Landos Biopharma Reports Second Quarter 2021 Financial Results and Provides Business Updates

July 29, 2021

Following the recent positive End-of-Phase 2 meeting with the FDA, Landos initiated global pivotal Phase 3 clinical trial site feasibility studies of omilancor in ulcerative colitis (UC)

Initiated enrollment of Phase 2 trial of omilancor in Crohn's Disease (CD);
topline data expected in 1H 2022

Initiated enrollment of Phase 1b trial of NX-13 in UC;
topline data expected in 1H 2022

Entered into non-dilutive strategic agreement with LianBio, including $18 million upfront and an up to $200 million commitment in future milestone payments,
to develop and commercialize omilancor and NX-13 for China and select Asian markets

Ended Q2 2021 with all programs on track and in a strong financial position, including $115 million in cash and operating runway extending until the end of 2023

Awarded a $3 million grant from the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) to study the clinical efficacy and mechanism of action of omilancor in CD patients

BLACKSBURG, Va., July 29, 2021 (GLOBE NEWSWIRE) -- Landos Biopharma, Inc (NASDAQ: LABP), a late-clinical-stage biopharmaceutical company utilizing its LANCE® Advanced A.I. platform to develop novel oral therapeutics for patients with autoimmune diseases, today announced financial results for the second quarter ended June 30, 2021 and provided business updates.

"We made substantial progress during the second quarter to advance omilancor, our novel once-daily, oral, gut-restricted candidate, toward global pivotal Phase 3 clinical trials for mild-to-moderate ulcerative colitis patients," said Dr. Josep Bassaganya-Riera, Ph.D., Chairman, President, and CEO of Landos. "During the second quarter, we initiated patient enrollment in two additional clinical trials, each of which we expect will deliver promising topline data during the first half of 2022. We also strengthened our capital position and operating runway with a non-dilutive strategic agreement with LianBio, including $18 million received upfront and an up to $200 million commitment in future milestone payments, to develop and commercialize omilancor and NX-13 for Greater China and select Asian markets. In addition, we look forward to collaborating with the Mount Sinai School of Medicine and New York Gastroenterology Associates on an upcoming trial of omilancor in CD funded with a $3 million NIH grant, underscoring omilancor's potential as a transformative therapy for patients living with CD and other autoimmune diseases."

"Furthermore, our proprietary LANCE ® A.I. platform continues to help accelerate our drug development efforts by uncovering new pathways and prioritizing associated new precision medicine candidates based on their ability to modulate specific types of immune responses," added Dr. Josep Bassaganya-Riera. "In short, the Landos team remains laser-focused on building significant value for all shareholders with omilancor and each of our 17 product candidates in our portfolio of oral disease-modifying precision medicine drugs that target new immunometabolic mechanisms."

Recent Highlights and Upcoming Milestones:

Omilancor
Omilancor is a novel, once-daily, oral, gut-restricted LANCL2 agonist in development for the treatment of ulcerative colitis (UC), Crohn's disease (CD), Eosinophilic Esophagitis (EoE) and in topical cream formulation for psoriasis and atopic dermatitis. These 5 indications alone have the potential of targeting combined prescription market volumes that are expected to grow to $157 billion by 2029. Landos has a strong patent position of 48 patents on omilancor in 43 countries with a long patent life.

Omilancor - UC

- In July 2021, Landos advanced the global pivotal Phase 3 program in UC with the initiation of clinical trial site feasibility studies in 32 countries and hundreds of sites worldwide.
- In July 2021, Landos announced that positive data from the Phase 2 trial of omilancor in UC was accepted for oral presentation at the United European Gastroenterology Week (UEGW) 2021, taking place October 3-5, 2021. The new translational data of omilancor in UC demonstrated that after 12 weeks of treatment, patients had 55% lower IL-6 colonic concentrations and 44% lower TNF-alpha colonic concentrations. This data is consistent with the increased levels of regulatory CD4+ T cells, myeloid cells and IL-10 expression in remitters (p = 0.036), as well as the statistically significant decrease in TNF-alpha expressing myeloid cells (p = 0.037) in the colonic mucosa of UC patients and the statistically significant normalization of fecal calprotectin levels (p = 0.048) observed in the successful Phase 2 trial. The UEGW presentation will also illustrate that patients treated with omilancor maintained low Mayo scores and UC 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.
- In June 2021, Landos reported a positive outcome from an End-of-Phase 2 meeting with the U.S. Food and Drug

