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): May 12, 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.)**

1800 Kraft Drive, Suite 216 **Blacksburg, Virginia** **(Address of Principal Executive Offices)**	**24060** **(Zip Code)**

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

Not Applicable
(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 (see General Instructions A.2. below):

☐ 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 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 May 12, 2022, Landos Biopharma, Inc. issued a press release announcing its financial results for the three months ended March 31, 2022. A copy of this press release is furnished as Exhibit 99.1 hereto.

The information in this Item 2.02 and the Exhibit 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 May 12, 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, as amended, the Company has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Landos Biopharma, Inc.

Dated: May 12, 2022

By: /s/ Tim M. Mayleben
Tim M. Mayleben
President and Chief Executive Officer

FOR IMMEDIATE RELEASE

Landos Biopharma Reports First Quarter 2022 Results and Provides Business Update

On Track to Complete Review of Clinical Development Plans by Mid-2022

Top-Line Results for NX-13 Phase 1b and LABP-104 Phase 1 Trials Remain On Track for Mid-2022

Plans to Announce Timing of Phase 2b Trial of Omilancor Later this Year

NEW YORK, May 12, 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 first quarter ended March 31, 2022 and provided a business update.

“We are making strong progress on the review of our clinical development plans and look forward to providing a comprehensive update by mid-year,” said Chris Garabedian, Chairman of the Board. “Our entire team remains focused on advancing our three clinical-stage product candidates – omilancor, NX-13 and LABP-104. We are confident in our path forward as we build momentum for these programs.”

“We are pleased with our progress in building a drug-development-focused team and streamlining the company. We remain highly confident in the scientific foundations of Landos and the potential of our clinical-stage programs to address the therapeutic needs of patients suffering from autoimmune diseases,” said Tim Mayleben, Interim President and CEO of Landos. “Our team is finalizing focused development plans for omilancor, NX-13 and LABP-104, which we believe will optimize successful outcomes for these programs. We look forward to providing our clinical development roadmap as we deliver on our goals of enhancing value for patients, physicians and shareholders.”

Clinical Development Updates

Omilancor

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

- Landos is continuing to work on a reformulated drug product candidate, 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.

- The Phase 1b trial of NX-13 in moderate UC patients is expected to achieve data base lock in the second quarter of 2022, with top-line results on track for the third quarter of 2022.

- Long-term toxicology studies for NX-13 are now complete, with results on track for the third quarter of 2022.
- The timing for initiation of a Phase 2 clinical trial of NX-13 in moderate-to-severe UC patients is expected to be announced later this year.

LABP-104

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

- Landos is conducting a Phase 1a trial of LABP-104 evaluating the safety, tolerability and pharmacokinetics of LABP-104 in healthy volunteers. Landos expects to report top-line results from this trial in mid-2022.
- Landos expects to announce the timing for the initiation of a Phase 2 trial of LABP-104 later this year.

Summary of First Quarter 2022 Results

Cash, Cash Equivalents and Marketable Securities:

As of March 31, 2022, the Company had cash, cash equivalents and marketable securities of approximately $73.8 million, which it believes will be sufficient to fund planned operations into the second half of 2023.

Research and Development Expenses:

Research and development expenses were $10.8 million for the first quarter of 2022, compared to $7.3 million in the first quarter of 2021. The increase was primarily attributable to increased costs associated with the Company's ongoing development activities related to omilancor, NX-13 and LABP-104. Costs in the first quarter of 2022 include those related to closing two trials of omilancor for the treatment of patients with moderate-to-severe Crohn's Disease.

General and Administrative Expenses:

General and administrative expenses were $4.2 million for the first quarter of 2022, compared to $2.6 million in the first quarter of 2021. The increase was primarily attributable to increased compensation related expenses, including stock-based compensation, increased expenses related to professional services and insurance, other costs associated with becoming a public company and a one-time charge incurred in connection with a lease termination of approximately $0.3 million.

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. Our core expertise is the discovery of novel pathways at the interface of immunity and metabolism. We leverage our proprietary advanced artificial intelligence-based integrated computational and experimental precision medicine platform, our LANCE platform, to identify novel therapeutic targets based on predictions of immunometabolic function. We then identify and create novel therapeutic

candidates to engage those novel targets in areas of unmet medical need. We have identified seven novel immunometabolic pathways or targets. 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 SLE and/or RA.

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, the Company's anticipated milestones and future expectations and plans and prospects for the Company, the impact of the Company's reallocation of resources and anticipated related cost savings 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 March 31,	
	2022	**2021**
Operating expenses:		
Research and development	$ 10,800	$ 7,254
General and administrative	4,153	2,646
Total operating expenses	14,953	9,900
Loss from operations	(14,953)	(9,900)
Interest and other income, net	89	82
Net loss	$ (14,864)	$ (9,818)
Net loss per share, basic and diluted	$ (0.37)	$ (0.38)
Weighted-average number of shares used to compute net loss per share, basic and diluted	40,254,890	26,070,455

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

	March 21, 2022 (Unaudited)	**December 31, 2021**
Assets		
Current assets:		
Cash and cash equivalents	$ 11,288	$ 8,305
Marketable securities, available-for-sale	62,508	82,575
Prepaid expenses and other current assets	3,563	1,266
Total current assets	77,359	92,146
Property and equipment, net	224	707
Other assets	27	26
Total assets	$ 77,610	$ 92,879
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 9,803	$ 12,908
Accrued liabilities	5,704	3,703
Total current liabilities	15,507	16,611
Total liabilities	15,507	16,611
Commitments and contingencies		
Stockholders' equity:		
Common stock	403	403
Additional paid-in-capital	171,182	170,241
Accumulated other comprehensive loss	(467)	(225)
Accumulated deficit	(109,015)	(94,151)
Total stockholders' equity	62,103	76,268
Total liabilities and stockholders' equity	$ 77,610	$ 92,879