

**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): August 26, 2021

Landos Biopharma, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-39971
(Commission
File Number)

81-5085535
(IRS Employer
Identification No.)

**1800 Kraft Drive, Suite 216
Blacksburg, Virginia**
(Address of Principal Executive Offices)

24060
(Zip Code)

(540) 218-2232
(Registrant's Telephone Number, Including Area Code)

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

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 (see General Instructions A.2. below):

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ 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 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 August 26, 2021, Landos Biopharma, Inc. (the “**Company**”) issued a press release to announce a research collaboration into the NLRX1 Pathway in Multiple Sclerosis with Johns Hopkins University School of Medicine. A copy of the press release is furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K.

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

<u>Exhibit Number</u>	<u>Exhibit Description</u>
99.1	Press Release, dated August 26, 2021.
104	The cover page from Landos Biopharma, Inc.’s Form 8-K filed on August 26, 2021, formatted in Inline XBRL.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Landos Biopharma, Inc.

Dated: August 26, 2021

By: /s/ Josep Bassaganya-Riera

Josep Bassaganya-Riera

Chief Executive Officer

Landos Biopharma Announces Research Collaboration into the NLRX1 Pathway in Multiple Sclerosis with Johns Hopkins University School of Medicine

BLACKSBURG, Va., August 26, 2021 — 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 that it has entered into a research collaboration with Peter Calabresi, M.D., Director of the Multiple Sclerosis Center and Professor of Neurology at Johns Hopkins University (JHU) School of Medicine. This research funded by the National Institutes of Health (NIH) will focus on further validating the NLRX1 immunometabolic pathway in Multiple Sclerosis (MS).

“We are honored to collaborate with Dr. Calabresi to continue research on the NLRX1 pathway with the goal to develop disease-modifying precision therapies in central nervous system (CNS) disorders, including MS,” said Dr. Josep Bassaganya-Riera, Chairman, President, and CEO of Landos. “Similar to our pioneering work on the NLRX1 pathway in autoimmune diseases and the recent positive, de-risking results for NX-13, our lead NLRX1 agonist for ulcerative colitis and Crohn’s disease, we are excited to further investigate the translatability of these ground-breaking scientific discoveries in treating CNS diseases and look forward to advancing LABP-66 and other therapeutic candidates in our extensive inflammation and immunology portfolio into clinical testing.”

Current treatments for MS are designed to target a single cell type in the brain. In contrast, Landos’ candidate LABP-66 is designed to target the NLRX1 pathway in the CNS and in turn, promote beneficial effects in CD4+ T cells, microglia and neurons. Moreover, Landos’ pioneering research on the importance of the NLRX1 pathway in immunometabolic control of CD4+ T cells and other autoimmune diseases is complementary to the research Dr. Calabresi is conducting at JHU. LABP-66 has the potential to become an improved treatment option for patients with MS and Alzheimer’s Disease.

Landos’ novel NLRX1 agonist, LABP-66, is an oral once-daily therapy in development for the treatment of MS, Alzheimer’s Disease, and other debilitating CNS diseases. Approximately 1.0 million Americans suffer from MS, which is expected to grow to 1.2 million by 2028. The market for MS drugs is expected to increase from \$18.6 billion in 2021 to \$26.6 billion by the year 2028 at an average growth rate of 5.2% annually. Of note, a majority of these sales are from biologics (injectables); LABP-66 is an oral therapeutic candidate.

About LABP-66

LABP-66 is a once-daily, orally active, systemic small molecule therapeutic candidate which activates NLRX1, a mitochondria-associated receptor with the ability to modulate immune responses. By activating the NLRX1 pathway, LABP-66 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. LABP-66 recently entered IND-enabling studies and Landos expects to file for an IND in 2022. Oral treatment with LABP-66 has reduced markers of inflammation and neuronal cell stress in the CNS in addition to disease activity scores.

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 plus several

additional undisclosed immunometabolic pathways. Landos has 17 active development programs targeting these novel pathways at the interface of immunity and metabolism across 14 indications. Lead asset omilancor targets the LANCL2 pathway and is a novel oral, gut-restricted small molecule drug candidate currently being prepared for global pivotal Phase 3 trials for the treatment of ulcerative colitis, in an active Phase 2 trial in Crohn's disease and, is anticipated to initiate Phase 1b studies in Eosinophilic Esophagitis and, in topical cream formulation, for psoriasis and atopic dermatitis. NX-13 targets the NLRX1 pathway and is a novel oral, gut-restricted small molecule drug candidate currently in an active Phase 1b trial in ulcerative colitis. 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.

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