Landos Biopharma Reports Fourth Quarter and Full Year 2021 Results and Provides Business Update

March 24, 2022

Continued Progress Towards Optimizing Clinical Development Plans

On Track to Initiate Phase 2b Study of Omilancor in Ulcerative Colitis Later this Year

Completed Enrollment of Phase 1b Trial of NX-13 in Ulcerative Colitis and Phase 1a Trial of LABP-104 in Normal Healthy Volunteers; Top Line Results for Both Studies Expected in Mid-2022

BLACKSBURG, Va., March 24, 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 fourth quarter and full year ended December 31, 2021, and provided a business update.

“Over the past several months, we have continued to make progress on our strategic review of Landos’ programs, which has further reinforced our decision to focus on our three clinical-stage product candidates – omilancor, NX-13 and LABP-104,” said Chris Garabedian, Chairman of the Board. “Our search for a permanent CEO is well underway and we are actively advancing our development programs while refining our clinical development roadmap and bolstering key talent across the organization. With our enhanced focus on pursuing the most promising therapies and target indications, we are confident Landos will create value for patients, physicians and shareholders alike. We look forward to sharing our clinical results and development plans later this year.”

“Consistent with our sharpened clinical focus, we have been recruiting highly experienced drug development leaders to position us for future development success,” said Tim Mayleben, Interim President and CEO of Landos. “We are actively allocating resources and talent towards our three clinical-stage product candidates, and as a result, we have reduced headcount in other parts of the organization, which will provide Landos with future operating efficiencies as we progress our clinical strategy. While decisions that affect people are never easy, we are focused on building a targeted and committed team to drive our programs to success.”

Mr. Mayleben continued, “The goal of the ongoing clinical review is to optimize development plans and create multiple near-term value drivers for Landos’ portfolio. To that end, we are developing comprehensive strategies for each of our clinical-stage programs, leveraging our data and past learnings to inform trial designs, including optimizing dosing and drug product formulations, determining the optimal clinical endpoints, powering assumptions and regulatory strategy. In addition to our ongoing clinical strategy work, we continue to explore potential partnerships to support Landos’ internal development efforts. We remain confident in the significant opportunities for Landos to address the needs of patients suffering from autoimmune diseases and deliver value for patients, physicians 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) as a once-daily oral treatment.

- As previously disclosed, Landos is leveraging the results of the prior Phase 2 study of omilancor in UC patients to design a Phase 2b study in moderate and severe UC patients. In Q1 2022, Landos completed an exhaustive re-analysis of the Phase 2 data and initiated a re-evaluation of doses and drug product formulations. These ongoing efforts will help guide the design of the Phase 2b study beginning later this year. Landos looks forward to sharing the results of these efforts and plans for the Phase 2b study when it initiates the study, which is expected to occur before the end of 2022.

- In January, Landos halted further enrollment in the Phase 2 trial of omilancor in moderate-to-severe Crohn’s Disease for a number of reasons, including low enrollment, and plans to fully close out the study over the next two quarters. Landos will evaluate reinitiating clinical development in CD pending results of the expected Phase 2b study in moderate and severe UC.

- Landos no longer plans to file an orphan drug designation application for pediatric UC patients.

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.

- In March 2022, Landos completed enrollment in the Phase 1b trial of NX-13 in moderate and severe UC patients. The Company remains on-track to report top-line results in mid-2022.

- Landos is completing long-term toxicology studies for NX-13, which are well underway. These studies are on-track for completion in Q3 2022.

- Landos will announce the design and timing for initiation of a Phase 2 study of NX-13 in moderate and severe UC patients 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 received FDA clearance of an IND for LABP-104 in October 2021. In March 2022, Landos completed enrollment in the Phase 1 trial of LABP-104 evaluating the safety, tolerability and pharmacokinetics of LABP-104 in healthy volunteers. The Company remains on-track to report top-line results from this study in mid-2022.

- Landos is initiating long-term toxicology studies for LABP-104 with full results expected in early 2023.

