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 1, 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 ☒

Business and Risk Factor Updates

ASLAN Pharmaceuticals Limited (the "Company") is filing certain information for the purpose of updating descriptions of the Company's business and risk factors contained in the Company's other filings with the Securities and Exchange Commission (the "SEC"). Copies of the additional disclosures are attached as Exhibits 99.1 and 99.2 to this report and incorporated herein by reference.

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) and Registration Statement on Form S-8 (File No. 333-252118).

Exhibits

Exhibit Number	Exhibit Description
99.1	Updated Business Description.
99.2	Updated Risk Factors

This Form 6-K contains forward-looking statements about the Company and its industry that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this report, including statements regarding the Company's strategy, current and future financial condition, future operations, research and development, planned clinical trials and preclinical studies, discovery programs, the timing and likelihood of regulatory filings and approvals for the Company's product candidates, and the potential benefits of collaborations, projected costs, prospects, plans, objectives of management, are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "aim," "anticipate," "assume," "believe," "contemplate," "continue," "could," "design," "due," "estimate," "expect," "goal," "intend," "may," "objective," "plan," "positioned," "potential," "predict," "seek," "should," "target," "will," "would" and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology.

The Company has based these forward-looking statements largely on its current expectations and projections about future events and financial trends that the Company believes may affect its financial condition, results of operations, business strategy and financial needs. These forward-looking statements are subject to a number of known and unknown risks, uncertainties and assumptions described in the Company's filings with the SEC, including the section titled "Risk Factors" in Exhibit 99.2 attached to this report. Moreover, the Company operates in a very competitive and rapidly changing environment. New risk factors emerge from time to time, and it is not possible for the Company's management to predict all risk factors nor can the Company assess the impact of all factors on its business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in, or implied by, any forward-looking statements.

In light of the significant uncertainties in these forward-looking statements, you should not rely upon forward-looking statements as predictions of future events. Although the Company believes that it has a reasonable basis for each forward-looking statement contained in this report, the Company cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur at all. You should refer to the section titled "Risk Factors" in Exhibit 99.2 attached to this report for a discussion of important factors that may cause the Company's actual results to differ materially from those expressed or implied by the Company's forward-looking statements. Furthermore, if the Company's forward-looking statements prove to be inaccurate, the inaccuracy may be material. Except as required by law, the Company undertakes no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise.

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 1, 2021

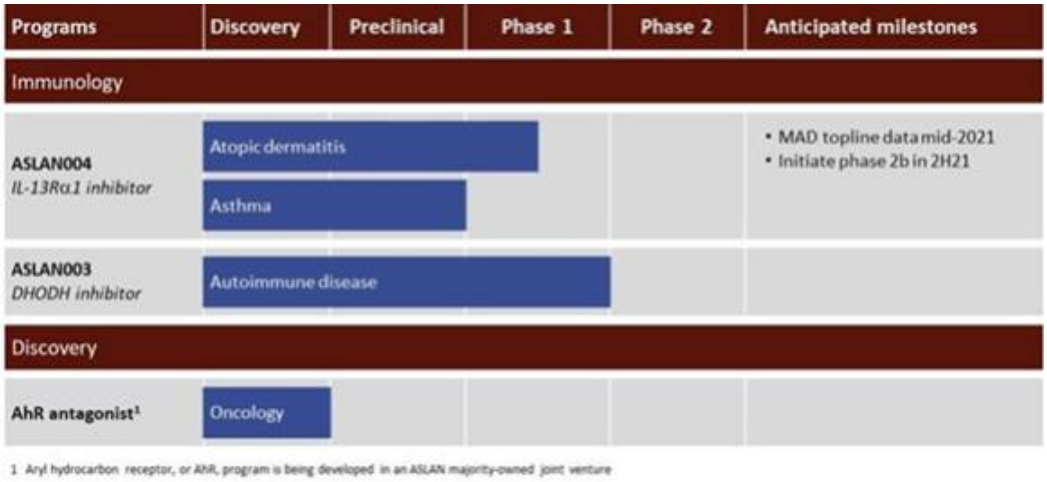
Company Overview

We are a clinical-stage immunology focused biopharmaceutical company developing innovative treatments to transform the lives of patients.

Our portfolio is led by ASLAN004, a potential first-in-class human monoclonal antibody that binds to the IL-13 receptor α1 subunit (IL-13Rα1), blocking signaling of two pro-inflammatory cytokines, IL-4 and IL-13 which are central to triggering symptoms of atopic dermatitis, such as redness and itching of the skin. ASLAN004 has the potential to be best-in-disease for atopic dermatitis and asthma. We are conducting a Phase 1 clinical trial investigating ASLAN004 as a therapeutic antibody for moderate-to-severe atopic dermatitis. Interim results demonstrate a competitive profile with the potential to differentiate over existing therapies. We expect to report topline data from this trial in mid-2021. In addition, we plan to explore additional indications for ASLAN004 for in the second half of 2021. We are also planning to develop ASLAN003, an orally active, potent inhibitor of human dihydroorotate dehydrogenase, or DHODH, for autoimmune conditions.

Our Product Candidates

The following table summarizes our product candidate pipeline and discovery programs:



We hold global rights to all of our product candidates with the exception of ASLAN003, of which BioGenetics Co., Ltd., or BioGenetics, acquired rights for the Republic of Korea, or South Korea.

ASLAN004. ASLAN004 is a fully human monoclonal antibody that binds to the IL-13 receptor α1 subunit (IL-13Rα1), blocking signaling of two pro-inflammatory cytokines, IL-4 and IL-13, which are central to triggering symptoms of atopic dermatitis, such as redness and itching of the skin. We have initiated a Phase 1 clinical trial investigating ASLAN004 as a therapeutic antibody for atopic dermatitis. A single ascending dose, or SAD, clinical trial in healthy volunteers was completed in the second quarter of 2019. In October 2019, we initiated a multiple ascending dose, or MAD, clinical trial in moderate-to-severe atopic dermatitis patients Interim results demonstrate a competitive profile with the potential to differentiate over existing therapies. We expect to report topline data from this trial in mid-2021. In addition, we plan to explore additional indications for ASLAN004 for in the second half of 2021.

ASLAN003. ASLAN003 is an orally active, potent small-molecule inhibitor of DHODH. In preclinical studies, ASLAN003 was shown to be efficacious in various animal models of autoimmune disease. Recently published data demonstrated that out of six DHODH inhibitors tested, ASLAN003 had the lowest potential for hepatotoxicity despite being one of the most potent inhibitors of DHODH, suggesting that ASLAN003 has the potential to be best-in-class for the treatment of autoimmune disease. We are planning to develop ASLAN003 for the treatment of autoimmune conditions.

Additional Discovery Programs. We have established a joint venture called JAGUAHR Therapeutics Pte. Ltd. with Bukwang Pharmaceutical Co., Ltd., or Bukwang, a leading research and development focused Korean pharmaceutical company, to develop antagonists of the aryl hydrocarbon receptor, or AhR, an immune checkpoint inhibitor.

Recent Clinical Developments

ASLAN004 – Multiple Ascending Dose Clinical Trial in Moderate-to-Severe Atopic Dermatitis

The randomized, double-blind, placebo-controlled MAD clinical trial evaluated three doses (200mg, 400mg and 600mg) of ASLAN004 delivered weekly via subcutaneous injection. Based on a review of blinded safety data, the highest dose, 600mg, was selected for the expansion cohort, which will recruit at least 24 additional patients. The primary endpoint is safety and tolerability. Secondary endpoints include efficacy at eight weeks as measured by improvement in the Eczema Area and Severity Index, or EASI, score, EASI-50, EASI-75, EASI-90, Investigators Global Assessment, or IGA, pruritis numeric rating scale, and Patient-Oriented Eczema Measure. The trial will recruit up to 50 moderate-to-severe atopic dermatitis patients and recruitment into the expansion cohort started in January 2021. We expect to report topline data from this trial in mid-2021. The trial was designed with 80% power to detect a 39% improvement in EASI compared to placebo at eight weeks. After completion of the MAD trial, we plan to initiate a Phase 2b dose-range finding trial in atopic dermatitis patients.

On March 1, 2021, we reported positive interim unblinded data from the first three dose cohorts (200mg, 400mg and 600mg) of the ongoing MAD clinical trial. The first three cohorts randomized 25 patients from the United States, Australia and Singapore. Three patients discontinued the trial due to restrictions imposed in response to COVID-19. Of the remaining 22 patients, 18 completed at least 29 days of dosing and assessment and were evaluable for efficacy. The average baseline EASI score of patients was 32.5 and the average IGA score was 3.4 (n=18). At week 8, the average reduction in EASI from baseline at therapeutic doses (400mg and 600mg cohorts) was 74% (n=9) compared to 42% (n=5) for patients on placebo. 89% of patients achieved EASI-50 versus 40% on placebo; 67% achieved EASI-75 versus 0% on placebo; 56% achieved EASI-90 versus 0% on placebo; and 22% of patients achieved IGA of 0 or 1 versus 0% on placebo. Peak pruritus improved after just one dose and continued to improve by an average of 46% relative to baseline at week 8 compared to 16% for patients on placebo. The proportion of patients with adverse events and treatment-related adverse events were similar across treatment and placebo arms. There were no treatment-related adverse events in the active arm that led to discontinuation.

