

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

September 27, 2021

(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)

83 CLEMENCEAU AVENUE
#12-03 UE SQUARE
SINGAPORE 239920
(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 announces positive data conclusively establishing proof of concept for ASLAN004 in atopic dermatitis

On September 27, 2021, ASLAN Pharmaceuticals Limited (the “Company”) announced positive topline data from its randomized, double-blind, placebo-controlled, 8-week, multiple ascending dose Phase 1 study of ASLAN004 for the treatment of moderate-to-severe atopic dermatitis, or AD.

ASLAN004 was shown to be well tolerated across all doses. Data from the study conclusively establishes proof of concept, and supports the potential of ASLAN004 as a differentiated, novel treatment for AD.

In March 2021, ASLAN announced interim data from three dose escalation cohorts, then continued to enroll and treat an additional 27 patients in an expansion cohort at the highest dose (600mg). The results announced today compare results from all patients receiving 600mg to all receiving placebo (n=39). The Intent to Treat, or ITT, population (n=38) comprised patients from 10 sites and represented all patients dosed excluding one patient that discontinued from the study prematurely due to COVID-19 restrictions.

ASLAN004 achieved a statistically significant improvement ($p < 0.025$) versus placebo in the primary efficacy endpoint of percent change from baseline in the Eczema Area Severity Index, or EASI, and also showed significant improvements ($p < 0.05$) in other key efficacy endpoints: EASI-50, EASI-75, peak pruritus and the Patient-Oriented Eczema Measure, or POEM.

Following discussions with the Data Monitoring Committee prior to unblinding, a Revised ITT population, or RITT (n=29), was defined to exclude one study site at which all patients enrolled in the study appeared atypical of moderate-to-severe AD patients based on biomarkers, such as TARC, and patient medical history. In the RITT population, which is more comparable to other published studies in moderate-to-severe AD, ASLAN004 also achieved a statistically significant improvement ($p < 0.025$) versus placebo in percent change from baseline in EASI and showed a greater improvement over placebo in the key efficacy endpoints versus the ITT population.

Key study results are set out below:

- In the RITT population, the average reduction from baseline in EASI at 8 weeks was 65% (n=16) compared to 27% (n=13) for patients on placebo ($p=0.021$).
 - 69% achieved EASI-75 versus 15% on placebo ($p=0.005$);
 - 44% of patients achieved Investigator’s Global Assessment, or IGA, of 0 or 1 versus 15% on placebo ($p=0.107$).
- In the 32 patients who completed at least 29 days of dosing across all sites, defined in the protocol as the efficacy evaluable data set, the average reduction from baseline in EASI at 8 weeks was 73% (n=19) compared to 44% (n=13) for patients on placebo ($p=0.007$).
- The proportion of patients with adverse events and treatment-related adverse events were similar across treatment and placebo arms. There were no incidences of conjunctivitis in the expansion cohort.

Further information is set out in the press release attached hereto as Exhibit 99.1 and which 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. 333-234405), Registration Statement on Form F-3 (File No. 333-252575), Registration Statement on Form F-3 (File No. 333-254768) and Registration Statement on Form S-8 (File No. 333-252118).

Forward Looking Statements

This Form 6-K contains forward-looking statements. These statements are based on the current beliefs and expectations of the management of ASLAN Pharmaceuticals Limited and/or its affiliates (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 ASLAN004; the safety and efficacy of ASLAN004, including its potential to be best-in-class; the Company’s plans and expected timing with respect to clinical trials, clinical trial enrolment and clinical trial results for ASLAN004; and the potential for ASLAN004 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; clinical site activation rates or clinical trial enrolment rates that are lower than expected; the impact of the COVID-19 pandemic 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 US Securities and Exchange Commission filings and reports (Commission File No. 001-38475), including the Company’s Annual Report on Form 20-F filed with the US Securities and Exchange Commission on April 23, 2021. All statements other than statements of historical fact are forward-looking statements. The words “believe,” “view,” “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 [Press release dated September 27, 2021 regarding announcement of positive data conclusively establishing proof of concept for ASLAN004 in atopic dermatitis.](#)

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: September 27, 2021

PRESS RELEASE

ASLAN PHARMACEUTICALS ANNOUNCES POSITIVE DATA CONCLUSIVELY ESTABLISHING PROOF OF CONCEPT FOR ASLAN004 IN ATOPIC DERMATITIS