Administration (FDA) for omilancor in mild-to-moderate UC patients. Landos and the FDA agreed on key elements necessary for regulatory approval, enabling the Company to initiate the pivotal global Phase 3 program, consisting of two simultaneous global trials: PACIFY I and PACIFY II. The studies will be conducted for patients with mild-to-moderate active UC, measuring a single dose of omilancor versus placebo. The company believes that the agreed upon patient inclusion criteria of the pending global Phase 3 omilancor program in UC may make omilancor eligible for approximately 90% of all UC patients, encompassing pre-biologics patients and patients who failed biologics. According to Global Data, sales of UC drugs in the U.S. in 2021 are anticipated to approximate $5.7 billion and may reach $7.3 billion in 2025 when omilancor may be ready to be commercialized.

Omilancor - CD

- In July 2021, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) at the National Institutes of Health (NIH), awarded Landos a $3 million competitive R01 grant to study the clinical efficacy and mechanism of action of omilancor in CD patients. The project provides an independent peer scientific and clinical validation of Landos' novel mechanisms and drug development efforts. The clinical trial is a part of a clinical research collaboration between Landos, Mount Sinai School of Medicine and New York Gastroenterology Associates.
- In May 2021, Landos dosed the first patient in an ongoing Phase 2 trial of omilancor in moderate-to-severe CD. Results from the Phase 2 trial are anticipated in 1H 2022. According to market research, in 2020, prescription therapeutics used to treat CD in the United States generated approximately $10.7 billion in sales and are anticipated to grow at over 4.1% per annum over the coming years.

Omilancor – Psoriasis

- In May 2021, Landos presented a late-breaking abstract of omilancor in psoriasis at the 2021 American Association of Immunologists (AAI) Annual Meeting. The data showed that omilancor, when delivered topically, could significantly suppress inflammation and reduce disease severity in preclinical mouse models of psoriasis by activating key immunometabolic mechanisms. Landos expects to initiate a Phase 1b trial of omilancor in psoriasis in 2022. According to market research, in 2020, prescription therapeutics used to treat psoriasis in the U.S. generated over $9.5 billion in sales and are anticipated to grow over 5.2% per year over the coming decade.

Omilancor – Atopic Dermatitis (AD)

- Landos anticipates filing an IND for omilancor in AD in 1H 2022. According to market research, prescription therapeutics used to manage the symptoms of AD generated approximately $6.5 billion in sales in 2020 and are anticipated to grow in excess of 10.0% per year over the coming years.

Omilancor – EoE

- In April 2021, the FDA cleared the Company's IND application of omilancor for the treatment of EoE. Utilizing Landos' rapidly dissolving orodispersable tablet formulation, omilancor is formulated to enable exposure to the upper gastrointestinal tract. Landos expects to initiate a Phase 1b trial of omilancor in EoE in 1H 2022 and anticipates receiving an orphan drug designation for this indication from the FDA in 2H 2021. EoE is frequently underdiagnosed but is nonetheless estimated to affect up to 135,000 patients in the U.S., growing at approximately 6.0% per annum. Based on our market research, we believe that a safe, oral drug, with biologic like or better efficacy may potentially capture a large share of each of the markets that we are targeting with omilancor.