Financial Update

While we have not finalized our full financial results for the fiscal year ended December 31, 2020, we expect to report that we had approximately $14.3 million of cash and cash equivalents as of December 31, 2020. This amount is preliminary, has not been audited and is subject to change upon completion of the audit of our consolidated financial statements as of and for the year ended December 31, 2020. Additional information and disclosures would be required for a more complete understanding of our financial position and results of operations as of December 31, 2020.

On February 28, 2021, we sold 25,568,180 ordinary shares in a private placement for gross proceeds of approximately $18.0 million pursuant to a securities purchase agreement we entered into with the purchasers in the private placement. In addition, as of the date hereof, we have sold 8,862,972 ADSs (representing 44,314,860 ordinary shares) for net proceeds of approximately $21.5 million after deducting commissions but before deducting any offering expenses under the Open Market Sale Agreement℠, or Sale Agreement, that we entered into with Jefferies LLC, or Jefferies, on October 9, 2020, of which 4,908,987 ADSs (representing 24,544,935 ordinary shares) were sold after December 31, 2020 for net proceeds of approximately $14.1 million after deducting commissions but before deducting any offering expenses under the Sale Agreement with Jefferies.

RISK FACTORS

An investment in our American Depositary Shares, or ADSs, involves a high degree of risk. You should carefully consider the following risk factors, together with the information contained in our Annual Report on Form 20-F for the year ended December 31, 2019 filed with the Securities and Exchange Commission, or the SEC, on April 16, 2020 and our financial statements for the quarter ended September 30, 2020 included in the Form 6-K filed with the SEC on January 29, 2021 before deciding whether to invest in our ADSs. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and/or prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this report and those we may make from time to time. In such an event, the market price of our ADSs could decline and you may lose all or part of your investment. You should consider all of the risk factors described when evaluating our business.

Summary of Risk Factors

Our business is subject to a number of risks of which you should be aware before making a decision to invest in our ADSs. These risks include, among others, the following:

- We have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future.
- We currently do not generate any revenue from product sales, have generated only limited revenue since inception, and may never be profitable.
- We will need to obtain substantial additional financing for our operations, and if we fail to obtain additional financing, we may be forced to delay, reduce or eliminate our product development programs or commercialization efforts.
- We are heavily dependent on the success of our two product candidates, ASLAN004 and ASLAN003 and we cannot give any assurance that ASLAN004 or ASLAN003 will successfully complete clinical development or receive regulatory approval, which is necessary before they can be commercialized.
- Clinical development is a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. Failure can occur at any stage of clinical development. We have never completed a pivotal clinical trial for our product candidates or submitted a New Drug Application, or NDA, or a Biologics License Application, or BLA, to the U.S. FDA or similar drug approval filings to comparable foreign authorities.
- Delays in clinical trials are common and have many causes, and any delay could result in increased costs to us and jeopardize or delay our ability to obtain regulatory approval and commence product sales.
- The regulatory approval processes of the U.S. FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.
- We rely on third parties to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.
- If we are unable to obtain or protect intellectual property rights related to our current product candidates or any future product candidates which we may develop, we may not be able to compete effectively in our market.

- You may face difficulties in protecting your interests, and your ability to protect your rights through U.S. courts may be limited, because we are incorporated under Cayman Islands law, we conduct the majority of our operations and substantially all of our directors and executive officers reside outside of the United States.
- We qualify as a foreign private issuer and, as a result, we are not subject to U.S. proxy rules and are subject to Exchange Act reporting obligations that permit less detailed and frequent disclosures than those of a U.S. domestic public company.
- Our business is subject to economic, political, regulatory and other risks associated with international operations.
- Our business could continue to be adversely affected by the effects of health pandemics or epidemics, including the effects of the COVID-19 pandemic.

Risks Related to Our Financial Condition and Need for Additional Capital

We have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future.

We are a clinical-stage immunology focused biopharmaceutical company developing innovative treatments to transform the lives of patients. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will not demonstrate adequate effectiveness in the targeted indication or an acceptable safety profile, gain regulatory approval or become commercially viable. All of our product candidates will require substantial additional development time and resources before we would be able to apply for or receive regulatory approvals and begin generating revenue from product sales. We are not profitable and have incurred significant net losses in each year since our inception, including net losses of $47.0 million for fiscal year 2019, and $10.3 million for the ninth months ended September 30, 2020. As of September 30, 2020, we had an accumulated deficit of $189.8 million.

We have devoted substantially all our financial resources to developing our product candidates and targeted discovery work, including preclinical development activities and clinical trials. We expect to continue to incur substantial expenses, losses and negative cash flows as we expand our development activities and advance our clinical programs, particularly with respect to our planned clinical development for ASLAN004. If our product candidates are not successfully developed or commercialized, including because of a lack of capital, or if we do not generate enough revenue following marketing approval, we will not achieve profitability and our business may fail.

We currently do not generate any revenue from product sales, have generated only limited revenue since inception, and may never be profitable.

We do not anticipate generating revenue from sales of our proprietary product candidates for the foreseeable future. Our ability to generate future revenue from product sales depends on our success in completing clinical development of, obtaining regulatory approval for, and launching and successfully commercializing any product candidates.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to predict the timing or amount of increased expenses, when, or if, we will begin to generate revenue from product sales, or when, or if, we will be able to achieve or maintain profitability. In addition, our expenses could increase beyond planned levels if we are required by the U.S. FDA to perform studies in addition to those that we currently anticipate or if such studies are larger, take longer or are otherwise more expensive to conduct than we expect.

Even if one or more of our product candidates is approved for commercial sale, to the extent we do not engage a third-party collaborator, we anticipate incurring significant costs associated with commercializing any approved product candidate. Even if we are able to generate revenue from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations.

We will need to obtain substantial additional financing for our operations, and if we fail to obtain additional financing, we may be forced to delay, reduce or eliminate our product development programs or commercialization efforts.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is expensive and we have consumed substantial amounts of capital since inception. To date, we have financed our operations through government subsidies and grants, collaboration payments and the sale of equity securities and convertible debt. We will need substantial additional financing to continue our operations and do not expect revenues from product sales or potential licensing transactions to be sufficient to offset our development expenses as we advance our clinical programs.

While we have not finalized our full financial results for the fiscal year ended December 31, 2020, we expect to report that we had approximately $14.3 million of cash and cash equivalents as of December 31, 2020. This amount is preliminary, has not been audited and is subject to change upon completion of the audit of our consolidated financial statements as of and for the year ended December 31, 2020. As we are in the clinical research and development phase, we will be seeking future funding based on the requirements of our business operations. We intend to continue to explore various means of fundraising to meet our funding requirements to carry out our business operations, such as offerings of ADSs, follow-on offerings of ordinary shares, venture debt and shareholder loans. We may also use other means of financing such as out-licensing to generate revenue and cash. We have the ability to exercise discretion and flexibility to deploy our capital resources used in research and development activities according to the amount and timing of our financing activities. Accordingly, we believe that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements and meet our obligations for at least the next twelve months from the date of this prospectus supplement. However, our future viability depends on our ability to raise additional capital to finance our operations. Regardless of our expectations as to how long our existing cash and cash equivalents will fund our operations, changing circumstances beyond our control may cause us to consume capital more rapidly than we currently anticipate. For example, our clinical trials may encounter technical, enrollment or other difficulties that could increase our development costs more than we expect. We may also incur expenses as we create additional infrastructure to support our planned commercialization efforts and our operations as a U.S. public company. In any event, we will require additional capital prior to completing pivotal studies of, filing for regulatory approval for, or commercializing ASLAN003, ASLAN004 or any of our other preclinical product candidates.

We cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we are unable to raise additional capital when required or on acceptable terms, we may be required to:

- significantly delay, scale back or discontinue the development or commercialization of our product candidates;
- seek corporate partners for our product candidates when we would otherwise develop our product candidates on our own, or at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available;
- relinquish or license on unfavorable terms, our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves; or
- significantly curtail or cease operations.

If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we will be prevented from pursuing development and commercialization efforts, which will have an adverse effect on our business, operating results and prospects.

Risks Related to Clinical Development and Regulatory Approval

We are heavily dependent on the success of our two product candidates, ASLAN004 and ASLAN003 and we cannot give any assurance that ASLAN004 or ASLAN003 will successfully complete clinical development or receive regulatory approval, which is necessary before they can be commercialized.

