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 10, 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.)**

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 10, 2022, Landos Biopharma, Inc. issued a press release announcing its financial results for the three months ended September 30, 2022. 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

Exhibit No.	Description
99.1	Press Release, dated November 10, 2022.
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: November 10, 2022

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

Exhibit 99.1

Landos Biopharma Reports Third Quarter 2022 Results and Provides Business Update

On Track to Complete Comprehensive Review of Clinical Development Plans in the Coming Weeks

NEW YORK, November 10, 2022 — Landos Biopharma, Inc. (NASDAQ: LABP), a clinical-stage biopharmaceutical company developing novel, oral medicines for patients with autoimmune diseases, today announced financial results for the third quarter ended September 30, 2022, and provided a business update.

"Landos has made significant progress advancing our clinical-stage programs – omilancor, NX-13 and LABP-104," said Gregory Oakes, President and CEO of Landos. "In August, we announced positive top-line results from our NX-13 Phase 1b trial, which showed a favorable safety and tolerability profile in ulcerative colitis (UC) patients across a range of doses, as well as promising early efficacy signals. We continue to believe in NX-13's potential to be an important new oral, once-daily treatment for UC."

"We are in the final stages of our comprehensive review of the Company's clinical development plans, and we are working through a few remaining items. This thorough strategic review process has only reinforced our confidence in the significant potential of our promising pipeline and strong foundation of clinical data. We are excited about our future and look forward to providing an update on our plans to advance our clinical-stage assets and position Landos for continued clinical success. We are finalizing our review and expect to provide an update in the coming weeks," continued Mr. Oakes.

Clinical Development Updates

Omilancor
Omilancor is a novel, oral, gut-restricted LANCL2 agonist in development for the treatment of UC as a once-daily oral treatment.

- Landos continues to optimize drug product formulation, including a dose selection assessment. The Company expects to announce both the timing and next steps in the development of omilancor later this year.

NX-13
NX-13 is a novel, oral, gut-restricted NLXR1 agonist in development for the treatment of UC as a once-daily oral treatment.

- In August 2022, the Company announced top-line results from its Phase 1b trial in UC patients. The data showed favorable safety and tolerability across a range of doses, as well as signals of clinical improvement as soon as two weeks in patients' symptoms and four weeks by endoscopy in exploratory endpoints.

- The Company provided additional information regarding results of the NX-13 Phase 1b trial in a supplemental presentation posted on the Company's investor relations website.

- Landos plans to initiate a Phase 2 proof of concept clinical trial of NX-13 in UC patients to evaluate safety, efficacy, and optimal dosing. The Company expects to announce the details and timing of this trial later this year.

LABP-104
LABP-104 is a novel, oral, systemically distributed LANCL2 agonist in development for the treatment of systemic lupus erythematosus (SLE) and/or rheumatoid arthritis (RA) as a once-daily oral treatment.

- Landos conducted a Phase 1a clinical trial of LABP-104 in healthy volunteers and expects top-line results to be reported later this year.

- The Company expects to announce both the timing and next steps in the development of LABP-104 later this year.

Summary of Third Quarter 2022 Results

Cash, Cash Equivalents and Marketable Securities:
As of September 30, 2022, the Company had cash, cash equivalents and marketable securities of $48.0 million, which it believes will be sufficient to fund its planned operations for at least the next 12 months. The Company plans to provide further details regarding its operating plans and capital resources upon completion of the portfolio review later this year.

Research and Development Expenses:
Research and development expenses were $4.9 million for the third quarter of 2022, compared to $9.3 million in the third quarter of 2021. The decrease of $4.4 million was primarily attributed to a decrease in clinical research organization and clinical data management costs, as well as a decrease in compensation costs upon terminating further enrollment in two omilancor clinical trials for the treatment of Crohn's Disease.

General and Administrative Expenses:
General and administrative expenses were $3.0 million for the third quarter of 2022, compared to $3.1 million in the third quarter of 2021. The decrease of $0.1 million was primarily attributable to a decrease in consulting costs, partially offset by increases in employee-related expenses, including stock-based compensation, as well as an increase in legal fees.

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 omilancor, NX-13 and LABP-104, 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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenue - license fee:	$ -	$ -	$ -	$ 18,000
Operating expenses:				
Research and development	4,862	9,344	22,266	28,120
General and administrative	2,967	3,059	11,782	8,300
Total operating expenses	7,829	12,403	34,048	36,420
Loss from operations	(7,829)	(12,403)	(34,048)	(18,420)
Other income (loss), net	(67)	(201)	4	95
Net loss	$ (7,896)	$ (12,604)	$ (34,044)	$ (18,325)
Net loss per share, basic and diluted	$ (0.20)	$ (0.32)	$ (0.85)	$ (0.50)
Weighted-average shares used to compute net loss per share, basic and diluted	40,254,890	39,962,069	40,254,890	36,662,627

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

	September 30, 2022	December 31, 2021
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 28,880	$ 8,305
Marketable securities, available-for-sale	19,111	82,575
Prepaid expenses and other current assets	1,497	1,266
Total current assets	49,488	92,146
Property and equipment, net	—	707
Other assets	—	26
Total assets	$ 49,488	$ 92,879
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,204	$ 12,908
Accrued liabilities	2,271	3,703
Total current liabilities	5,475	16,611
Total liabilities	5,475	16,611
Commitments and contingencies		
Stockholders’ equity:		
Common stock	403	403
Additional paid-in capital	172,016	170,241
Accumulated other comprehensive loss	(211)	(225)
Accumulated deficit	(128,195)	(94,151)
Total stockholders’ equity	44,013	76,268
Total liabilities and stockholders’ equity	$ 49,488	$ 92,879