- **Topline data from multiple-ascending-dose study supports a potentially differentiated safety and efficacy profile**
- **ASLAN004 achieved a statistically significant improvement ($p < 0.025$)¹ versus placebo in the primary efficacy endpoint of percent change from baseline in EASI with significant improvements in other efficacy endpoints**
- **Well-tolerated with no cases of conjunctivitis in the expansion cohort**
- **On track to enroll first patient in global Phase 2b study in 4Q 21**
- **Management to host conference call and webcast today, 27 September, at 8am ET / 8pm SGT**

Menlo Park, California, and Singapore, 27 September, 2021 – ASLAN Pharmaceuticals (Nasdaq: ASLN), a clinical-stage, immunology-focused biopharmaceutical company developing innovative treatments to transform the lives of patients, today announced positive topline data from its randomized, double-blind, placebo-controlled, 8-week, multiple-ascending-dose (MAD) Phase 1 study of ASLAN004 for the treatment of moderate-to-severe atopic dermatitis (AD). ASLAN004, a potential first-in-class monoclonal antibody that targets the IL-13 receptor, was shown to be well tolerated across all doses. Data from the study conclusively establishes proof of concept, and supports the potential of ASLAN004 as a differentiated, novel treatment for AD.

In March 2021, ASLAN announced interim data from three dose escalation cohorts, then continued to enroll and treat an additional 27 patients in an expansion cohort at the highest dose (600mg). The results announced today compare results from all patients receiving 600mg to all receiving placebo (n=39). The Intent to Treat (ITT) population (n=38) comprised patients from 10 sites and represented all patients dosed excluding one patient that discontinued from the study prematurely due to COVID-19 restrictions.

ASLAN004 achieved a statistically significant improvement ($p < 0.025$)¹ versus placebo in the primary efficacy endpoint of percent change from baseline in the Eczema Area Severity Index (EASI), and also showed significant improvements ($p < 0.05$)¹ in other key efficacy endpoints: EASI-50, EASI-75, peak pruritus and the Patient-Oriented Eczema Measure (POEM).

Following discussions with the Data Monitoring Committee prior to unblinding, a Revised ITT population (RITT, n=29) was defined to exclude one study site at which all patients enrolled in the study appeared atypical of moderate-to-severe AD patients based on biomarkers, such as TARC, and patient medical history². In the RITT population, which is more comparable to other published studies³ in moderate-to-severe AD, ASLAN004 also achieved a statistically significant improvement ($p < 0.025$)¹ versus placebo in percent change from baseline in EASI and showed a greater improvement over placebo in the key efficacy endpoints versus the ITT population.

¹ One-sided p-value. Study was powered to assess statistical significance in the primary efficacy endpoint at the one-sided 5% level.

² The average level of TARC, a biomarker that correlates with AD severity, in the RITT was 4,652 pg/ml (compared to 461 pg/ml at the site excluded from the RITT), in line with previous published clinical studies³ in moderate-to-severe AD, which had average TARC levels between 4,832 and 6,230 pg/ml. Only one out of nine patients at the excluded site had allergic co-morbidities compared to 87% in other sites. Other measures, such as eosinophils and enzyme LDH were also atypical of moderate-to-severe AD.

³ Beck et al (2014) N Engl J Med 371:130. Hamilton et al (2019), 49th Annual ESDR Meeting Sep 18-21, 2019

Key study results

- In the RITT population, the average reduction from baseline in EASI at 8 weeks was 65% (n=16) compared to 27% (n=13) for patients on placebo (p=0.021).
 - 69% achieved EASI-75 versus 15% on placebo (p=0.0051);
 - 44% of patients achieved Investigator's Global Assessment (IGA) of 0 or 1 versus 15% on placebo (p=0.1071).
- In the 32 patients that completed at least 29 days of dosing across all sites, defined in the protocol as the efficacy evaluable data set, the average reduction from baseline in EASI at 8 weeks was 73% (n=19) compared to 44% (n=13) for patients on placebo (p=0.0071).
- The proportion of patients with adverse events and treatment-related adverse events were similar across treatment and placebo arms. There were no incidences of conjunctivitis in the expansion cohort.