Our business and future success is substantially dependent on our ability to successfully develop, obtain regulatory approval for, and successfully commercialize ASLAN004 and ASLAN003. Any delay or setback in the development of ASLAN004 or ASLAN003 could adversely affect our business and cause the price of our ADSs or ordinary shares to decline. Should our planned clinical development of ASLAN004 or ASLAN003 fail to be completed in a timely manner or at all, we will need to rely on our other preclinical product candidates, which will require additional time and resources to obtain regulatory approval and proceed with commercialization. We cannot assure you that our planned clinical development for our product candidates will be completed in a timely manner in our planned indications, or at all, or that we will be able to obtain approval for any of our product candidates from the U.S. FDA, or any comparable foreign regulatory authority.

Clinical development is a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. Failure can occur at any stage of clinical development. We have never completed a pivotal clinical trial for our product candidates or submitted an NDA or a BLA to the U.S. FDA or similar drug approval filings to comparable foreign authorities.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of subsequent clinical trials. We have a limited operating history and to date have not demonstrated our ability to complete large scale pivotal clinical trials.

Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. In addition to the safety and efficacy traits of any product candidate, clinical trial failures may result from a multitude of factors including flaws in trial design, dose selection, placebo effect and patient enrollment criteria. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Based upon negative or inconclusive results, we or any potential future collaborator may decide, or regulators may require us, to conduct additional clinical trials or preclinical studies. In addition, data obtained from trials and studies are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval. Our future clinical trials may not be successful.

If any product candidate is found to be unsafe or lack efficacy, we will not be able to obtain regulatory approval for it and our business may be materially harmed. For example, if the results of our ongoing Phase 1 clinical trial of ASLAN004 in atopic dermatitis, or any other clinical trials for our product candidates, demonstrate unexpected safety findings or do not achieve the primary efficacy endpoints, the prospects for approval of these product candidates, as well the price of our ADSs and ordinary shares and our ability to create shareholder value would be materially and adversely affected.

In some instances, there can be significant variability in safety and/or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in composition of the patient populations, adherence to the dosing regimen and other trial protocols and the dropout rate among clinical trial participants. For example, we could be required to use a primary endpoint in our pivotal trials that is different from endpoints in our Phase 2 clinical trials, which could result in negative or less compelling efficacy results in pivotal trials despite promising results in Phase 2 clinical trials. We do not know whether any future clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market our product candidates. If we are unable to bring any of our current or future product candidates to market, our ability to create long-term shareholder value will be limited.

Delays in clinical trials are common and have many causes, and any delay could result in increased costs to us and jeopardize or delay our ability to obtain regulatory approval and commence product sales.

We may experience delays in clinical trials of our product candidates. Our planned clinical trials may not begin on time, have an effective design, enroll a sufficient number of patients, or be completed on schedule, if at all. Our clinical trials can be delayed for a variety of reasons, including:

- inability to raise funding necessary to initiate or continue a trial;
- delays in obtaining regulatory approval to commence a trial;
- delays in reaching agreement with the U.S. FDA or other regulatory authorities on final trial design;
- imposition of a clinical hold for safety reasons or following an inspection of our clinical trial operations or trial or manufacturing sites by the U.S. FDA or other regulatory authorities;
- delays in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites;
- delays in obtaining required institutional review board, or IRB, approval at each site;
- delays in recruiting suitable patients to participate in a trial;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- clinical sites dropping out of a trial to the detriment of enrollment;
- time required to add new clinical sites;
- delays by our contract manufacturers to produce and deliver sufficient supply of clinical trial materials; or
- disruptions caused by man-made or natural disasters or public health pandemics or other business interruptions, including, for example, the COVID-19 pandemic.

For example, in April 2020 the recruitment of new patients into our multiple ascending dose, or MAD, clinical trial of ASLAN004 in moderate-to-severe atopic dermatitis had to be paused in light of government restrictions in Singapore to contain the spread of COVID-19. In August 2020, those restrictions were lifted and we resumed screening patients. However, three of the patients discontinued study due to restriction imposed in response to COVID-19. In addition, we opened clinical sites in the United States and Australia in September 2020.

We could also experience delays if physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of our product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles. Further, a clinical trial may be suspended or terminated by us, the institutional review boards for the institutions in which such trials are being conducted, any data monitoring committee for such trial, or by the U.S. FDA or other regulatory authorities due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of clinical trial or manufacturing sites by the U.S. FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Furthermore, we rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and while we have agreements governing their committed activities, we have limited influence over their actual performance. If we experience termination of, or delays in the completion of, any clinical trial of our product candidates, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenues will be delayed. In addition, any delays in completing our clinical trials will increase our costs and slow down our product development and approval process. Any of these occurrences may harm our business, prospects, financial condition and results of operations significantly.

Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval for our product candidates.

Because we have multiple product candidates in our clinical pipeline and are considering a variety of target indications, we may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we must focus our research and development efforts on those product candidates and specific indications that we believe are the most promising. As a result, we may forego or delay pursuit of opportunities with other product candidates or other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities.

We may in the future spend our resources on other research programs and product candidates for specific indications that ultimately do not yield any commercially viable products. Furthermore, if we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights.

Our product candidates may cause adverse events or have other properties that could delay or prevent their regulatory approval or limit the scope of any approved label or market acceptance.

Adverse events, or AEs, caused by our product candidates or other potentially harmful characteristics of our product candidates could cause us, other reviewing entities, clinical trial sites or regulatory authorities to interrupt, delay or halt clinical trials and could result in the denial of regulatory approval.

Serious adverse events observed in any of our clinical trials may adversely impact our ability to obtain regulatory approval for our product candidates. Further, if any of our approved products cause serious or unexpected side effects after receiving market approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the product or impose restrictions on its distribution;
- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications;
- we may be required to change the way the product is administered or conduct additional clinical studies;
- we could be sued and held liable for harm caused to patients; or
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidate and could substantially increase the costs of commercializing our product candidates.

The regulatory approval processes of the U.S. FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

The time required to obtain approval by the U.S. FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. For example, we cannot guarantee that our Phase 1 clinical trial of ASLAN004 in atopic dermatitis will be sufficient to allow subsequent development or that the U.S. FDA or comparable foreign regulatory authorities will not require additional or different clinical trials prior to subsequent development of ASLAN004 or that the required primary endpoints in subsequent pivotal trials or other clinical trials will not be different than those in Phase 2 clinical trials.

Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the U.S. FDA or comparable foreign regulatory authorities may disagree with the design, scope or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the U.S. FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the U.S. FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the U.S. FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA, BLA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the U.S. FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the U.S. FDA or comparable foreign regulatory authorities may change significantly in a manner rendering our clinical data insufficient for approval.

This lengthy approval process, as well as the unpredictability of future clinical trial results, may result in our failing to obtain regulatory approval to market our product candidates, which would harm our business, results of operations and prospects significantly.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could harm the commercial prospects for our product candidates.

We have not previously submitted an NDA, BLA or any similar drug approval filing to the U.S. FDA or any comparable foreign authority for any product candidate, and we cannot be certain that any of our product candidates will be successful in clinical trials or receive regulatory approval. Further, our product candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market one or more of our product candidates, our revenue will be dependent, to a significant extent, upon the size of the markets in the territories for which we gain regulatory approval. If the markets for patients or indications that we are targeting are not as significant as we estimate, we may not generate significant revenue from sales of such products, if approved.

Even if we obtain regulatory approval for our product candidates, we will still face extensive regulatory requirements and our products may face future development and regulatory difficulties.

Even if we obtain regulatory approval in the United States or other markets, the U.S. FDA or other regulatory authorities, as applicable, may still impose significant restrictions on the indicated uses or marketing of our product candidates, or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. Our product candidates, if approved, will also be subject to ongoing U.S. FDA and/or other applicable regulatory requirements governing the labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, record-keeping and reporting of safety and other post-market information. The holder of an approved NDA or BLA is obligated to monitor and report AEs and any failure of a product to meet the specifications in the NDA or BLA, as applicable. The holder of an approved NDA or BLA must also submit new or supplemental applications and obtain U.S. FDA approval for certain changes to the approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with U.S. FDA rules and are subject to U.S. FDA review, in addition to other potentially applicable federal and state laws.

In addition, manufacturers of drug products and their facilities are subject to payment of user fees and continual review and periodic inspections by the U.S. FDA and other regulatory authorities for compliance with current good manufacturing practices, or cGMP, and adherence to commitments made in the NDA. If we or a regulatory agency discovers previously unknown problems with a product, such as AEs of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions relative to that product or the manufacturing facility, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

If we fail to comply with applicable regulatory requirements following approval of a product candidate, a regulatory agency may:

- issue a warning letter asserting that we are in violation of the law;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending NDA or supplements to an NDA submitted by us;
- seize product; or
- refuse to allow us to enter into supply contracts, including government contracts.

