

**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 09, 2023**

**Landos Biopharma, Inc.**

(Exact name of Registrant as Specified in Its Charter)

**Delaware**  
(State or Other Jurisdiction  
of Incorporation)

**001-39971**  
(Commission File Number)

**81-5085535**  
(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 2.02 Results of Operations and Financial Condition.**

On November 9, 2023, Landos Biopharma, Inc. (the “Company”) issued a press release announcing its financial results for the three months ended September 30, 2023. A copy of this press release is furnished as Exhibit 99.1 hereto.

The information in this Item 2.02 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

<u>Exhibit No.</u>	Description
99.1	<a href="#">Press Release, dated November 9, 2023.</a>
104	Cover page Interactive Data File (embedded within the Inline XBRL document).

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**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 9, 2023

By: /s/ Gregory Oakes

Gregory Oakes

Chief Executive Officer

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## Landos Biopharma Provides Company Update and Reports Third Quarter 2023 Results

*NEXUS Phase 2 Clinical Trial of NX-13 for Ulcerative Colitis Remains On Track with Top-line Results Planned for Q4 2024*

*Sufficient Cash to Fund Planned Operations into First Half of 2025*

**NEW YORK, November 9, 2023** -- Landos Biopharma, Inc. (NASDAQ: LABP), a clinical-stage biopharmaceutical company developing novel, oral medicines for patients with autoimmune diseases, today provided a business update and announced financial results for the quarter ended September 30, 2023.

“The NX-13 Phase 2 clinical program (NEXUS) remains our top priority, and we are pleased with our execution and progress during the third quarter,” said Gregory Oakes, President and CEO of Landos. “We believe NX-13 can deliver on the potential of immunometabolism and its role in breaking the inflammatory cycle for the millions of patients suffering from moderate-to-severe ulcerative colitis.”

### Third Quarter 2023 Clinical Development Highlights

NX-13 is a novel, gut-selective NLRX1 agonist in development as a once-daily, oral treatment for ulcerative colitis (UC).

- NEXUS Phase 2 proof-of-concept clinical trial:
    - o The NEXUS trial of NX-13 remains on track as the Company continues to recruit, screen and randomize patients for the trial.
    - o 20 sites in the United States and Europe have been activated.
    - o NEXUS is a randomized, statistically powered, multicenter, double-blind, placebo-controlled, multiple dose, 12-week induction study evaluating 80 patients with moderate-to-severe UC with a long-term extension (LTE) period out to one year. All subjects will be randomized to receive either a 250 mg or 750 mg immediate release dose of NX-13 or placebo. The primary objective of the trial is to evaluate the clinical efficacy, safety and pharmacokinetics of oral NX-13 vs. placebo (NCT05785715 ClinicalTrials.gov).
    - o NEXUS top-line results are expected to be reported in the fourth quarter of 2024.
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- In September 2023, the Company announced a strategic research collaboration with the Inflammatory Bowel Disease Team at KU Leuven and University Hospitals Leuven, a leading European research university and hospital network known for its innovation in Leuven, Belgium. The goal of this collaboration is to further characterize the effects of NX-13 on epithelial cells using UC patient-derived organoid models that mimic in vivo conditions while allowing for controlled in vitro studies. The results are expected to provide additional insights regarding the impact of NX-13 on gene expression, gene regulation and cytokine responses. Results from this research collaboration are expected to be presented at appropriate medical conferences in 2024.
- In October 2023, the Company presented additional findings from its Phase 1b study of NX-13 for the treatment of UC, including detailed results on the rapid symptomatic relief and improvement in multiple biomarkers observed in the study.
  - o Presented two oral presentations and one poster at the United European Gastroenterology Week (UEGW) 2023.
  - o Presented three posters at the American College of Gastroenterology (ACG) 2023 Annual Scientific Meeting.

### **Third Quarter 2023 Financial Highlights**

- As of September 30, 2023, the Company had cash, cash equivalents and marketable securities of \$42.5 million, which it believes will be sufficient to fund operating expenses and capital requirements into the first half of 2025.
- Research and development expenses were \$3.1 million for the third quarter of 2023, compared to \$4.9 million for the third quarter of 2022. The decrease was primarily attributable to the wind down of omilancor and LABP-104 clinical trials and a reduction in NX-13 Phase 1b clinical trial costs, partially offset by initiation of the NEXUS trial. Additionally, there were increases in compensation costs, partially offset by a decrease in consulting costs.
- General and administrative expenses were \$2.1 million for the third quarter of 2023, compared to \$3.0 million for the third quarter of 2022. The decrease was primarily attributable to decreased costs in consulting and Directors & Officers (D&O) insurance.

### **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.

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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](http://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](http://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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**Landos Biopharma, Inc. Unaudited Condensed Consolidated Statements of Operations (in thousands, except share and per share amounts)**

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2023</b>	<b>2022</b>	<b>2023</b>	<b>2022</b>
Operating expenses:				
Research and development	\$ 3,063	\$ 4,862	\$ 8,852	\$ 22,266
General and administrative	2,136	2,967	7,265	11,782
<b>Total operating expenses</b>	<b>5,199</b>	<b>7,829</b>	<b>16,117</b>	<b>34,048</b>
Loss from operations	(5,199)	(7,829)	(16,117)	(34,048)
Other (expense) income, net	(661)	(67)	301	4
Net loss	\$ (5,860)	\$ (7,896)	\$ (15,816)	\$ (34,044)
Net loss per share, basic and diluted	\$ (0.94)	\$ (1.96)	\$ (2.51)	\$ (8.46)
Weighted-average shares used to compute net loss per share, basic and diluted	6,207,638	4,025,489	6,298,846	4,025,489

**Landos Biopharma, Inc. Condensed Consolidated Balance Sheets (in thousands)**

	<b>September 30, 2023</b>	<b>December 31, 2022</b>
	<u>(Unaudited)</u>	
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 42,408	\$ 36,640
Marketable securities, available-for-sale	62	7,762
Restricted cash	50	—
Prepaid expenses and other current assets	710	851
Total current assets	<u>43,230</u>	<u>45,253</u>
Total assets	<u>\$ 43,230</u>	<u>\$ 45,253</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 1,135	\$ 3,435
Accrued liabilities	4,431	2,687
Total current liabilities	<u>5,566</u>	<u>6,122</u>
Total liabilities	<u>5,566</u>	<u>6,122</u>
Commitments and contingencies		
Stockholders' equity:		
Common stock	31	40
Additional paid-in capital	186,877	172,575
Accumulated other comprehensive loss	(1)	(57)
Accumulated deficit	(149,243)	(133,427)
Total stockholders' equity	<u>37,664</u>	<u>39,131</u>
Total liabilities and stockholders' equity	<u>\$ 43,230</u>	<u>\$ 45,253</u>

