Landos Biopharma Reports Second Quarter 2022 Results and Provides Business Update

August 11, 2022

Positive Top-Line Results From NX-13 Phase 1b Trial in Ulcerative Colitis Demonstrate a Favorable Safety and Tolerability Profile Across Range of Once-Daily Oral Doses, as well as Promising Early Efficacy Signals

Phase 2 Proof of Concept Clinical Trial for NX-13 in Ulcerative Colitis Planned

On Track to Complete Comprehensive Review of Clinical Development Plans Later this Year

NEW YORK, Aug. 11, 2022 (GLOBE NEWSWIRE) -- 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 second quarter ended June 30, 2022, and provided a business update.

“Landos continues to make progress advancing our clinical-stage programs – omilancor, NX-13 and LABP-104 – and positioning the Company for the future,” said Gregory Oakes, President and CEO of Landos. “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. The results support our belief that NX-13 has the potential to be an important new oral, once-daily treatment for UC. These positive results also highlight our sharpened strategic focus on pursuing what we believe are the most promising molecules and target indications.”

“As we finalize our comprehensive review of the Company’s clinical development plans, Landos is well positioned to advance our clinical stage assets and deliver on our mission of addressing the therapeutic gap for patients with autoimmune diseases. We look forward to providing a comprehensive update on our pipeline later this year,” 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 NLRX1 agonist in development for the treatment of UC as a once-daily oral treatment.

- The Company recently 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 the safety, efficacy, and optimal dosing.

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 trial of LABP-104 in healthy volunteers and expects topline 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 Second Quarter 2022 Results

Cash, Cash Equivalents and Marketable Securities:
As of June 30, 2022, the Company had cash, cash equivalents and marketable securities of $55.8 million, which it believes will be sufficient to fund its planned operations for at least the next 12 months. Upon completion of its portfolio prioritization review later this year, the Company will provide further details into its operating plans and capital resources.

Research and Development Expenses:
Research and development expenses were $6.6 million for the second quarter of 2022, compared to $11.5 million in the second quarter of 2021. The decrease was primarily attributed to a reduction in contract research and clinical data management costs following the planned termination of further enrollment in two clinical trials of omilancor for the treatment of Crohn’s Disease. This was partially offset by an increase in consulting and temporary labor costs for the three months ended June 30, 2022.

General and Administrative Expenses:
General and administrative expenses were $4.7 million for the second quarter of 2022, compared to $2.6 million in the second quarter of 2021. The increase was primarily attributable to increases in employee-related expenses, including stock-based compensation, as well as an increase in recruiting and 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

Tanner Kaufman / Kara Sperry
Joele Frank, Wilkinson Brimmer Katcher
212-355-4449

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Revenue - license fee:	$ —	$18,000	$ —	$18,000
Operating expenses:				
Research and development	$6,604	$11,522	$17,404	$18,776
General and administrative	4,662	2,596	8,815	5,241
Total operating expenses	11,266	14,118	26,219	24,017
(Loss) income from operations	(11,266)	3,882	(26,219)	(6,017)
Other (loss) income, net	(18)	215	71	296
Net (loss) income	$(11,284)	$4,097	$(26,148)	$(5,721)
Net (loss) income per share, basic and diluted	$(0.28)	$0.12	$(0.65)	$(0.19)
Weighted-average shares used to compute net (loss) income per share, basic	40,254,890	33,639,481	40,254,890	29,875,877
Weighted-average shares used to compute net (loss) income per share, diluted	40,254,890	34,384,784	40,254,890	29,875,877

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

	June 30, 2022	December 31, 2021
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$19,241	$8,305
Marketable securities, available-for-sale	36,510	82,575
Prepaid expenses and other current assets	2,287	1,266
Total current assets	58,038	92,146

Property and equipment, net	—	707
Other assets	—	26
Total assets	$58,038	$92,879
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$4,711	$12,908
Accrued liabilities	1,799	3,703
Total current liabilities	6,510	16,611
Total liabilities	6,510	16,611
Commitments and contingencies		
Stockholders’ equity:		
Common stock	403	403
Additional paid-in capital	171,816	170,241
Accumulated other comprehensive loss	(392)	(225)
Accumulated deficit	(120,299)	(94,151)
Total stockholders’ equity	51,528	76,268
Total liabilities and stockholders’ equity	$58,038	$92,879