In particular, we may seek accelerated approval from the U.S. FDA for our product candidates which will likely require a further confirmatory trial. If this confirmatory trial is not successful, we will be required to withdraw our product candidate from the U.S. market and potentially other markets.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize our products and generate revenue.

In addition, if any of our product candidates are approved and we are found to have improperly promoted off-label uses of those products, we may become subject to significant liability. The U.S. FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, such as our product candidates, if approved. In particular, a product may not be promoted for uses that are not approved by the U.S. FDA or such other regulatory agencies as reflected in the product's approved labeling. However, companies may share truthful and not misleading information that is otherwise consistent with the product's FDA approved labeling. If we are found to have promoted such off-label uses, we may become subject to significant liability, which would materially adversely affect our business and financial condition.

Even if we obtain U.S. FDA approval for our product candidates in the United States, we may never obtain approval to commercialize our product candidates outside of the United States, which would limit our ability to realize their full market potential.

In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods.

Seeking foreign regulatory approval could result in difficulties and costs for us and require additional non-clinical studies or clinical trials which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of our products will be harmed.

We rely on third parties to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon third-party CROs to conduct our preclinical studies and clinical trials, including investigator-initiated studies sponsored by the investigator's institution, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with U.S. FDA laws and regulations regarding current good clinical practice, or cGCP, which are also required by the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities in the form of International Council for Harmonization, or ICH, guidelines for all of our products in clinical development. Regulatory authorities enforce cGCP through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable cGCP, the clinical data generated in our clinical trials may be deemed unreliable and the U.S. FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with cGCP regulations. In addition, our U.S. clinical trials must be conducted with product produced under cGMP regulations. While we have agreements governing activities of our CROs, we have limited influence over their actual performance. In addition, portions of the clinical trials for our product candidates are expected to be conducted at various locations great distances from where our principal operations are located in Singapore, which will make it more difficult for us to monitor CROs and perform visits of our clinical trial sites and will force us to rely heavily on CROs to ensure the proper and timely conduct of our clinical trials and compliance with applicable regulations, including cGCP. Failure to comply with applicable regulations in the conduct of the clinical trials for our product candidates may require us to repeat clinical trials, which would delay the regulatory approval process.

Some of our CROs have an ability to terminate their respective agreements with us if, among other reasons, it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated. If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our preclinical and clinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. Consequently, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase substantially and our ability to generate revenue could be delayed significantly.

Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

Risks Related to Our Business Operations and Industry

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on the principal members of our executive team, the loss of whose services may adversely impact the achievement of our objectives. While we have entered into employment agreements with each of our executive officers, any of them could leave our employment at any time, subject to any applicable notice requirements. Recruiting and retaining other qualified employees for our business, including scientific and technical personnel, will also be critical to our success. Competition for skilled personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical companies for individuals with similar skill sets. In addition, failure to succeed in clinical studies may make it more challenging to recruit and retain qualified personnel. The inability to recruit or loss of the services of any executive or key employee might impede the progress of our development and commercialization objectives.

We will need to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.

As of December 31, 2020, we had 18 full-time employees. In the future we may expand our employee base to increase our managerial, scientific, clinical, operational, financial and other resources, to add a sales and marketing function and to hire more consultants and contractors. Future growth would impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors.

Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Future growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of our existing or future product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and grow revenue could be reduced, and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our product candidates, if approved, and compete effectively will depend, in part, on our ability to effectively manage any future growth.

The terms of our loan agreements place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.

In connection with the license agreement with CSL Limited, or CSL, related to ASLAN004, in May 2014 we entered into a loan agreement with CSL Finance Pty Ltd, or CSL Finance, pursuant to which CSL Finance agreed to provide a ten-year facility for $4.5 million, or the CSL Facility. Borrowings under the CSL Facility are unsecured and can be used to reimburse a portion of eligible invoices for certain research and development costs or expenses incurred by us in connection with developing ASLAN004 and approved by CSL Finance at each drawdown period. In addition, we are required to mandatorily prepay amounts outstanding if we receive any income or revenue in connection with the commercialization or out-licensing of any intellectual property rights (other than under the license agreement with CSL Limited related to ASLAN004), in which case we are required to apply at least a low double digit percentage of such income or revenue against any amounts then-outstanding under the CSL Facility. Under the CSL Facility, we are subject to customary reporting and restrictive covenants. If an event of default occurs, CSL Finance can terminate the commitment under the CSL Facility and accelerate all amounts outstanding.

In September 2019, we entered into a $1.0 million loan facility, which we refer to as the September 2019 Loan Facility. The September 2019 Loan Facility has a two-year term with a 10% interest rate per annum, commencing upon the date we draw down on such facility. In October 2019, we drew down on $1.0 million under the September 2019 Loan Facility. We have the option to repay the amounts owed under the September 2019 Loan Facility at any time, subject to certain conditions. The lender has the right to convert, at its option, any outstanding principal amount plus accrued and unpaid interest under the September 2019 Loan Facility into that number of our newly issued ADSs which is calculated by dividing (i) such outstanding principal amount and accrued and unpaid interest by (ii) 90% of the volume-weighted average price of our ADSs on the date of the conversion notice. The ability to convert is subject to certain conditions, and expires at the expiry of the term of the loan.

In October 2019, we entered into a loan facility with certain existing stockholders/directors, or affiliates thereof, and in November 2019, we entered into a related loan facility with the affiliate of another existing stockholder, for an aggregate amount of $2.25 million, which we refer to as the October/November 2019 Loan Facility. The October/November 2019 Loan Facility has a two-year term with a 10% interest rate per annum, commencing upon the date we draw down the facility, which must be drawn down in full. We have the option to repay not less than $1.0 million of the amounts owed under the October/November 2019 Loan Facility at any time, subject to certain conditions. In the event that we raise net proceeds of more than ten times the aggregate loan amount in a single financing transaction during the loan term, we will be obligated to repay any unpaid portion of the principal amount and accrued interest thereunder within 30 days of the receipt of the proceeds from such financing transaction. The October/November 2019 Loan Facility further provides that, during the time that any amount is outstanding thereunder, we will not (i) incur any finance debt which is secured by a security interest or (ii) carry out or implement any merger, consolidation, reorganization (other than our solvent reorganization), recapitalization, reincorporation, share dividend or other changes in our capital structure which may have a material adverse effect on the rights of the lenders, in each case except with the prior written consent of the lenders. In addition, upon an event of default, the lenders may declare the principal amounts then outstanding and all interest thereon accrued and unpaid to be immediately due and payable to the lenders.

If we are liquidated, the rights of our lenders to repayment would be senior to the rights of the holders of our ordinary shares to receive any proceeds from the liquidation. Any declaration by our lenders of an event of default could significantly harm our business and prospects and could cause the price of our ordinary shares to decline. If we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

We may face potential product liability, and, if successful claims are brought against us, we may incur substantial liability.

The use of our product candidates in clinical trials and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our products and product candidates. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation;

- withdrawal of clinical trial participants;
- costs due to related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- the inability to commercialize our product candidates; and
- decreased demand for our product candidates, if approved for commercial sale.

Our current clinical trial liability insurance coverage may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and in the future we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If and when we obtain marketing approval for our product candidates, we intend to expand our insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. A successful product liability claim or series of claims brought against us could cause the price of our ADSs or ordinary shares to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

If our security measures are compromised, or our information technology systems or those of our vendors, and other relevant third parties, fail or suffer security breaches, loss or leakage of data, and other disruptions, this could result in a material disruption of our operations, compromise sensitive information related to our business, harm our reputation, trigger our breach notification obligations, prevent us from accessing critical information, and expose us to liability or other adverse effects to our business.

In the ordinary course of our business, we may collect, process and store proprietary, confidential and sensitive information, including personal information, intellectual property, trade secrets and proprietary business information owned or controlled by ourselves or other parties. Despite the implementation of security measures, our internal computer systems and those of our CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, public health pandemics or epidemics (including, for example, the COVID-19 pandemic), terrorism, war and telecommunication and electrical failures. Moreover, cyberattacks, malicious internet-based activity and offline fraud are prevalent and continue to increase. In addition to traditional computer "hackers," threat actors, software bugs, malicious code (such as viruses and worms), employee theft or misuse, denial-of-service attacks (such as credential stuffing), and ransomware attacks, sophisticated nation-state and nation-state supported actors now engage in attacks (including advanced persistent threat intrusions). We also may be the subject of phishing attacks, viruses, malware installation, server malfunction, software or hardware failures, loss of data or other computer assets, adware or other similar issues.

If we, our service providers, partners or other relevant third parties have experienced, or in the future experience, any security incident(s) that result in any data loss, deletion or destruction, unauthorized access to, loss of, unauthorized acquisition or disclosure of, or inadvertent exposure or disclosure of sensitive information, or compromise related to the security, confidentiality, integrity or availability of our (or their) information technology, software, services, communications or data, it may result in a material adverse impact, including without limitation, regulatory investigations or enforcement actions, litigation, indemnity obligations, negative publicity, an interruption to our operations or financial loss. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Such incidents may also inhibit our ability to conduct our analyses, deliver test results, process claims and appeals, provide assistance for patients or their physicians, conduct research and development activities, collect, process and prepare company financial information, and provide information about our tests and other patient and physician education and outreach efforts through our website. Likewise, we rely on other third parties to manufacture our product candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business.

