Landos Biopharma Provides Business Update and Reports Fourth Quarter and Full Year 2023 Results

March 21, 2024

Top-line Results from the NEXUS Phase 2 Clinical Trial of NX-13 for Ulcerative Colitis Planned for Q4 2024

Sufficient Cash to Fund Planned Operations into mid-2025

NEW YORK, March 21, 2024 (GLOBE NEWSWIRE) -- Landos Biopharma, Inc. (NASDAQ: LABP) ("Landos" or "the Company"), a clinical-stage biopharmaceutical company developing novel, oral medicines for patients with autoimmune diseases, today provided a business update and reported financial results for the fourth quarter and the full year ended December 31, 2023.

"We were focused in 2023 on advancing the NX-13 clinical program and establishing Landos as a leader in targeting immunometabolic pathways and developing novel and first-in-class, oral therapies for autoimmune diseases," said Gregory Oakes, President and CEO of Landos. "We continue to advance the NEXUS Phase 2 study of NX-13 in ulcerative colitis and are excited about the strong momentum we have generated."

Fourth Quarter 2023 and Recent Highlights

- NEXUS is a Phase 2 proof-of-concept clinical trial of NX-13, a novel, gut-selective NLRX1 agonist, in development as a once-daily, oral treatment for ulcerative colitis ("UC").
  - The Company continues to recruit, screen and randomize patients for the trial in the United States and Europe, with 28 sites activated to date.
  - NEXUS, evaluating the clinical efficacy, safety and pharmacokinetics of oral NX-13, is a randomized, 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 are randomized to receive either a 250 mg or 750 mg immediate release dose of NX-13 or placebo (NCT05785715).
  - Top-line results are planned for the fourth quarter of 2024.
- In October 2023, the Company presented two oral presentations and one poster at the United European Gastroenterology Week (UEGW) and three posters at the American College of Gastroenterology (ACG) 2023 Annual Scientific Meeting. These presentations included additional findings from the 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.
- In November 2023, a peer-reviewed manuscript describing the safety, tolerability, pharmacokinetic and clinical efficacy results for the NX-13 Phase 1b trial in patients with UC was published in the *Journal of Crohn's and Colitis* .
- In February 2024, the Company presented six abstracts at the 19th Annual Congress of the European Crohn's and Colitis Organisation (ECCO) in Stockholm, Sweden. These poster presentations highlighted new and additional data on immunometabolism modulation by activating NLRX1 and PLXDC2 with novel agonists such as NX-13 and LABP-69.

Summary of Fourth Quarter and Full Year 2023 Financial Results

Cash and Cash Equivalents

- As of December 31, 2023, the Company had cash and cash equivalents of $37.5 million, which it believes will be sufficient to fund planned operations into mid-2025.

Fourth Quarter 2023

- Research and development expenses were $3.1 million for the fourth quarter of 2023, compared to $3.4 million for the fourth quarter of 2022. The decrease was primarily attributable to reduced clinical activities due to the wind down of the omilancor and LABP-104 programs and a reduction in NX-13 Phase 1b clinical trial expenses, partially offset by the initiation of the NX-13 Phase 2 trial.
- General and administrative expenses were $3.5 million for the fourth quarter of 2023, compared to $3.1 million for the fourth quarter of 2022. The increase was primarily attributable to an increase in legal expenses, partially offset by a decrease in insurance and compensation expenses.

Full Year 2023

- Research and development expenses were $12.0 million for the full year ended December 31, 2023, compared to $25.7

million for the full year ended December 31, 2022. The decrease was primarily attributable to reduced clinical activities due to the wind down of the omilancor and LABP-104 programs and a reduction in NX-13 Phase 1b clinical trial expenses, partially offset by the initiation of the NX-13 Phase 2 trial.

- General and administrative expenses were $10.7 million for the full year ended December 31, 2023, compared to $14.9 million for the full year ended December 31, 2022. The decrease was primarily attributable to a decrease in compensation, insurance, and consulting expenses, partially offset by an increase in legal expenses.

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 oral 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 multiple 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 plan to report topline results in the fourth quarter of 2024.

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 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, the Company's 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. 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.

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

	Three Months Ended December 31,		Year Ended December 31,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 3,147	$ 3,414	$ 11,999	$ 25,680
General and administrative	3,463	3,099	10,728	14,881
Total operating expenses	6,610	6,513	22,727	40,561
Loss from operations	(6,610)	(6,513)	(22,727)	(40,561)
Other income, net	491	1,281	792	1,285
Net loss	$ (6,119)	$ (5,232)	$ (21,935)	$ (39,276)
Net loss per share, basic and diluted	$ (0.99)	$ (1.30)	$ (3.50)	$ (9.76)
Weighted-average shares used to compute net loss per share, basic and diluted	6,207,637	4,025,489	6,275,856	4,025,489

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

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 37,499	$ 36,640
Marketable securities, available-for-sale	—	7,762
Restricted cash	50	—
Prepaid expenses and other current assets	491	851
Total current assets	38,040	45,253
Total assets	$ 38,040	$ 45,253
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,375	$ 3,435
Accrued liabilities	4,874	2,687
Total current liabilities	6,249	6,122
Total liabilities	6,249	6,122
Commitments and contingencies		
Stockholders' equity:		
Common stock	31	40
Additional paid-in capital	187,122	172,575
Accumulated other comprehensive loss	—	(57)
Accumulated deficit	(155,362)	(133,427)
Total stockholders' equity	31,791	39,131
Total liabilities and stockholders' equity	$ 38,040	$ 45,253