to Further Characterize the Effects of NX-13 on Epithelial Cells

Collaboration Will Focus on Defining the Effects Of NX-13 in Ulcerative Colitis Patient Derived Organoid Models

NEW YORK, September 14, 2023 –– Landos Biopharma, Inc. (NASDAQ: LABP), a clinical-stage biopharmaceutical company developing novel, oral medicines for patients with autoimmune diseases, today announced a strategic research collaboration to investigate the effects of NX-13 on epithelial cells with the Inflammatory Bowel Disease (IBD) Team at KU Leuven and University Hospitals Leuven (KU Leuven), a leading European research university and hospital network known for its innovation in Leuven, Belgium.

NX-13 is the first-in-class, oral, gut-selective, NLRX1 agonist with a bimodal mechanism of action that addresses both extracellular signals and the intracellular environment to reduce pro-inflammatory signals restore immune and microbiome balance and improve epithelial barrier integrity. The NEXUS Phase 2 proof-of-concept clinical trial of NX-13 in patients with moderate-to-severe ulcerative colitis (UC) was initiated during the second quarter of 2023. Recruitment, screening and randomization of patients continues, with top-line results on track for the fourth quarter of 2024.

Bram Verstockt, M.D., Ph.D., an assistant professor and IBD specialist at KU Leuven, will lead the research collaboration together with professor Séverine Vermeire, MD, PhD, aiming to elucidate the direct effects of NX-13 in epithelial cells by using UC patient-derived organoid models. These organoid models are ex-vivo 3D cell cultures containing formed mucosal and epithelial layers that mimic in vivo conditions while allowing for controlled in vitro studies. The results are expected to provide further insight into the impact of NX-13 on gene expression and regulation, and cytokine responses.

“We are thrilled to collaborate with Dr. Verstockt and the IBD Team at KU Leuven, an established global research center at the leading edge of clinical and translational research.” commented Dr. Fabio Cataldi, Executive Vice-President & Chief Medical Officer at Landos. “We expect this research will broaden our already strong data foundation for the novel and unique bimodal mechanism of action of NX-13 and further validate the role of immunometabolism in inflammation and IBD.”

“We look forward to collaborating with Landos on NX-13 and believe our patient-derived organoid models are the right system to measure the effect of NX-13 on epithelial cells. We are hoping that the learnings from this research collaboration will support the potential of NX-13 in breaking the vicious inflammatory cycle in UC, which remains a significant unmet need in effectively treating patients” concluded Dr. Verstockt.

Landos expects to present results from this research collaboration at appropriate medical conferences in 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 diseases. 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 the second quarter of 2023 and expect to report topline results by the fourth quarter of 2024.

For more information, please visit www.landosbiopharma.com.

About KU Leuven and University Hospitals Leuven

KU Leuven is Europe’s most innovative university (Reuters) and ranks 42nd in the Times Higher Education World University Rankings. As Belgium's largest university, KU Leuven welcomes 65,000 students from over 140 countries. Its nearly 8,000 researchers are active in a comprehensive range of disciplines. KU Leuven is a founding member of the League of European Research Universities (LERU) and has a strong European and international orientation. University Hospitals Leuven, its network of research hospitals, provides high-quality healthcare and develops new therapeutic and diagnostic insights with an emphasis on translational research.

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, the results of the strategic collaboration with KU Leuven, 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. 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

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