We may be unable to detect, anticipate, measure or prevent threats or techniques used to detect or exploit vulnerabilities in our own (or our third parties') information technology, services, communications or software, or cause security breaches, because such threats and techniques change frequently, are often sophisticated in nature, and may not be detected until after an incident has occurred. In addition, security researchers and other individuals have in the past and will continue in the future to actively search for and exploit actual and potential vulnerabilities in our (or our third parties') information technology, services, communications or software. We cannot be certain that we will be able to address any such vulnerabilities, in whole or part. Furthermore, we do not have formal internal disaster recovery procedures. If our systems experience a disaster or are otherwise unavailable, we may not be able to operate our business, which could have a material adverse effect on our financial conditions, reputation or business prospects. In addition, theft or other exposure of data may interfere with our ability to protect our or our licensors' intellectual property, trade secrets, and other information critical to our operations.

Failures or significant downtime of our information technology or telecommunication systems or those used by our third-party service providers could cause significant interruptions in our operations and adversely impact the confidentiality, integrity and availability of sensitive or confidential information, including preventing us from conducting clinical trials, tests or research and development activities and preventing us from managing the administrative aspects of our business.

Applicable data protection laws, privacy policies and data protection obligations may require us to notify relevant stakeholders of security breaches or other unauthorized access of data. Such disclosures are costly, and the disclosures or the failure to comply with such requirements could lead to material adverse impacts, including without limitation, negative publicity, a loss of confidence in our operations or security measures or breach of contract claims. Certain data breaches must also be reported to affected individuals and the government, and in some cases to the media, under provisions of the U.S. Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, other U.S. federal and state law, and requirements of non-U.S. jurisdictions, including the European Union General Data Protection Regulation, and financial penalties may also apply. Such disclosures are costly, and the disclosure, or the failure to comply with such requirements, could lead to material adverse impacts, including without limitation, negative publicity, a loss of partner or customer confidence in our systems or security measures, or breach of contract claims.

Our insurance policies may not be adequate to compensate us for the potential losses arising from breaches, failures or disruptions of our infrastructure, catastrophic events and disasters or otherwise. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and defending a suit, regardless of its merit, could be costly and divert management's attention. The successful assertion of one or more large claims against us that exceeds our available insurance coverage, or results in changes to our insurance policies (including premium increases or the imposition of large deductible or co-insurance requirements), could have an adverse effect on our business. Additionally, there can be no assurance that the limitations of liability in our contracts would be enforceable or adequate or would otherwise protect us from liabilities or damages if we fail to comply with applicable data protection laws, privacy policies or data protection obligations related to information security or security breaches.

In addition to in-licensing or acquiring product candidates, we may engage in future business acquisitions that could disrupt our business, cause dilution to our ADS holders and harm our financial condition and operating results.

While we currently have no specific plans to acquire any other businesses, we have, from time to time, evaluated acquisition opportunities and may, in the future, make acquisitions of, or investments in, companies that we believe have products or capabilities that are a strategic or commercial fit with our current product candidates and business or otherwise offer opportunities for our company. In connection with these acquisitions or investments, we may:

- issue shares that would dilute our ADS holders' percentage of ownership;
- incur debt and assume liabilities; and
- incur amortization expenses related to intangible assets or incur large write-offs.

We also may be unable to find suitable acquisition candidates and we may not be able to complete acquisitions on favorable terms, if at all. If we do complete an acquisition, we cannot assure you that it will ultimately strengthen our competitive position or that it will not be viewed negatively by customers, financial markets or investors. Further, future acquisitions could also pose numerous additional risks to our operations, including:

- problems integrating the purchased business, products or technologies;
- increases to our expenses;
- the failure to have discovered undisclosed liabilities of the acquired asset or company;
- diversion of management's attention from their day-to-day responsibilities;
- harm to our operating results or financial condition;
- entrance into markets in which we have limited or no prior experience; and
- potential loss of key employees, particularly those of the acquired entity.

We may not be able to complete one or more acquisitions or effectively integrate the operations, products or personnel gained through any such acquisition without a material adverse effect on our business, financial condition and results of operations.

Our operations could be subject to natural disasters, health pandemics or epidemics and other business disruptions, which could have a material adverse effect on our business, results of operation and financial condition.

Our operations, and in particular our clinical trials, are being conducted across areas of Asia that may be prone to natural disasters, such as earthquakes, cyclones, monsoons and floods, which could cause interruptions to our operations.

Any occurrence of these natural disasters or pandemic diseases or other adverse public health developments in the areas in which we operate our clinical trials could disrupt or delay our business operations or clinical development, which could materially adversely affect our business.

Our business could continue to be adversely affected by the effects of health pandemics or epidemics, including the effects of the COVID-19 pandemic.

Our business could continue to be adversely affected by the effects of health pandemics or epidemics, including the effects of the current COVID-19 pandemic, and other recent outbreaks of diseases, such influenza A, or H1N1, avian influenza, or H7N9, and severe acute respiratory syndrome, or SARS. The COVID-19 pandemic was declared by the World Health Organization as a global pandemic, and is resulting in travel restrictions, quarantine orders and other restrictions by governments to reduce the spread of the disease. As a result, a large part of our workforce has been working remotely since March 2020 and plans to fully reopen our offices have not yet been initiated. The effects of the restrictions related to the COVID-19 pandemic and our work-from-home policies may negatively impact productivity, disrupt our business and delay our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. These and similar, and perhaps more severe, disruptions in our operations could negatively impact our business, operating results and financial condition.

Quarantines, shelter-in-place and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, related to COVID-19 or other infectious diseases could impact personnel at third-party manufacturing facilities in Asia, or the availability or cost of materials, which would disrupt our supply chain. While many of these materials may be obtained by more than one supplier, port closures and other restrictions resulting from the coronavirus outbreak in the region or other regions may disrupt our supply chain or limit our ability to obtain sufficient materials for our product candidates.

In addition, our clinical trials have been affected by the ongoing COVID-19 pandemic. Site initiation and patient enrollment has been and may be further delayed due to prioritization of hospital resources toward the COVID-19 pandemic, and some patients may not be able or willing to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19, has been delayed and may be further delayed or disrupted, which has had an adverse effect on our clinical trial operations. For example, in April 2020 the recruitment of new patients into our MAD clinical trial of ASLAN004 in moderate-to-severe atopic dermatitis had to be paused in light of government restrictions in Singapore to contain the spread of COVID-19. However, three of the patients discontinued study due to restriction imposed in response to COVID-19. In August 2020, those restrictions were lifted and we resumed screening patients. In addition, we opened clinical sites in the United States and Australia in September 2020.

The spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. While the potential economic impact brought by, and the duration of, the COVID-19 pandemic, may be difficult to assess or predict, it is currently resulting in significant disruption of global financial markets. This disruption, if sustained or recurrent, could make it more difficult for us to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our ADSs.

The global pandemic of COVID-19 continues to rapidly evolve. The ultimate impact of the ongoing COVID-19 pandemic or a similar health pandemic or epidemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, healthcare systems or the global economy as a whole. These effects could have a material impact on our operations, and we will continue to monitor the COVID-19 situation closely.

Our business is subject to economic, political, regulatory and other risks associated with international operations.

As a company based in Singapore, our business is subject to risks associated with conducting business outside of the United States. Many of our suppliers and collaborative and clinical trial relationships are located outside the United States. Accordingly, our future results could be harmed by a variety of factors, including:

- economic weakness, including inflation, or political instability;
- differing and changing regulatory requirements for drug approvals;
- differing jurisdictions could present different issues for securing, maintaining or obtaining freedom to operate in such jurisdictions;
- potentially reduced protection for intellectual property rights;
- difficulties in compliance with local laws and regulations;
- changes in local regulations and customs, tariffs and trade barriers;
- changes in currency exchange rates, including the Singapore dollar;
- changes in a specific country’s or region’s political or economic environment;
- trade protection measures, import or export licensing requirements or other restrictive actions;
- differing reimbursement regimes and price controls;

- negative consequences from changes in tax laws;
- compliance with tax, employment, immigration and labor laws for employees;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- difficulties associated with staffing and managing international operations, including differing labor relations;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities;
- disruptions on us or our strategic partners, third-party manufacturers, suppliers and other third parties upon which we rely resulting from the impact of public health epidemics or pandemics (including, for example, the COVID-19 pandemic); and
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters including typhoons, floods and fires.

