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 15, 2021

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 November 15, 2021, Landos Biopharma, Inc. (the "**Registrant**") issued a press release announcing its financial results for the quarter ended September 30, 2021. This press release has been furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

In accordance with General Instruction B.2. of Form 8-K, the information in this Item 2.02, and Exhibit 99.1 hereto, 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 liability of that section, nor shall it be deemed incorporated by reference in any of the Registrant's filings under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any incorporation language in such a filing, 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 November 15, 2021
104	The cover page from Landos Biopharma, Inc.'s Form 8-K filed on November 15, 2021, formatted in Inline XBRL.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Landos Biopharma, Inc.

Dated: November 15, 2021

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

Exhibit 99.1

Landos Biopharma Reports Third Quarter 2021 Financial Results and Provides Corporate Update

Enhancing Focus on High-Impact Clinical-Stage Programs to Ensure Optimal Path to Commercialization

Refining Ulcerative Colitis Clinical Development Plans for Omilancor to Generate Additional Phase 2b Data Prior to Initiating Pivotal Phase 3 Program

Determining Optimal Enrollment for Phase 2 Clinical Study of Omilancor in Crohn's Disease and Phase 1b Study of NX-13 in UC

Initiated Dosing for LABP-104 in Healthy Volunteers in October 2021 with Results Expected in 1H 2022

Corporate Update Conference Call Scheduled for 8:00 am ET Today

BLACKSBURG, Va., November 15, 2021 – Landos Biopharma, Inc. (NASDAQ: LABP), a clinical-stage biopharmaceutical company utilizing its LANCE® Advanced A.I. platform to discover and develop novel therapeutics for patients with autoimmune diseases, today announced financial results for the third quarter ended September 30, 2021 and provided a corporate update on its clinical development plans.

"Landos is well-positioned to continue its evolution as a biopharmaceutical company. In parallel with our search for Landos' next leader, our Board, leadership team and advisors are reviewing our product development strategies and clinical plans to ensure that we are focusing on the most value-enhancing near-and long-term opportunities," said Tim Mayleben, Interim President and CEO of Landos. "Landos has already established itself as a research and discovery leader based on the productivity of the LANCE Advanced A.I. platform. Leveraging that success, we are taking steps to evaluate and optimize our product development and clinical strategies, and we will be prioritizing our three clinical-stage product candidates, omilancor, NX-13, and LABP-104, and concentrating on the immune-mediated inflammatory disease indications of ulcerative colitis, Crohn's disease, Eosinophilic Esophagitis, Systemic Lupus Erthematosus, and Rheumatoid Arthritis. In addition, we will be reviewing our preclinical programs to optimize the priorities and sequence of these product candidates and their respective clinical applications. We believe that narrowing our focus on advancing our core, high-impact clinical-stage programs will support the strongest outcomes for these product candidates and best position Landos for regulatory approval and commercial success in the future. We look forward to providing continued updates on our progress and deliver value for patients and our shareholders."

Clinical Development Updates

Omilancor

Omilancor is a novel, oral, gut-restricted LANCL2 agonist in development for the treatment of ulcerative colitis (UC), Crohn's disease (CD) and Eosinophilic Esophagitis (EoE) as a once-daily oral treatment.

- In October 2021, Landos presented positive translational data from the Phase 2 trial of omilancor in mild-to-moderate UC at United European Gastroenterology Week (UEGW). Patients remaining on omilancor after the induction phase of the trial maintained low Mayo scores and showed little to no symptoms beyond 1 year of treatment, with nearly 90% of patients achieving remission thresholds in stool frequency and rectal bleeding after 36 weeks of open-label treatment.

- Prior to initiating a pivotal Phase 3 study, Landos plans to leverage the results of the prior Phase 2 study of omilancor in mild-to-moderate UC patients to design and initiate a Phase 2b study in 2022. The Phase 2b study is expected to provide additional data to inform the pivotal Phase 3 study design and support regulatory approval.
- Enrollment in the Phase 2 trial of omilancor in moderate-to-severe CD continues. Landos is actively evaluating the sample size to ensure the Company optimizes the powering of its data. Given the ongoing evaluation, Landos is removing prior guidance for the timing of top-line results.
- Landos plans to file an orphan drug designation application for pediatric UC patients in Q4 2021.

NX-13

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

- In October 2021, Landos presented results of its Phase 1a trial of NX-13 in healthy volunteers at UEGW 2021. The trial met all primary and secondary endpoints. The data also demonstrated a signal of efficacy in terms of lowering fecal calprotectin levels, increasing IL-10 concentrations and decreasing IL-6 concentrations in plasma.
- Enrollment in the Phase 1b trial of NX-13 in the U.S. and Europe continues. Landos is actively evaluating the sample size to ensure the Company optimizes the powering of its data. Given the ongoing evaluation, Landos is removing prior guidance for the timing of top-line results.

LABP-104

LABP-104 is a novel, oral, systemically distributed LANCL2 agonist in development for the treatment of systemic lupus erythematosus (SLE) and rheumatoid arthritis (RA) as a once-daily oral treatment. LABP-104 activates the LANCL2 pathway to restore the immune system to homeostasis through the enhancement of regulatory T cell (Treg) function and increasing mitochondrial metabolism.