NX-13

NX-13 is a novel, once-daily, oral, gut-restricted NLRX1 targeting compound in development for the treatment of UC and CD, with plans to also target irritable bowel syndrome (IBS). According to Global Data, prescription therapeutics used to manage the symptoms of IBD generated approximately $15 billion in sales in 2020 and are anticipated to grow in excess of 4% per year over the coming years. The IBS treatment market size is estimated to reach over $2 billion by 2026, registering a CAGR of 8.2% from 2019 to 2026. Landos has patents on NX-13 in the U.S., a patent application accepted for issuance in Canada, and additional national and regional patent applications that have the possibility of yielding patent protection in over 50 additional countries.

- In April 2021, Landos dosed the first patient in a Phase 1b clinical study of NX-13 in UC. Results from the study are anticipated in the 1H 2022.
- Landos will present an abstract containing the results of our Phase 1a trial of NX-13 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.
- Landos plans to file an IND for NX-13 in irritable bowel syndrome in Q4 2021 and is planning IND filings for additional indications.

LABP-104

A novel, once-daily, systemically distributed small molecule anti-inflammatory therapeutic targeting and activating the LANCL2 pathway for the treatment of lupus erythematosus and rheumatoid arthritis. Marketable sales for Lupus and Rheumatoid Arthritis are expected to grow at an annual growth rate of 7.0% and 1.0% respectively, to nearly $32.7 billion combined. Landos has a patent application on LABP-104 accepted for issuance in the U.S., an international (Patent Cooperation Treaty) patent application available for filing in over 150 contracting states, and a patent application in Argentina.

- In July 2021, Landos completed IND-enabling studies for LABP-104.
- Landos' advanced A.I. LANCE ® platform identified a transcriptional signature in whole blood capable of classifying LABP-104-treated individuals in both healthy and lupus conditions.
- Landos expects to submit two IND applications to the FDA for LABP-104 in lupus and rheumatoid arthritis in Q3 2021.
- Landos expects to advance LABP-104 into a Phase 1a clinical trial in the fourth quarter of 2021 for systemic lupus erythematosus and rheumatoid arthritis. Data readout is expected in 1H 2022.

LABP-69

LABP-69 is an oral, once-daily, systemically distributed first-in-class PLXDC2 agonist for the treatment of rheumatoid arthritis and diabetic nephropathy. Landos has patent applications on LABP-69 in the U.S. and Argentina and an international (Patent Cooperation Treaty) patent application available for filing in over 150 contracting states.

- In May 2021, Landos presented a late-breaking abstract of LABP-69 in rheumatoid arthritis at the 2021 AAI Annual Meeting. The preclinical data demonstrated that activating the PLXDC2 pathway led to a decrease of inflammation, anti-angiogenic actions and enhanced preservation of joint structure in animal models.
- Landos expects to file two INDs for LABP-69 in rheumatoid arthritis and diabetic nephropathy in 1H 2022. An estimated 9.3 million Americans suffer from diabetic nephropathy which is expected to increase at an average growth rate of 4.2% annually to 12.9 billion by 2029. The marketable sales are estimated to grow from $3.7 billion in 2021 to nearly $6.0 billion by 2029 at an average growth rate of 4.7% annually.

Corporate Highlights:

- In May 2021, Landos entered into a collaboration and license agreement with LianBio to develop and commercialize omilancor and NX-13 in Greater China and select Asian markets. Landos received an upfront cash payment of $18 million from LianBio and is eligible to receive development and commercial milestone payments of up to $200 million as well as low- to mid-double-digit royalties on omilancor and NX-13 net sales in the licensed territories. Landos anticipates satisfying the terms of the agreement to realize up to $95 million in development related milestones over the coming three years. Under the agreement, LianBio will also help to recruit up to 25% of the patients in the pending global Phase 3 trials of omilancor (i.e., PACIFY I and PACIFY II) in UC.
- We are actively seeking non-dilutive product candidate licensing agreements that may include meaningful upfront cash payments, milestone and royalty payments on future sales globally and/or select territories outside the United States for our pipeline while advancing our core programs to commercialization in the United States.