More specifically, the economy in Asia differs from most developed markets in many respects, including the level of government involvement, level of development, growth rate, control of foreign exchange, government policy on public order and allocation of resources. In some of the Asian markets, governments continue to play a significant role in regulating industry development by imposing industrial policies. Moreover, some local governments also exercise significant control over the economic growth and public order in their respective jurisdictions through allocating resources, controlling payment of foreign currency-denominated obligations, setting monetary policies, and providing preferential treatment to particular industries or companies. In addition, some Asian markets have experienced, and may in the future experience, political instability, including strikes, demonstrations, protests, marches, coups d'état, guerilla activity or other types of civil disorder. These instabilities and any adverse changes in the political environment could increase our costs, increase our exposure to legal and business risks, or disrupt our clinical operations.

We are subject to stringent privacy and data security laws, information security policies, government regulation, contractual obligations and standards governing the use, processing, and cross-border transfer of personal information and our data privacy and security practices. The actual or perceived failure by us, our business partners, or vendors to comply with increasingly stringent laws, regulations, external and internal privacy and security policies and representations, and contractual obligations relating to privacy, data protection, and data security could harm our reputation, disrupt or adversely affect our business operations, and subject us to significant fines and liability.

We receive, generate, process, use, transfer, disclose, make accessible, protect, share and store significant and increasing volumes of sensitive information, such as employee, personal and patient data. We are or may become subject to a variety of local, state, national and international laws, directives and regulations that apply to the collection, use, retention, protection, disclosure, transfer and other processing of personal data in the different jurisdictions in which we operate, including comprehensive regulatory systems in the U.S. and Europe. Legal requirements relating to the collection, storage, handling, and transfer of personal information and personal data continue to evolve and may result in ever-increasing public scrutiny and escalating levels of enforcement, sanctions and increased costs of compliance. Additionally, we are or may become subject to the terms of external and internal privacy and security policies, representations, certifications, standards, publications and frameworks, and contractual obligations to third parties related to privacy, information security and processing.

Compliance with U.S. and international data protection laws, regulations and other internal and external privacy and cybersecurity commitments could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business. Complying with these various laws and other obligations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. If we or our personnel, partners, or vendors fail, or are perceived to have failed, to comply with U.S. and international data privacy and protection laws, regulations and other obligations or representations, it could result in government enforcement actions (which could include civil or criminal penalties), inability to process personal data, regulatory scrutiny, disruptions to our operations, diversion of time and effort, private litigation and/or adverse publicity and could negatively affect our operating results and business. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend, could result in fines or other financial penalties, could result in adverse publicity or other regulatory scrutiny and could have a material adverse effect on our business, financial condition and results of operations.

The California Consumer Privacy Act, or CCPA, which took effect on January 1, 2020, is an example of how data protection and data security regulation has become more stringent in the United States. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance cost and potential liability.

The collection and use of personal data in the European Union, or EU, are governed by the General Data Protection Regulation, or GDPR. The GDPR imposes stringent requirements for controllers and processors of personal data, including, for example, more robust disclosures to individuals and a strengthened individual data rights regime, shortened timelines for data breach notifications, limitations on retention of information, increased requirements pertaining to special categories of data, such as health data, and additional obligations when we contract with third-party processors in connection with the processing of the personal data. In addition, the GDPR provides that EU member states may make their own further laws and regulations limiting the processing of personal data, including genetic, biometric or health data.

The GDPR also includes restrictions on cross-border data transfers. A recent decision by the Court of Justice of the EU, or the "Schrems II" ruling, however, has invalidated the EU-U.S. Privacy Shield Framework, which was one of the primary mechanisms used by U.S. Companies to import personal information from Europe, and raised questions about whether the European Commission's Standard Contractual Clauses, or SCCs, one of the primary alternatives to the Privacy Shield, can lawfully be used for personal information transfers from Europe to the United States or most other countries. Similarly, the Swiss Federal Data Protection and Information Commissioner recently opined that the Swiss-U.S. Privacy Shield is inadequate for transfers of data from Switzerland to the U.S. The United Kingdom, whose data protection laws are similar to those of the EU, may similarly determine that the EU-U.S. Privacy Shield is not a valid mechanism for lawfully transferring personal information from the UK to the United States. The European Commission recently proposed updates to the SCCs, and additional regulatory guidance has been released that seeks to impose additional obligations on companies seeking to rely on the SCCs. Given that, at present, there are few, if any, viable alternatives to the EU-U.S. Privacy Shield and the SCCs, any transfers by us or our vendors of personal data from Europe may not comply with European data protection law, which may increase our exposure to the GDPR's heightened sanctions for violations of its cross-border data transfer restrictions and may prohibit our transfer of EU personal data outside of the EU (including clinical trial data), and may adversely impact our operations, product development and ability to provide our products.

Further, the United Kingdom's vote in favor of exiting the EU, often referred to as Brexit, has created uncertainty with regard to data protection regulation in the United Kingdom. As of the beginning of 2021, the UK is deemed to be a "third country" under the GDPR and transfers of European personal information to the U.K. will require an adequacy mechanism to render such transfers lawful under the GDPR. Compliance with the GDPR and applicable EU member states and the United Kingdom privacy laws will be a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities. In addition, our failure to comply with GDPR and privacy laws of EU member states or the United Kingdom may result in regulators prohibiting our processing of the personal information of EU data subjects, which could impact our operations and ability to develop our products and provide our services, including interrupting or ending EU clinical trials.

The GDPR applies extraterritorially, and we may be subject to the GDPR when our data processing activities involve the personal data of individuals located in the EU, such as in connection with any EU clinical trials. GDPR regulations may impose additional responsibility and liability in relation to the personal data that we process and we may be required to put in place additional mechanisms to ensure compliance with the new data protection rules. This may be onerous and may interrupt or delay our development activities, and adversely affect our business, financial condition, results of operations and prospects.

Other jurisdictions outside the EU are similarly introducing or enhancing privacy and data security laws, rules, and regulations, which could increase our compliance costs and the risks associated with non-compliance. We cannot guarantee that we may be in compliance with all applicable international regulations as they are enforced now or as they evolve. For example, our privacy policies may be insufficient to protect any personal information we collect, or may not comply with applicable laws, in which case we may be subject to regulatory enforcement actions, lawsuits or reputational damage, all of which may adversely affect our business. If we fail to comply with the GDPR and the applicable national data protection laws of the EU member states, or if regulators assert we have failed to comply with these laws, it may lead to regulatory enforcement actions, which can result in monetary penalties of up to €20,000,000 or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, and other administrative penalties. If any of these events were to occur, our business and financial results could be significantly disrupted and adversely affected.

Risks Related to Our Intellectual Property

If we are unable to obtain or protect intellectual property rights related to our current product candidates or any future product candidates which we may develop, we may not be able to compete effectively in our market.

We rely upon a combination of patents, trade secret protection, confidentiality agreements and proprietary know-how, and intend to seek marketing exclusivity for any approved product, in order to protect the intellectual property related to product candidates. The patent prosecution process is expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions, is highly uncertain, and has, in the recent years, been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates in the United States or in other foreign countries for a number of reasons, including because of a finding of lack of novelty or that the claimed inventions are already in the public domain. If this were to occur, early competition from third parties could be expected against our product candidates.

Even if patents do successfully issue, third parties may challenge their validity, enforceability or scope, which may result in such patents being invalidated, rendered unenforceable, narrowed or deemed as not infringing. Also, a third party may challenge our ownership of patents and patent applications assigned to us, or may challenge our exclusive rights to patents and patent applications that we license from third parties. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from circumventing our patents by developing products similar to or competing with our product candidates. If the patent applications we hold with respect to our other product candidates fail to issue or if their breadth or strength of protection is threatened, it could dissuade companies from collaborating with us to develop them, and threaten our ability to commercialize any resulting products. We cannot offer any assurances about which, if any, applications will issue as patents or whether any issued patents will be found not invalid and not unenforceable or will go unthreatened by third parties. In addition, due to the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Furthermore, patent applications by third parties can result in an interference proceeding in the United States being invoked by a third party or instituted by us to determine who was the first to invent any of the subject matter covered by the patent claims of our applications or patents.

Because patent applications in the United States, Europe and many other jurisdictions are typically not published until 18 months after filing, and because publications of discoveries in scientific literature lag behind actual discoveries, we cannot be certain that we were the first to make the inventions claimed in our issued patents or pending patent applications, or that we were the first to file for protection of the inventions set forth in our patents or patent applications. As a result, we may not be able to obtain or maintain protection for certain inventions. Therefore, the enforceability and scope of our patents in the United States, Europe and in many other jurisdictions cannot be predicted with certainty and, as a result, any patents that we own or license may not provide sufficient protection against competitors. We may not be able to obtain or maintain patent protection from our pending patent applications, from those we may file in the future, or from those we may license from third parties. Moreover, even if we are able to obtain patent protection, such patent protection may be of insufficient scope to achieve our business objectives.