- Landos will announce the design and timing for initiation of a Phase 2 study of LABP-104 for the potential treatment of SLE or RA later this year.

Additional Business Updates

- Appointed Roger Adsett, a seasoned healthcare executive with extensive experience developing and commercializing innovative IBD and GI therapies, to the Landos Board, with plans to recruit additional Board members in 2022.

- Continuing to strengthen leadership team with highly experienced drug development leaders.

- Actively allocating resources and talent towards clinical-stage assets. Reduced headcount by over 50% consistent with enhanced focused on our three most promising programs. Substantial operating cost efficiencies expected to be fully realized in the second half of 2022.

Summary of Fourth Quarter and Full Year 2021 Results

Cash, Cash Equivalents and Marketable Securities:
As of December 31, 2021, the Company had cash, cash equivalents and marketable securities of approximately $91 million, which it believes will be sufficient to fund planned operations into the second half of 2023.

Revenue:
In May 2021, we received an upfront cash payment of $18.0 million from LianBio in connection with the May 2021 grant of an exclusive license for them to develop, manufacture and commercialize omilancor and NX-13 in China and other specified territories. No similar payments were received in any other periods.

Research and Development Expenses:
Research and development expenses were $13.4 million for the three months ended December 31, 2021 and $41.6 million for the full year ended December 31, 2021, compared to $10.0 million and $25.3 million for the comparable periods in 2020. The increase in both periods was primarily attributable to increased costs associated with ongoing development activities related to omilancor, NX-13 and LABP-104 and an increase in headcount.

General and Administrative Expenses:
General and administrative expenses were $7.0 million for the three months ended December 31, 2021 and $15.3 million for the full year ended December 31, 2021, compared to $1.4 million and $5.3 million for the comparable periods in 2020. The increase in both periods was primarily attributable to increased costs associated with operating as a public company, including insurance and legal, costs incurred in connection with the management transition announced in November 2021 and an increase in headcount.

Net Loss:
Net loss was $20.1 million for the three months ended December 31, 2021 and $38.4 million for the full year ended December 31, 2021, compared to $11.3 million and $30.1 million for the comparable periods in 2020.

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 ulcerative colitis, or UC, NX-13 for the treatment of UC and LABP-104 for the potential treatment of systemic lupus erythematosus, or SLE, and rheumatoid arthritis, 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 cost savings related to

such right-sizing 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

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

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

	Years Ended December 31,	
	2021	**2020**
Revenue – License Fee	$ 18,000	$ -
Operating expenses:		
Research and development	41,564	25,338
General and administrative	15,252	5,338
Total operating expenses	56,816	30,676
Loss from operations	(38,816)	(30,676)
Interest and other income, net	394	532
Net loss	$ (38,422)	$ (30,144)
Net loss per share, basic and diluted	$ (1.02)	$ (2.47)
Weighted-average number of shares used to compute net loss per share, basic and diluted	37,558,464	12,227,823

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

	December 31,	
	2021	**2020**
Assets		
Current assets:		
Cash and cash equivalents	$ 8,305	$ 2,416
Marketable securities, available for-sale	82,575	25,718
Prepaid expenses and other current assets	1,266	356
Deferred offering costs	-	1,398
Total current assets	92,146	29,888
Property and equipment, net	707	444
Other assets	26	-
Total assets	$ 92,879	$ 30,332
Liabilities, Convertible Preferred Stock and Stockholders’ Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 12,908	$ 8,606
Accrued liabilities	3,703	1,939
Other current liabilities	-	489
Total current liabilities	16,611	11,034
Other liabilities	-	276

Total liabilities	16,611	11,310
Commitments and contingencies	-	-
Convertible preferred stock	-	73,037
Stockholders' equity (deficit):		
Common stock	403	71
Additional paid-in-capital	170,241	1,633
Accumulated other comprehensive (loss) income	(225)	10
Accumulated deficit	(94,151)	(55,729)
Total stockholders' equity (deficit)	76,268	(54,015)
Total liabilities, convertible preferred stock, and stockholders' equity (deficit)	$ 92,879	$ 30,332