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

FORM 6-K

**REPORT OF FOREIGN ISSUER
PURSUANT TO RULE 13a-16 OR 15d-16
OF THE SECURITIES EXCHANGE ACT OF 1934**

March 11, 2024

(Commission File No. 001-38475)

ASLAN PHARMACEUTICALS LIMITED

(REG. NO. 289175)

(Translation of registrant's name into English)

CAYMAN ISLANDS

(Jurisdiction of incorporation or organization)

**3 Temasek Avenue
Level 18 Centennial Tower
Singapore 039190**

(Address of registrant's principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F.
Form 20-F Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101 (b) (1):
Yes No

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101 (b) (7):
Yes No

ASLAN Pharmaceuticals provides TREK-DX study update and highlights potential of *eblasakimab* in *dupilumab*-experienced atopic dermatitis patients

On March 11, 2024, ASLAN Pharmaceuticals Limited (the “Company”) announced that it has started enrolling patients in its TREK-DX study in the US under an updated protocol and that new European sites are on track to open in the first half of 2024. TREK-DX is the first randomized, double-blind, placebo-controlled study to be conducted in an atopic dermatitis (AD) patient population who have discontinued *dupilumab* treatment for any reason.

Further, the Company announced that at the time of the data cut off for this preliminary review of blinded data from 22 patients enrolled under the original inclusion criteria, who were randomized 2:1 active to placebo, 17 patients completed the 16 week treatment period and 5 patients discontinued before the completion of the 16 week treatment period. At 16 weeks or the last visit, EASI score decreased at least 90% (EASI-90) in 10 patients, or 45%, and 11 patients, or 50%, achieved a validated Investigator Global Assessment (vIGA) score of 0 or 1 (clear or almost clear skin). Of the 9 patients who previously had an inadequate response to *dupilumab*, 5 patients (56%) achieved EASI-90 and 5 patients (56%) a vIGA score of 0 or 1.

Treatments have been well-tolerated to date and no new safety signals were identified. There have been no reports of conjunctivitis and no reports of injection site reactions. Topline unblinded data from the full dataset is expected at the end of 2024.

The Company also announced translational data which demonstrates differentiated effects of targeting IL-13R versus IL-4R, suggesting *eblasakimab* has the potential to be effective even in instances where *dupilumab* is not.

A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

The information contained in this Form 6-K is hereby incorporated by reference into the Company’s Registration Statement on Form F-3 (File No. 333-254768), Registration Statement on Form F-3 (File No. 333-270835), Registration Statement on Form F-3 (File No. 333-270837), Registration Statement on Form S-8 (File No. 333-252118), Registration Statement on Form S-8 (File No. 333-263843) and Registration Statement on Form S-8 (File No. 333-270832).

Forward Looking Statements

This release contains forward-looking statements. These statements are based on the current beliefs and expectations of the management of the Company. These forward-looking statements may include, but are not limited to statements regarding the Company’s business strategy and clinical development plans; the Company’s plans to develop and commercialize *eblasakimab*; statements related to the safety and efficacy of *eblasakimab*, including preliminary blinded data; the Company’s plans and expected timing with respect to manufacturing activities, clinical trials, clinical trial enrolment and clinical trial results for *eblasakimab*; and the potential of *eblasakimab* as a first-in-class treatment for atopic dermatitis. The Company’s estimates, projections and other forward-looking statements are based on management’s current assumptions and expectations of future events and trends, which affect or may affect the Company’s business, strategy, operations or financial performance, and inherently involve significant known and unknown risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of many risks and uncertainties, which include, unexpected safety or efficacy data observed during preclinical or clinical studies; risks that future clinical trial results may not be consistent with interim, initial or preliminary results or results from prior preclinical studies or clinical trials; risks that results or observations based on preliminary blinded data may not be consistent with unblinded data; clinical site activation rates or clinical trial enrolment rates that are lower than expected; the impact of geopolitical conflicts and bank failures on the Company’s business and the global economy; general market conditions; changes in the competitive landscape; and the Company’s ability to obtain sufficient financing to fund its strategic and clinical development plans. Other factors that may cause actual results to differ from those expressed or implied in such forward-looking statements are described in the Company’s Securities and Exchange Commission (“SEC”) filings and reports (Commission File No. 001-38475), including the Company’s Annual Report on Form 20-F filed with the SEC on March 24, 2023. All statements other than statements of historical fact are forward-looking statements.

The words “believe,” “may,” “might,” “could,” “will,” “aim,” “estimate,” “continue,” “anticipate,” “intend,” “expect,” “plan,” or the negative of those terms, and similar expressions that convey uncertainty of future events or outcomes are intended to identify estimates, projections and other forward-looking statements. Estimates, projections and other forward-looking statements speak only as of the date they were made, and, except to the extent required by law, the Company undertakes no obligation to update or review any estimate, projection or forward-looking statement.