Moreover, some of our owned patents and patent applications are, and may in the future be, co-owned with third parties. For example, under our license agreement with CSL, we and CSL co-own certain intellectual property that we jointly developed prior to the completion of the recent single ascending dose clinical trial. While we currently have an exclusive license to CSL's rights under such co-owned intellectual property, if we are unable to maintain such exclusive license, or if we are unable to obtain and maintain an exclusive license to any of our other third-party co-owners' rights under any intellectual property that we co-own, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Our inability to protect our confidential information and trade secrets would harm our business and competitive position.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our drug development process that involve proprietary know-how, information or technology that is not covered by patents. Trade secrets can be difficult to protect. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors, and other third parties. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Furthermore, we cannot guarantee that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. If we are unable to prevent material disclosure of the non-patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

We may not be able to protect our intellectual property and proprietary rights throughout the world.

Filing, prosecuting, and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions.

Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but enforcement is not as strong as that in the United States. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. If we are unable to block the commercialization of these products, these products may erode our commercial position in the market place.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Several countries have compulsory licensing laws under which, in certain circumstances, a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations, and prospects may be adversely affected.

In China, the validity, enforceability and scope of protection available under the relevant intellectual property laws are uncertain and still evolving. Implementation and enforcement of Chinese intellectual property-related laws have historically been inconsistent. Accordingly, intellectual property and confidentiality legal regimes in China may not afford protection to the same extent as in the United States or other countries. Policing unauthorized use of proprietary technology is difficult and expensive, and we may need to resort to litigation to enforce or defend patents issued to us or to determine the enforceability, scope and validity of our proprietary rights or those of others. The experience and capabilities of Chinese courts in handling intellectual property litigation varies, and outcomes are unpredictable. Further, such litigation may require a significant expenditure of cash and may divert management's attention from our operations, which could harm our business, financial condition and results of operations. An adverse determination in any such litigation could materially impair our intellectual property rights and may harm our business, prospects and reputation in China.

If we fail to comply with our obligations in the agreements under which we license rights to technology from third parties, or if the license agreements are terminated for other reasons, we could lose license rights that are important to our business.

We are heavily reliant upon licenses to certain patent rights and proprietary technology from third parties that are important or necessary to the development of our product candidates. Accordingly, we are party to a number of technology licenses that are important to our business and expect to enter into additional licenses in the future. For example, our rights to ASLAN004 are the subject of an exclusive license agreement with CSL. If we fail to comply with our obligations under our agreement with CSL (including, among other things, if we fail to develop and commercialize ASLAN004 in a proper, efficient, skillful, diligent and competent manner) or our other license agreements, or we are subject to insolvency or liquidation, our licensors may have the right to terminate the license.

In addition, under our agreement with CSL, in the event of a change of control, we are required to receive CSL's prior consent to engage in such a transaction if the change of control, in CSL's reasonable opinion, adversely affects our ability to carry out the development of ASLAN004 or would damage CSL's reputation. A breach of this obligation may result in termination of the license. In the event that any of our important technology licenses were to be terminated by the licensor, we may need to negotiate new or reinstated agreements, which may not be available to us on equally favorable terms, or at all, or we could lose our rights under these agreements, including our rights to intellectual property or technology important to our development programs, which would likely cause us to cease further development of the related program, including ASLAN004. Furthermore, under certain of our collaboration agreements, our licensors may retain the right to grant non-exclusive licenses to the licensed patents and technology to other academic or research institutions for non-commercial research purposes, in which case we would not have exclusive rights to such licensed patents and technologies.

Our technology agreements under which we currently license intellectual property or technology to and from third parties are complex and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, increase what we believe to be our financial or other obligations under the relevant agreement or decrease the third party's financial or other obligations under the relevant agreement, any of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our existing collaborative development relationships and any collaboration relationships we might enter into in the future;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our current and future licensors and us; and
- the priority of invention of patented technology.

We are generally also subject to all of the same risks with respect to protection of intellectual property that we license, as we are for intellectual property that we own, which are described elsewhere under "Risks Related to Our Intellectual Property." If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize products could suffer. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

Third-party claims of intellectual property infringement may prevent or delay our development and commercialization efforts.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions, reexamination, post-grant review, *inter partes* review, and derivation proceedings before the U.S. Patent and Trademark Office, or USPTO, and equivalent proceedings in foreign jurisdictions (*e.g.*, opposition proceedings). Numerous U.S. and foreign issued patents and pending patent applications which are owned by third parties, exist in the fields in which we and our collaborators are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.

Third parties may assert that we or our product candidates are infringing, misappropriating or otherwise violating their intellectual property without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe.

In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any drug substance formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtain a license under the applicable patents, which may not be available on commercially reasonable terms or at all, or until such patents are invalidated or expire. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations or methods of use, the holders of any such patent may be able to block our ability to develop and commercialize the applicable product candidate formulation or use unless we obtain a license, which may not be available on commercially reasonable terms or at all, or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all.

Parties making intellectual property claims against us may request and/or obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. Even if we believe any third-party intellectual property claims are without merit, there is no assurance that a court would find in our favor on questions of validity, enforceability, priority, or non-infringement. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products or manufacturing processes, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research, manufacture clinical trial supplies or allow commercialization of our product candidates. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development or commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our products, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. If we or one of our licensors were to initiate legal proceedings against a third party to enforce a patent covering one of our products, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States or in Europe, defendant counterclaims alleging invalidity or unenforceability are commonplace. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, may narrow the scope of our or our licensor's patents, or may refuse to stop the defendant from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

Interference proceedings provoked by third parties or brought by us may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our collaborators or licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our ADSs.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time-consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Recent patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act, or Leahy-Smith Act, could increase those uncertainties and costs. The Leahy-Smith Act includes provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents, and may also affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, inter partes review and derivation proceedings. In addition, assuming that other requirements for patentability are met, prior to March 15, 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 15, 2013, under the Leahy-Smith Act, the United States transitioned to a first inventor to file system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can (i) result in abandonment or lapse of, or (ii) otherwise affect the patentability of, the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors that control the prosecution and maintenance of our licensed patents fail to maintain the patents and patent applications covering our product candidates, our competitors might be able to enter the market, which would have a material adverse effect on our business.

In addition, as licensees we may not be responsible for or have control over the prosecution or enforceability of our licensed patents. In such cases, we have to rely on the licensor to comply with the requisite obligations of the patent offices, including the duty of disclosure, filing assignments, etc. We cannot guarantee that our licensed patents and patent applications will be prosecuted, maintained and enforced in a manner consistent with the best interests of our business. As licensees, we may not be in a position to assess if these duties have been complied with or have the ability to complete these duties on behalf of the licensor. Failure by our licensors to comply with such duties may affect the enforceability of the patent rights, narrow the scope of our patent protection and, more generally, could affect the value of our patent rights. If our patent protection is reduced or eliminated, we may not be able to prevent our competitors or other third parties from developing or commercializing products similar to ours and may be required to cease development of our product candidates, which could have a material adverse effect on our business.

If we do not obtain patent term extension for any product candidates we may develop, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop, one or more of our owned or in-licensed U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, or Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent term extension of up to five years as compensation for the patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. Similar issues apply in the patent legal systems of other key markets such as the EU. If we are unable to obtain patent term extension or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations and prospects could be materially harmed.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We employ individuals, and work with consultants or independent contractors, who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information, including trade secrets, of any such individual's former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. There is no guarantee of success in defending these claims, and even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees.

In addition, while it is our policy to require our employees, consultants and independent contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing (and may require further action), or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects.

If our trademarks and tradenames are not adequately protected, then we may not be able to build name recognition in our markets and our business may be adversely affected.

We have registered or applied to register certain trademarks to protect our company name and plan to apply to register trademarks to cover product names in the future once our product candidates are closer to commercialization. We cannot assure you that our trademark applications will be approved or that we will seek registered trademark protection for each of our product names in each jurisdiction in which we operate. During trademark registration proceedings, we may receive rejections. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in proceedings before the USPTO and in proceedings before comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources toward advertising and marketing new brands. Further, we cannot assure you that competitors will not infringe our trademarks or that we will have adequate resources to enforce our trademarks.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products that are similar to any product candidates we may develop or utilize similar technology but that are not covered by the claims of the patents that we license or may own in the future;
- we, or our license partners or current or future collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or may own in the future;
- we, or our license partners or current or future collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or licensed intellectual property rights;
- it is possible that our pending licensed patent applications or those that we may own in the future will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Risks Related to Commercialization of Our Product Candidates

Our commercial success depends upon attaining significant market acceptance of our product candidates, if approved, among physicians, healthcare payors, patients and the medical community.

