# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**Washington, D.C. 20549**

# FORM 8-K

**CURRENT REPORT**
**PURSUANT TO SECTION 13 OR 15(d)**
**OF THE SECURITIES EXCHANGE ACT OF 1934**

**Date of Report (Date of earliest event reported) October 6, 2021**

# Landos Biopharma, Inc.
**(Exact name of Registrant as Specified in its Charter)**

| Delaware | 001-39971 | 81-5085535 |
|---|---|---|
| (State or Other Jurisdiction of Incorporation) | (Commission file Number) | (IRS Employer Identification No.) |

| 1800 Kraft Drive, Suite 216, Blacksburg, Virginia | 24060 |
|---|---|
| (Address of Principal Executive Offices) | (Zip Code) |

**Registrant's telephone number, including area code (540) 218-2232**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-2 under the Exchange Act (17 CFR 240.14a-2)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|---|---|---|
| **Common Stock, par value $0.01 per share** | **LABP** | **The Nasdaq Stock Market LLC** |

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

**Item 7.01 Regulation FD Disclosure.**

On October 6, 2021, Landos Biopharma, Inc. issued the press release furnished herewith as Exhibit 99.1 to announce the publication of a peer-reviewed article in *Scientific Reports* titled "First-in-class topical therapeutic omilancor ameliorates disease severity and inflammation through activation of the LANCL2 pathway in psoriasis." The article describes omilancor's therapeutic efficacy in animal models of psoriasis.

The information in this Item 7.01 of this Current Report on Form 8-K (including Exhibit 99.1) is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

**Item 9.01 Financial Statements and Exhibits.**

**(d) Exhibits**

| | |
|---|---|
| 99.1 | Press Release of Landos Biopharma, Inc., dated October 6, 2021 |
| 104 | The cover page from Landos Biopharma, Inc.'s Form 8-K filed on October 8, 2021, formatted in Inline XBRL. |

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized on this 8th day of October, 2021.

LANDOS BIOPHARMA, INC.

By: */s/ Josep Bassaganya-Riera*
Name: Josep Bassaganya-Riera
Title: Chairman, President and Chief Executive Officer

**Exhibit 99.1**

**Landos Biopharma Announces Publication in Scientific Reports of Novel Preclinical Findings Demonstrating Omilancor's Therapeutic Potential in Models of Psoriasis and Further Validating the LANCL2 Mechanism**

BLACKSBURG, Va., Oct. 06, 2021 — Landos Biopharma, Inc. (NASDAQ: LABP), a late-clinical-stage biopharmaceutical company utilizing its LANCE® Advanced A.I. platform to discover and develop novel therapeutics for patients with autoimmune diseases, today announced the publication of a peer-reviewed article titled "First-in-class topical therapeutic omilancor ameliorates disease severity and inflammation through activation of the LANCL2 pathway in psoriasis" in *Scientific Reports*. The peer-reviewed publication demonstrates omilancor's therapeutic efficacy in animal models of psoriasis.

"The results published in *Scientific Reports* showcase for the first time omilancor's therapeutic potential as a topical therapeutic for psoriasis, a chronic autoimmune condition impacting over 100 million patients globally," said Dr. Josep Bassaganya-Riera, Chairman, President, and CEO of Landos. "Omilancor is currently in clinical development for three indications – ulcerative colitis, Crohn's disease and eosinophilic esophagitis. Demonstrating therapeutic efficacy of a topical omilancor formulation in non-Gastrointestinal indications further validates LANCL2 activation and broadens the therapeutic potential of the LANCE A.I. platform and expansible inflammation and immunology pipeline. The topical omilancor formulation has the potential to offer patients a new, non-steroidal treatment for psoriasis leveraging the innovative LANCL2-based mechanism of action and could be a safe and effective long-term treatment option for this widespread and often debilitating skin condition."

The *Scientific Reports* article reports novel results from two preclinical models of psoriasis where administration of omilancor topically reduced disease severity, resulting in a 60% reduction of psoriasis area and severity index (PASI) score, a two-fold decrease of skin thickness and scaling and over 50% reduction of inflammatory reactions within the lymph nodes and spleen. Furthermore, activation of the LANCL2 pathway by omilancor through engagement of immunometabolic mechanisms led to significant downregulation of proinflammatory markers, decreased induction of Th17 responses and activation of skin cells without inducing systemic immune suppression. Overall, topical omilancor treatment promoted the preservation of healthy skin composition and structure and demonstrated the potential to restore tissue homeostasis.

The published *Scientific Reports* article will be available under the "Publications" section of the Company's website at www.landosbiopharma.com.

**About Psoriasis**

Psoriasis is a skin disorder that commonly manifests as plaque psoriasis, in which skin thickens and takes on a scaly appearance due to over-proliferation and dysregulated differentiation of skin cells. This over-proliferation and abnormal differentiation results from chronic inflammation of the skin, associated with infiltration and activation of key inflammatory subsets, such as dendritic cells, Th17 cells, and neutrophils. This often results in itchy and persistent rashes and has a significant impact on quality of life for patients. In terms of management, typically topical corticosteroids or immunosuppressants are used. For more severe cases or those presenting with psoriatic arthritis, systemic immunosuppressants (methotrexate, cyclosporine) or biologics targeting TNF or the IL-12/-23 pathway are prescribed. Similar to their usage in other autoimmune diseases, biologics and immunosuppressants require monitoring of liver functions and immunosuppression, as these agents have been linked to increased risks of infections and cancers. There is an urgent need to develop an alternative frontline therapy.

**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 enhancing regulatory T cells (Treg) function within the site of inflammation. Landos reported continued positive Phase 2 results of omilancor evaluating patients with ulcerative colitis (UC) in 2021 and, following a positive End-of-Phase-2 meeting, has initiated site feasibility studies for its global pivotal Phase 3 clinical program (PACIFY I and PACIFY II trials) in patients with mild-to-moderately active UC. Additionally, Landos has initiated two Phase 2 trials of omilancor for patients with Crohn's disease, with topline results for the first of these trials, involving 150 patients, expected in the first half of 2022. Landos also anticipates initiation of Phase 1 studies in eosinophilic esophagitis in 2022. Omilancor is also being studied in a topical formulation for psoriasis and atopic dermatitis.

**About Landos Biopharma**

Landos Biopharma is a late-clinical-stage biopharmaceutical company utilizing its LANCE® Advanced A.I. platform to discover and develop novel therapeutics for patients with autoimmune diseases. Using the LANCE® platform, the Company 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. Its lead product candidate, omilancor, targets the LANCL2 pathway and is a novel oral, gut-restricted, small-molecule potentially first-in-class therapeutic currently being prepared for global pivotal Phase 3 trials for the treatment of ulcerative colitis, in two active Phase 2 trials in Crohn's disease, and is anticipated to initiate Phase 1 studies in eosinophilic esophagitis in 2022. Omilancor is also being studied in a topical formulation for psoriasis and atopic dermatitis. Landos has another novel, oral, gut-restricted small-molecule drug candidate, NX-13, that is being investigated in an active Phase 1b trial in ulcerative colitis. NX-13 targets the NLRX1 pathway. Landos' sixth new product candidate, LABP-104, will be entering Phase 1 clinical testing in healthy volunteers in Q4 of 2021. Additional product candidates are in development for the treatment of lupus nephritis, rheumatoid arthritis, multiple sclerosis, Alzheimer's disease, non-alcoholic steatohepatitis (NASH), asthma, chronic obstructive pulmonary disease (COPD), diabetes, and diabetic nephropathy. 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 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.

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