Exhibits

Exhibit Number	Exhibit Description
99.1	<u>Press release dated March 11, 2024 regarding announcement of TREK-DX study update and potential of <i>eblasakimab</i> in <i>dupilumab</i>-experienced atopic dermatitis patients</u>

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, thereto duly authorized.

ASLAN PHARMACEUTICALS LIMITED

(Registrant)

By: /s/ Kiran Kumar Asarpota

Name: Kiran Kumar Asarpota

Title: Chief Operating Officer

Date: March 11, 2024

**PRESS RELEASE**

ASLAN PHARMACEUTICALS PROVIDES TREK-DX STUDY UPDATE AND HIGHLIGHTS POTENTIAL OF EBLASAKIMAB IN DUPILUMAB-EXPERIENCED ATOPIC DERMATITIS PATIENTS

- TREK-DX, the first randomized, double-blind, placebo-controlled study to be conducted in a *dupilumab*-experienced atopic dermatitis (AD) patient population, has started enrolling patients in the US under an updated protocol; new European sites are on track to open in the first half of 2024
- In a preliminary review of blinded data from 22 patients treated to date, 45% (10/22) of patients saw at least a 90% reduction in their EASI score (EASI-90) and 50% (11/22) of patients achieved a vIGA score of 0 or 1 (clear or almost clear skin) after 16 weeks. Topline unblinded data from the full dataset is expected at the end of 2024
- Translational data demonstrates differentiated effects of targeting IL-13R versus IL-4R, suggesting *eblasakimab* has the potential to be effective in AD patients that do not achieve an adequate response to *dupilumab*, a significant and underserved patient population with few safe and long-term treatment options

San Mateo, California, and Singapore, March 11, 2024 – ASLAN Pharmaceuticals Ltd. (Nasdaq: ASLN), a clinical-stage, immunology focused biopharmaceutical company developing innovative treatments to transform the lives of patients, today announced that it has begun to enroll patients in the US under an updated protocol in the ongoing TREK-DX trial, studying *eblasakimab* in *dupilumab*-experienced patients with moderate-to-severe atopic dermatitis (AD).

TREK-DX is the first randomized, double-blind, placebo-controlled trial to be conducted in AD patients who have been previously treated with *dupilumab*, a market estimated to reach \$10 billion by 2029¹. Based on findings from the TREK-AD study which highlighted the changing AD patient population in the US, the TREK-DX inclusion criteria have been tightened to enroll patients with a baseline Eczema Area and Severity Index (EASI) score of at least 18, instead of 16. In conjunction with this, independent reviewer confirmation of baseline EASI scores has also been implemented. US sites are now enrolling patients according to the updated criteria and additional sites in Europe are on track to open in the first half of 2024.

TREK-DX will enroll approximately 75 patients who have discontinued *dupilumab* treatment for any reason, including inadequate control of AD, loss of access or an adverse event, and treat them with either 400mg *eblasakimab* or placebo once weekly for 16 weeks. At the time of the data cut off for this preliminary review of blinded data from 22 patients enrolled under the original inclusion criteria, who were randomized 2:1 active to placebo, 17 patients completed the 16 week treatment period and 5 patients discontinued before the completion of the 16 week treatment period. At 16 weeks or the last visit, EASI score decreased at least 90% (EASI-90) in 10 patients, or 45%, and 11 patients, or 50%, achieved a validated Investigator Global Assessment (vIGA) score of 0 or 1 (clear or almost clear skin). Of the 9 patients who previously had an inadequate response to *dupilumab*, 5 patients (56%) achieved EASI-90 and 5 patients (56%) a vIGA score of 0 or 1. Treatments have been well-tolerated to date and no new safety signals were identified. There have been no reports of conjunctivitis and no reports of injection site reactions. Topline unblinded data from the full dataset is expected at the end of 2024.

“63% of *dupilumab*-treated patients fail to achieve clear or almost clear skin (IGA score of 0 or 1) after 16 weeks², and around half of those patients that do achieve this response do not maintain it after the subsequent 36 weeks³, so there is a significant need for additional biologic therapies that could provide a safe and efficacious long-term treatment option for patients that do not achieve an adequate response to *dupilumab*.”



EASI-90 and vIGA are among the most stringent of endpoints in AD studies. Although this is based on a preliminary review of the blinded data, we are encouraged to observe a high percentage of patients in the TREK-DX study meeting these endpoints to date. Our market research found that most AD patients are only moderately satisfied with their current treatment. This, together with the translational data we have generated, supports the potential role of *eblasakimab* as a treatment for these patients, and the data we are generating in the TREK-DX study could demonstrate that, for many patients, *eblasakimab* could control their disease even where *dupilumab* has not,” said Dr Carl Firth, Chief Executive Officer, ASLAN Pharmaceuticals.