Endpoint (8 weeks)	RITT (n=29)			ITT (n=38)		
	600mg (n=16)	Placebo (n=13)	p-value ¹	600mg (n=22)	Placebo (n=16)	p-value ¹
Mean % change from baseline in EASI	-64.9	-27.2	0.021	-61.3	-31.9	0.023
EASI-50 (%)	81.3	30.8	0.008	77.3	37.5	0.016
EASI-75 (%)	68.8	15.4	0.005	50.0	12.5	0.018
EASI-90 (%)	37.5	15.4	0.183	27.3	12.5	0.245
IGA 0/1 (%)	43.8	15.4	0.107	31.8	18.8	0.301
Mean % change from baseline in peak pruritus Numerical Rating Scale	-38.6	-15.3	0.051	-37.1	-15.7	0.032
Mean change from baseline in POEM	-9.8	-2.5	0.007	-9.0	-3.5	0.014

Dr Ken Kobayashi, Chief Medical Officer, ASLAN Pharmaceuticals, commented: “We’re delighted to report such positive data on ASLAN004. The data from the study wholly support our view that ASLAN004’s novel mechanism could represent a new treatment option for patients suffering with moderate-to-severe AD, with the potential to deliver best-in-class efficacy and best-in-class safety. We look forward to building upon this strong data set as we initiate the Phase 2b study in the coming weeks and explore monthly dosing regimens that could provide additional convenience to patients.”

Dr Steven Thng, Principal Investigator, said: “Atopic dermatitis is one of the most common dermatological diseases worldwide and presents with a range of symptoms that have a tremendous negative impact on a patient’s quality of life. Patients, especially those with moderate-to-severe disease, are still in great need of novel treatment options that are safe, efficacious and convenient to use to overcome the limitations of options currently available to them. The findings from the study show the potential benefit that ASLAN004 could offer patients in achieving almost completely clear skin and relief from the burden of atopic dermatitis on daily life.”

ASLAN is initiating a global Phase 2b study of ASLAN004 for the treatment of AD and is on track to enroll the first patient in 4Q 2021. ASLAN will host a KOL event on ASLAN004 in AD for investors in 4Q 2021. The full data from the MAD study will be submitted for presentation at a future scientific congress.



Conference call and webcast

ASLAN's management will host a webcast and conference call at 8am ET today, September 27, 2021, to discuss these data. The live webcast may be accessed in listen-only mode via <http://public.viavid.com/index.php?id=146567> or via the company's website at <https://ir.aslanpharma.com/webcasts-presentations>. For audio access dial +1 877-407-3982 for US callers and +1 201 493 6780 for international callers and enter the conference code: 13723237.

A replay of the call and webcast will be archived using the information above immediately after the live event.

Ends

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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 currently evaluating ASLAN004, a potential first-in-class antibody targeting the IL-13 receptor, in atopic dermatitis, and ASLAN003, a potent oral inhibitor of DHODH, which is being developed for autoimmune disease. ASLAN has a team in Menlo Park, California, and in Singapore. For additional information, please visit www.aslanpharma.com or follow ASLAN on LinkedIn.

About ASLAN004

ASLAN004 is a novel, potential first-in-class monoclonal antibody that targets the IL-13 receptor $\alpha 1$ subunit (IL-13R $\alpha 1$), a component of the Type 2 receptor. By blocking the Type 2 receptor, ASLAN004 prevents signaling through both interleukin 4 (IL-4) and interleukin 13 (IL-13), the key drivers of inflammation, central to triggering symptoms of allergy in atopic dermatitis, such as redness and itching of the skin, and in other atopic disease. We believe that this unique action of blocking the IL-13 receptor rather than the IL-4 receptor has the potential for improved efficacy, safety and dose regimen. ASLAN004 is the only IL-13R $\alpha 1$ inhibitor in clinical development for the treatment of AD.

About the study

The Phase 1 study was a multiple ascending dose study designed to deliver proof of concept and evaluated three doses of ASLAN004 (200mg, 400mg and 600mg) delivered subcutaneously compared to a placebo arm. Patients were dosed weekly for eight weeks to determine the safety and tolerability of ASLAN004, and to assess a number of secondary efficacy outcome measures. In total, 53 patients were randomized in the MAD study from 10 sites in the United States, Australia and Singapore.



Forward-looking statements

This release contains forward-looking statements. These statements are based on the current beliefs and expectations of the management of ASLAN Pharmaceuticals Limited and/or its affiliates (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 ASLAN004; the safety and efficacy of ASLAN004, including its potential to be best-in-class; the Company's plans and expected timing with respect to clinical trials, clinical trial enrolment and clinical trial results for ASLAN004; and the potential for ASLAN004 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; clinical site activation rates or clinical trial enrolment rates that are lower than expected; the impact of the COVID-19 pandemic 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 US Securities and Exchange Commission filings and reports (Commission File No. 001-38475), including the Company's Annual Report on Form 20-F filed with the US Securities and Exchange Commission on April 23, 2021. All statements other than statements of historical fact are forward-looking statements. The words "believe," "view," "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.