Landos Biopharma Provides Business Update and Reports Fourth Quarter and Full Year 2022 Results

March 23, 2023

On Track to Initiate Phase 2 Proof-of-Concept Trial in Ulcerative Colitis for NX-13 in the Second Quarter of 2023 and Report Topline Results by the Fourth Quarter of 2024

Projected Cash Runway into First Half of 2025

NEW YORK, March 23, 2023 (GLOBE NEWSWIRE) -- 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 fourth quarter and full year ended December 31, 2022.

“Meaningful progress has been made this year as we streamlined our product candidate portfolio to focus on our most promising asset. We believe Landos is uniquely positioned to transform the treatment paradigm for patients with ulcerative colitis with our novel, oral, once-daily treatment NX-13,” said Gregory Oakes, President and CEO of Landos. “Our capital efficient approach focuses resources towards advancing the clinical development of NX-13, while maximizing our ability to create value for our shareholders.”

NX-13 Clinical Development Updates
NX-13 is a novel, gut-selective NLXR1 agonist in development as a once-daily, oral treatment for ulcerative colitis (UC).

- In August 2022, the Company announced top-line results from the Phase 1b trial in patients with UC with early signals of clinical improvement as soon as two weeks in patients’ symptoms and four weeks by endoscopy in exploratory endpoints. Favorable safety and tolerability was shown across a range of doses.
- Pharmacokinetic (PK) and Pharmacodynamic (PD) data preliminary analyses demonstrated promising signals of target engagement and molecular dose response among 250 mg and 500 mg immediate release doses.
- *Next Steps:* Our Phase 2 proof-of-concept clinical trial remains on-track for initiation in the second quarter of 2023, with plans to share topline results by the fourth quarter of 2024.

Corporate Updates

- Updated clinical development strategy to focus exclusively on the NX-13 UC program, following a comprehensive review of the entire portfolio to ensure we are pursuing the most promising therapies and target indications.
- Secured $16.7 million in funding from Landos’ largest shareholder, Perceptive Advisors, through the sale of prefunded warrants.
- Announced the transfer of the LANCL portfolio, including omilancor, LABP-104 and LABP-111, to Landos’ founder and former CEO and certain affiliated individuals and entities. Under the terms of the transaction, the Company transferred the assets and paid $3.0 million in cash in exchange for approximately 9.1 million Landos shares previously held by Dr. Bassaganya-Riera and certain affiliated individuals and entities, representing approximately 23% of Landos’ outstanding shares. Additionally, the parties have entered into a royalty agreement whereby Landos will receive a 6% royalty on future commercial net sales from any approved products developed from the LANCL portfolio and Dr. Bassaganya-Riera and certain affiliated individuals and entities will receive a 2% royalty on future net sales from NX-13, LABP-73, LABP-66 and LABP-69, if approved. The parties have also agreed to a mutual, general release of liabilities and claims.

Summary of Fourth Quarter and Full Year 2022 Results

Cash, Cash Equivalents and Marketable Securities:

- We believe that our existing cash, cash equivalents and marketable securities as of December 31, 2022, in addition to the $16.7 million in gross proceeds from our private placement of pre-funded warrants in January 2023, will be sufficient to fund our operating expenses and capital requirements into the first half of 2025.

Quarter Ended December 31, 2022

- Research and development expenses were $3.4 million for the quarter ended December 31, 2022, compared to $13.4 million for the quarter ended December 31, 2021. The decrease was primarily attributed to reduced clinical activities due to

the wind down of omilancor and LABP-104-related clinical trials, as well as decreases in employee-related expenses.

- General and administrative expenses were $3.1 million for the quarter ended December 31, 2022, compared to $7.0 million for the quarter ended December 31, 2021. The decrease was primarily attributable to a decrease in consulting costs, employee-related expenses and office-related expenses.

Year Ended December 31, 2022

- Research and development expenses were $25.7 million for the full year ended December 31, 2022, compared to $41.6 million for the full year ended December 31, 2021. The decrease was primarily attributed to reduced clinical activities due to the wind down of omilancor and LABP-104 related clinical trials, as well as decreases in employee-related expenses, partially offset by increases in costs associated with the clinical development of NX-13.

- General and administrative expenses were $14.9 million for the full year ended December 31, 2022, compared to $15.3 million for the full year ended December 31, 2021. The decrease was primarily attributable to a reduction in consulting costs and office-related 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 disease. 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.

We are currently focused on advancing the clinical development of NX-13 in UC and are on-track to initiate a Phase 2 proof-of-concept trial in the second quarter of 2023, with plans to share topline data by 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 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 future clinical trials, including the planned 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 ability of Dr. Bassaganya-Riera and certain affiliated individuals and entities to successfully develop and commercialize the LANCL platform in order for Landos to receive royalties on sales of such products, 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. 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

Investors
Patrick Truesdell, Vice President and Controller
Landos Biopharma
ir@landosbiopharma.com

John Mullaly
LifeSci Advisors, LLC
jmullaly@lifesciadvisors.com

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

	Quarters Ended December 31,		Years Ended December 31,	
	2022	2021	2022	2021
Revenue - license fee:	$ -	$ -	$ -	$ 18,000
Operating expenses:				
Research and development	3,414	13,444	25,680	41,564

General and administrative	3,099	6,952	14,881	15,252
Total operating expenses	6,513	20,396	40,561	56,816
Loss from operations	(6,513)	(20,396)	(40,561)	(38,816)
Other income (loss), net	1,281	299	1,285	394
Net loss	$ (5,232)	$ (20,097)	$ (39,276)	$ (38,422)
Net loss per share, basic and diluted	$ (0.13)	$ (0.50)	$ (0.98)	$ (1.02)
Weighted-average shares used to compute net loss per share, basic and diluted	40,254,890	40,169,747	40,254,890	37,558,464

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

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 36,640	$ 8,305
Marketable securities, available-for-sale	7,762	82,575
Prepaid expenses and other current assets	851	1,266
Total current assets	45,253	92,146
Property and equipment, net	—	707
Other assets	—	26
Total assets	$ 45,253	$ 92,879
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,435	$ 12,908
Accrued liabilities	2,687	3,703
Total current liabilities	6,122	16,611
Total liabilities	6,122	16,611
Commitments and contingencies		
Stockholders' equity:		
Common stock	403	403
Additional paid-in capital	172,212	170,241
Accumulated other comprehensive loss	(57)	(225)
Accumulated deficit	(133,427)	(94,151)
Total stockholders' equity	39,131	76,268
Total liabilities and stockholders' equity	$ 45,253	$ 92,879