Summary of Second Quarter 2021 Financial Results

Cash, Cash Equivalents and Marketable Securities:

- As of June 30, 2021, the Company had cash, cash equivalents and marketable securities of $115.1 million, which it believes will be sufficient to fund its planned operations through the end of 2023. This amount includes the $18 million upfront cash payment associated with the LianBio development and commercialization agreement.

Research and Development ("R&D") Expenses:

- Research and development expenses were $11.5 million for the three months ended June 30, 2021 compared to $3.7 million for the three months ended June 30, 2020. The increase of $7.8 million was primarily attributable to increased costs associated with ongoing clinical trial activities for omilancor and NX-13, and preclinical IND-enabling activities for LABP-104.

General and Administrative ("G&A") Expenses:

- General and administrative expenses were $2.6 million for the three months ended June 30, 2021 compared to $1.4 million for the three months ended June 30, 2020. The increase of $1.2 million was primarily attributable to increases in D&O insurance costs and administrative expenses related to increased headcount.

Net Income (Loss):

- Our net gain was $4.1 million for the three months ended June 30, 2021 compared to a net loss of $4.8 million in the three

months ended June 30, 2020. The gain is attributable to a one-time receipt by the company of $18.0 million cash payment as part of the non-dilutive strategic agreement with LianBio for the development and potential commercialization of omilancor and NX-13 in China and other Asian territories.

About Omilancor

Discovered using Landos' proprietary LANCE ® Advanced A.I. platform, omilancor is a novel, oral, gut-restricted small molecule investigational drug that targets the Lanthionine Synthetase C-Like 2 (LANCL2) pathway impacting the gastrointestinal tract. LANCL2 plays an important role in the immunoregulatory process. By activating the LANCL2 pathway and modulating the interactions between immunological and metabolic signals in immune cells, omilancor is designed to create a favorable regulatory microenvironment in the gut, decreasing the production of key inflammatory mediators and increasing anti-inflammatory markers in regulatory T cells (Treg) within the site of inflammation. Landos reported continued positive Phase 2 results of omilancor evaluating patients with ulcerative colitis in 2021 and following a positive end-of-Phase 2 meeting has initiated site feasibility studies for its global pivotal Phase 3 program (PACIFY I and PACIFY II trials) in patients with mild-to-moderately active UC. Additionally, Landos initiated a Phase 2 trial of omilancor in patients with Crohn's disease in the first half of 2021 with topline results expected in the first half of 2022.

About NX-13

Discovered using Landos' proprietary LANCE ® A.I. platform**,** NX-13 is a first-in-class, gut-restricted, small molecule therapeutic candidate for the treatment of ulcerative colitis (US) and Crohn's disease (CD). NX-13 targets NLRX1, a mitochondria-associated receptor with the ability to modulate immune responses. By activating the NLRX1 pathway, NX-13 increases autophagy and oxidative phosphorylation in immune cells, while decreasing differentiation of effector CD4+ T cells, reactive oxygen species, inflammasome formation and production of inflammatory cytokines. The Company reported positive results from the Phase 1a study of NX-13 in healthy volunteers in Q1 2021, initiated a Phase 1b study of NX-13 in patients with ulcerative colitis in Q2 2021 and expects data readout in Q1 2022.

About Landos Biopharma

Landos Biopharma is a late-clinical-stage biopharmaceutical company utilizing its LANCE® Advanced A.I. platform to discover and develop novel oral therapeutics for patients with autoimmune diseases. LANCE has discovered new mechanisms of action, including the LANCL2, NLRX1 and PLXDC2 immunometabolic pathways. Landos Biopharma has 17 active development programs targeting these novel pathways at the interface of immunity and metabolism. Lead asset omilancor is a novel gut-restricted small molecule drug candidate for the treatment of ulcerative colitis, Crohn's disease, Eosinophilic Esophagitis and, in topical formulation, for psoriasis and atopic dermatitis that targets the LANCL2 pathway. NX-13 is a novel, gut-restricted small molecule drug candidate for the treatment of inflammatory bowel disease, that targets the NLRX1 pathway. Additional candidates are in development for the treatment of lupus nephritis, rheumatoid arthritis, multiple sclerosis, and diabetes. For more information, please visit www.landosbiopharma.com.