- In September 2021, Landos announced that the preclinical results of LABP-104 in SLE were accepted for an oral presentation at the American College of Rheumatology Convergence 2021 in November. The presentation will highlight how oral treatment with LABP-104 resulted in enhanced Treg function, maintained kidney function and reduced type I interferon signaling.
- Landos received FDA clearance in October 2021 of an IND for LABP-104 for the treatment of SLE and RA. A Phase 1 trial has been initiated to evaluate the safety, tolerability and pharmacokinetics of LABP-104 in healthy volunteers. Top-line results from this study are expected in 1H 2022.

Summary of Third Quarter 2021 Financial Results

Cash, Cash Equivalents and Marketable Securities:

As of September 30, 2021, the Company had cash, cash equivalents and marketable securities of $102.7 million, which it believes will be sufficient to fund planned operations through the end of 2023.

Research and Development (“R&D”) Expenses:

Research and development expenses were $9.3 million for the three months ended September 30, 2021 compared to $7.0 million for the three months ended September 30, 2020. The increase of $2.3 million was primarily attributable to increased costs associated with ongoing development activities related to omilancor, NX-13 and LABP-104.

General and Administrative (“G&A”) Expenses:

General and administrative expenses were $3.1 million for the three months ended September 30, 2021 compared to $1.5 million for the three months ended September 30, 2020. The increase of $1.6 million was primarily attributable to increases in D&O insurance costs and administrative expenses related to increased headcount.

Other Income (Expense):

Other expense, net was $0.2 million for the three months ended September 30, 2021 compared to other income, net of $0.2 million in the three months ended September 30, 2020. The change of $0.4 million was due to amortization of bond premium from investment activity and the gains (losses) from foreign exchange.

Conference Call Information

Landos will host a corporate update conference call today at 8:00 am ET. A webcast for this call can be accessed at https://ir.landosbiopharma.com/, or by dialing 1-877-317-6789 (Toll Free) or 1-412-317-6789 (International) and asking to join the Landos Corporate Update call. The webcast will be archived and be available for replay on the Company’s investor relations website.

About Landos Biopharma

Landos Biopharma is a clinical-stage biopharmaceutical company utilizing its LANCE® Advanced A.I. platform to discover and develop novel oral therapeutics for patients with autoimmune diseases. Using the LANCE® platform, the Company discovers new mechanisms of action, including the LANCL2, NLRX1 and PLXDC2 immunometabolic pathways at the interface of immunity and metabolism. Landos’ lead product candidate, omilancor, targets the LANCL2 pathway and is a novel oral, gut-restricted, small molecule first-in-class therapeutic in development for the treatment of ulcerative colitis, Crohn’s disease and Eosinophilic Esophagitis. Landos’ second product candidate, NX-13, targets the NLRX1 pathway and is a novel, oral, gut-restricted small molecule first-in-class therapeutic in development for the treatment of ulcerative colitis. Landos discovered and is also developing LABP-104, a novel, oral systemically distributed small molecule first-in-class therapeutic targeting the LANCL2 pathway for the treatment of systemic lupus erythematosus (SLE) and rheumatoid arthritis (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 and other statements containing the words “anticipate”, “plan”, “expect”, “may”, “will”, “could”, 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 Balance Sheets
(in thousands, except share and per share amounts)

	September 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 17,893	$ 2,416
Marketable securities, available for-sale	84,777	25,718
Incentive and tax receivables	3	154
Prepaid expenses and other current assets	1,645	202
Deferred offering costs	—	1,398
Total current assets	104,318	29,888
Property, plant and equipment, net	780	444
Total assets	$ 105,098	$ 30,332
Liabilities, convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 10,114	$ 8,606
Accrued liabilities	726	1,939
Other current liabilities	255	489
Total current liabilities	11,095	11,034
Other liabilities	85	276
Total liabilities	11,180	11,310
Commitments and contingencies		
Convertible preferred stock, $0.01 par value; no shares authorized, issued or outstanding as of September 30, 2021; 11,260,608 shares authorized, issued and outstanding as of December 31, 2020; aggregate liquidation preference of $70,254 as of December 31, 2020	—	73,037
Stockholders' equity (deficit)		
Common stock, $0.01 par value; 200,000,000 shares authorized, 40,053,157 and 12,767,909 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively	401	71
Additional paid-in-capital	167,440	1,633
Accumulated other comprehensive income	131	10
Accumulated deficit	(74,054)	(55,729)
Total stockholders' equity (deficit)	93,918	(54,015)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 105,098	$ 30,332

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenue – License Fee	$ —	$ —	$ 18,000	$ —
Operating expenses:				
Research and development	9,344	6,966	28,120	15,379
General and administrative	3,059	1,453	8,300	3,898
Total operating expenses	12,403	8,419	36,420	19,277
Loss from operations	(12,403)	(8,419)	(18,420)	(19,277)
Other income (expense):				
Gain (loss) from foreign exchange	(10)	84	3	37
Other income (expense), net	(191)	105	92	437
Other income (expense), net	(201)	189	95	474
Net loss	$ (12,604)	$ (8,230)	$ (18,325)	$ (18,803)
Net loss per share, basic and diluted	$ (0.32)	$ (0.67)	$ (0.50)	$ (1.56)
Weighted-average number of shares used to compute net loss per share, basic and diluted	39,962,069	12,260,804	36,662,627	12,068,515
Net loss	$ (12,604)	$ (8,230)	$ (18,325)	$ (18,803)
Unrealized gain on available-for-sales securities	273	25	121	113
Comprehensive loss	$ (12,331)	$ (8,205)	$ (18,204)	$ (18,690)