Translational data demonstrates differentiated effects of targeting IL-13R versus IL-4R, suggesting *eblasakimab* has the potential to be effective even in instances where *dupilumab* is not

Eblasakimab targets the IL-13 receptor (IL-13R) subunit of the Type 2 receptor, preventing signaling through both interleukin 4 (IL-4) and interleukin 13 (IL-13). Both are key drivers of inflammation in AD, however, recently published translational data highlighted the advantages of targeting IL-13R by *eblasakimab* over the IL-4 receptor (IL-4R), the target of *dupilumab*, in AD patient peripheral blood mononuclear cells⁴. IL-13R blockade resulted in more efficient reduction of cytokines implicated in Type 2-driven (allergic) inflammation compared to IL-4R blockade, as well as lower levels of Type 1 pro-inflammatory cytokines. Additional data from head-to-head studies between *eblasakimab* and *dupilumab* in skin biopsies from AD patients confirmed the differentiated effects of targeting IL-13R versus IL-4R⁵. In this study, *eblasakimab* reduced localized secretion of pro-inflammatory Type 2 cytokines by the skin tissue more efficiently than *dupilumab*, suggesting *eblasakimab* could have the potential to be effective in AD patients that do not achieve an adequate response to *dupilumab*.

References

1. Decision Resources Group (2023) Atopic Dermatitis Disease Landscape and Forecast Report
2. Thaci et al (2019) J Dermatol Sci 94(2):266-275
3. Worm et al (2020) JAMA Derm 156(2):131-143
4. Cevikbas et al (2023) 1st International Society of Investigative Dermatology Meeting, May 10-14, 2023
5. Cevikbas et al (2023) 7th Annual Dermatology Drug Development Summit, October 31-November 2, 2023

About TREK-DX

TREK-DX trial is a randomized, double-blind, placebo-controlled, multicenter trial to evaluate the efficacy and safety of *eblasakimab* in patients with moderate-to-severe AD previously treated with *dupilumab*. The trial will enroll approximately 75 patients who have discontinued *dupilumab* treatment for any reason, including inadequate control of AD, loss of access or an adverse event. The trial consists of a 16-week treatment period and an 8-week safety follow-up period. The primary efficacy endpoint is percentage change in Eczema Area Severity Index (EASI) score from baseline to week 16. Key secondary efficacy endpoints include the proportion of patients achieving validated Investigator Global Assessment (vIGA) score of 0 (clear) or 1 (almost clear), proportion of patients with a 75% or greater reduction in EASI (EASI-75), proportion of patients achieving EASI-50 and EASI-90, and changes in peak pruritus.

About *eblasakimab*

Eblasakimab is a potential first-in-class monoclonal antibody targeting the IL-13 receptor subunit of the Type 2 receptor, a key pathway driving several allergic inflammatory diseases. *Eblasakimab*'s unique mechanism of action enables specific blockade of the Type 2 receptor and has the potential to improve upon current biologics used to treat allergic disease. By blocking the Type 2 receptor, *eblasakimab* prevents signaling through both interleukin 4 (IL-4) and interleukin 13 (IL-13) – the key drivers of inflammation in AD and Type 2 driven COPD.



Positive results from the Phase 2b TREK-AD study in moderate-to-severe AD support *eblasakimab*'s potential to deliver a monthly dosing regimen from initiation in AD without compromising on efficacy and with an encouraging safety profile demonstrated to date, with preparations for Phase 3 underway. ASLAN is also investigating *eblasakimab* in *dupilumab* experienced, moderate-to-severe AD patients in the Phase 2 TREK-DX study.

About ASLAN Pharmaceuticals

ASLAN Pharmaceuticals (Nasdaq: ASLN) is a clinical-stage, immunology-focused biopharmaceutical company developing innovative treatments to transform the lives of patients. ASLAN is developing *eblasakimab*, a potential first-in-class antibody targeting the IL-13 receptor in moderate-to-severe atopic dermatitis (AD) with the potential to improve upon current biologics used to treat allergic disease, and has reported positive topline data from a Phase 2b, dose-ranging study in moderate-to-severe AD patients. ASLAN is also investigating *eblasakimab* in *dupilumab* experienced, moderate-to-severe AD patients in the Phase 2 TREK-DX study with a topline data readout expected at the end of 2024. *Farudodstat*, a potent oral inhibitor of the enzyme dihydroorotate dehydrogenase (DHODH), is being developed by ASLAN as a potential first-in-class treatment for alopecia areata (AA) in a Phase 2a, proof-of-concept trial with an interim readout expected in mid-2024. ASLAN has teams in San Mateo, California, and in Singapore. For additional information please visit ASLAN's website or follow ASLAN on LinkedIn.

Forward-looking statements

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Ends



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