Cautionary Note on Forward-Looking Statements

Any 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 by 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 our business are described in detail in our Securities and Exchange Commission ("SEC") filings, including in our 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 we make 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:

Michael K. Levitan (investors)
Solebury Trout
646-378-2920
mlevitan@soleburytrout.com

Hannah Gendel (media)
Solebury Trout
646-378-2943
hgendel@soleburytrout.com

Landos Biopharma, Inc.
Condensed Consolidated Balance Sheets
(Unaudited)
(in thousands, except share and per share amounts)

	June 30, 2021	December 31, 2020
Assets		

Current assets:		
Cash and cash equivalents	$ 18,687	$ 2,416
Marketable securities, available for sale	96,440	25,718
Incentive and tax receivables	2	154
Prepaid expenses and other current assets	2,598	202
Deferred offering costs	—	1,398
Total current assets	117,727	29,888
Property, plant and equipment-net	564	444
Total assets	$ 118,291	$ 30,332
Liabilities, convertible preferred stock and stockholders' (deficit) equity		
Current liabilities:		
Accounts payable	$ 10,685	$ 8,606
Accrued liabilities	1,590	1,939
Other current liabilities	255	489
Total current liabilities	12,530	11,034
Other liabilities	149	276
Total liabilities	12,679	11,310
Commitments and Contingencies	—	—
Convertible preferred stock, $0.01 par value; no shares authorized, issued or outstanding as of June 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' (deficit) equity:		
Preferred stock, $0.01 par value; 10,000,000 shares authorized, no shares issued or outstanding as of June 30,2021	—	—
Common stock, $0.01 par value; 200,000,000 shares authorized, 39,900,886 shares issued and outstanding as of June 30, 2021; 12,767,909 shares issued and outstanding as of December 31, 2020	399	71
Additional paid-in-capital	166,805	1,633
Accumulated other comprehensive gain (loss)	(142)	10
Accumulated deficit	(61,450)	(55,729)
Total stockholders' (deficit) equity	105,612	(54,015)
Total liabilities, convertible preferred stock and stockholders' (deficit) equity	$ 118,291	$ 30,332

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	**2020**	**2021**	**2020**
Revenue - License Fee:	$ 18,000		$ 18,000	
Operating expenses:				
Research and development	11,522	3,723	18,776	$ 8,413
General and administrative	2,596	1,365	5,241	2,445
Total operating expenses	14,118	5,088	24,017	10,858
Gain/(Loss) from operations	3,882	(5,088)	(6,017)	(10,858)
Other income (expenses):				
R&D Incentive Income	41	—	41	—
Gain/(loss) from foreign exchange	(5)	175	13	(47)
Other income, net	179	136	242	332
Other income (expense), net	215	311	296	285
Net income/(loss)	4,097	(4,777)	(5,721)	(10,573)
Net income/(loss) per share, basic and diluted	0.12	(0.73)	(0.19)	(1.61)
Weighted-average shares used to compute net loss per share, basic	33,639,481	12,067,905	29,875,877	11,971,314
Weighted-average shares used to compute net loss per share, diluted	34,384,784	12,067,905	29,875,877	11,971,314
Net income/(loss)	4,097	(4,777)	(5,721)	(10,573)

Unrealized gain/(loss) on available-for-sale securities	(40)	774	(152)	88
Comprehensive income/(loss)	4,057	(4,003)	(5,873)	(10,485)