Even if we obtain regulatory approval for our product candidates, the product may not gain market acceptance among physicians, healthcare payors, patients and the medical community, which is critical to commercial success. Market acceptance of any product candidate for which we receive approval depends on a number of factors, including:

- the efficacy and safety as demonstrated in clinical trials;
- the timing of market introduction of the product candidate as well as competitive products;
- the clinical indications for which the product candidate is approved;
- acceptance by physicians, the medical community and patients of the product candidate as a safe and effective treatment and also the willingness of physicians to prescribe a drug based on an active pharmaceutical ingredient, or API, that is less familiar to them than other drug APIs;
- the convenience of prescribing and initiating patients on the product candidate;
- the potential and perceived advantages of such product candidate over alternative treatments;
- the cost of treatment in relation to alternative treatments, including any similar generic treatments;
- favorable pricing and the availability of coverage and adequate reimbursement by third-party payors, such as government authorities;
- relative convenience and ease of administration;
- the prevalence and severity of adverse side effects; and
- the effectiveness of sales and marketing efforts.

If our product candidates are approved but fail to achieve an adequate level of acceptance by physicians, healthcare payors, patients and the medical community, we will not be able to generate significant revenue, and we may not become or remain profitable. In addition, even if any of our product candidates gain acceptance, the markets for the treatment of patients with our target indications may not be as significant as we estimate.

Our organization has no prior sales and marketing experience and resources.

We have never, as an organization, commercialized a product and there is no guarantee that we will be able to do so successfully. We will need to establish a commercial team and hire sales forces in the geographies where we are permitted and intend to market our drugs. We will also need to develop a marketing team and strategy in order to successfully market and sell our product candidates, which will require significant time and resources and the development of our ability to market and sell our product and generate revenues from our product candidates may be delayed or limited. We cannot assure you that our sales efforts will be effective or produce the results we expect. We will be competing with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel. Further, we may face difficulties or delays in obtaining and maintaining the required licenses and permits to sell our product candidates in individual states and jurisdictions. If the commercialization of any of our product candidates is unsuccessful or perceived as disappointing, the price of our ADSs could decline significantly and the long-term success of the product and our company could be harmed.

We may also seek to establish collaborations with pharmaceutical companies to maximize the potential of our products in other markets. For example, we are conducting a Phase 1 clinical trial to develop ASLAN004 as a treatment for atopic dermatitis, and, in the future, we may seek a global partner to support Phase 3 clinical trials and potential commercialization. We may not be successful in establishing development and commercialization collaborations which could adversely affect, and potentially prohibit, our ability to develop our product candidates.

Part of our business strategy is to establish collaborative relationships to commercialize and fund development and approval of certain of our product candidates. We may not succeed in establishing and maintaining collaborative relationships, which may significantly limit our ability to develop and commercialize products, for which we pursue this commercialization strategy.

We will need to establish and maintain successful collaborative relationships to obtain sales, marketing and distribution capabilities for the product candidates we do not intend to commercialize ourselves. The process of establishing and maintaining collaborative relationships is difficult, time-consuming and involves significant uncertainty, including:

- we may have limited control over the decisions of any partners and they may change the priority of any programs in a manner that would result in termination or significant delays to a partnered program;
- our ability to generate future payments and royalties from any partners will depend upon the ability of a partner to obtain regulatory approvals and achieve market acceptance of products developed from our product candidates;
- a partner may fail to properly initiate, maintain or defend our intellectual property rights, where applicable, or a party may use our proprietary information in such a way as to invite litigation that could jeopardize or potentially invalidate our proprietary information or expose us to potential liability;
- a partner may not devote sufficient capital or resources towards our product candidates; and,
- a partner may not comply with applicable government regulatory requirements necessary to successfully market and sell our products.

If any collaborator fails to fulfill its responsibilities in a timely manner, or at all, any clinical development, manufacturing or commercialization efforts pursuant to that collaboration could be delayed or terminated, or it may be necessary for us to assume responsibility for expenses or activities that would otherwise have been the responsibility of our collaborator. If we are unable to establish and maintain collaborative relationships on acceptable terms or to successfully and timely transition terminated collaborative agreements, we may have to delay or discontinue further development of one or more of our product candidates, undertake development and commercialization activities at our own expense or find alternative sources of capital.

Attempting to secure additional financing for a product candidate may also lead to the risks discussed under the risk factor titled “We will need to obtain substantial amounts of financing for our operations, and if we fail to obtain additional financing, we may be forced to delay, reduce or eliminate our product development programs or commercialization efforts” described above.

We rely completely on third parties to manufacture our preclinical and clinical drug supplies and we intend to rely on third parties to produce commercial supplies of any approved product candidate.

If we were to experience an unexpected loss of supply of our product candidates for any reason, whether as a result of manufacturing, supply or storage issues or otherwise (including, for example, any disruptions caused by the COVID-19 pandemic), we could experience delays, disruptions, suspensions or terminations of, or be required to restart or repeat, clinical trials. We do not currently have nor do we plan to acquire the infrastructure or capability internally to manufacture our preclinical and clinical drug supplies and we lack the resources and the capability to manufacture any of our product candidates on a clinical or commercial scale. The facilities used by our contract manufacturers or other third-party manufacturers to manufacture our product candidates must be approved by the U.S. FDA or other regulators pursuant to inspections. While we work closely with our third-party manufacturers on the manufacturing process for our product candidates, including quality audits, we generally do not control the implementation of the manufacturing process of, and are completely dependent on, our contract manufacturers or other third-party manufacturers for compliance with cGMP regulatory requirements and for manufacture of both active drug substances and finished drug products.

If our contract manufacturers or other third-party manufacturers cannot successfully manufacture material that conforms to applicable specifications and the strict regulatory requirements of the U.S. FDA or other regulators, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers or other third-party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the U.S. FDA or other regulators do not approve these facilities for the manufacture of our product candidates or if they withdraw any such approval in the future, we may need to find alternative manufacturing facilities, which could take several years and would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

We rely on our manufacturers to purchase from third-party suppliers the materials necessary to produce our product candidates for our clinical trials. There are a limited number of suppliers for raw materials that we use to manufacture our product candidates and there may be a need to assess alternate suppliers to prevent a possible disruption of the manufacture of the materials necessary to produce our product candidates for our clinical trials, and if approved, for commercial sale. We do not have any control over the process or timing of the acquisition of these raw materials by our manufacturers. Although we generally do not begin a clinical trial unless we believe we have a sufficient supply of a product candidate to complete the clinical trial, any significant delay in the supply of a product candidate, or the raw material components thereof, for an ongoing clinical trial due to the need to replace a contract manufacturer or other third-party manufacturer could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our product candidates. If our manufacturers or we are unable to purchase these raw materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenue from the sale of our product candidates.

We expect to continue to depend on contract manufacturers or other third-party manufacturers for the foreseeable future, and our requirements for and dependence upon these third-party manufacturers will increase when and if one or more of our product candidates is approved and commercialized. We have not entered into any long-term commercial supply agreements with our current contract manufacturers or with any alternate contract manufacturers. Although we intend to do so prior to any commercial launch of our product candidates, if approved by the U.S. FDA, in order to ensure that we maintain adequate supplies of finished drug product, we may be unable to enter into such an agreement or do so on commercially reasonable terms, which could have a material adverse impact upon our business, including delaying a product launch or subjecting our commercialization efforts to significant supply risk. Even if we are able to enter into long-term agreements with manufacturers for commercial supply on reasonable terms, we may be unable to do so with sufficient time prior to the launch of our product candidates, which would expose us to substantial supply risk and potentially jeopardize our launch.

Manufacturing issues may arise that could increase product and regulatory approval costs or delay commercialization.

As we scale up manufacturing of our product candidates and conduct required stability testing, product, packaging, equipment and process-related issues may require refinement or resolution in order to proceed with our planned clinical trials and obtain regulatory approval for commercial marketing. In the future, we may identify impurities, which could result in increased scrutiny by the regulatory agencies, delays in our clinical program and regulatory approval, increases in our operating expenses, or failure to obtain or maintain approval for our product candidates.

Guidelines and recommendations published by various organizations can reduce the use of our product candidates.

Government agencies promulgate regulations and guidelines directly applicable to us and to our product candidates. In addition, professional societies, such as practice management groups, private health and science foundations and organizations involved in various diseases from time to time may also publish guidelines or recommendations to the healthcare and patient communities. Recommendations of government agencies or these other groups or organizations may relate to such matters as usage, dosage, route of administration and use of concomitant therapies. Recommendations or guidelines suggesting the reduced use of our product candidates or the use of competitive or alternative products as the standard of care to be followed by patients and healthcare providers could result in decreased use of our product candidates.

We face significant competition from other biopharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

Our industry is intensely competitive and subject to rapid and significant technological change. While we believe that our Asia based development platform, knowledge, experience and scientific resources provide us with competitive advantages, we face substantial competition from multinational pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies, universities and other research institutions worldwide. For example, there are several therapies currently in clinical development for atopic dermatitis, including *lebrikizumab* being developed by Dermira, Inc./Eli Lilly and Company, and *tralokinumab* being developed by Leo Pharma A/S. In addition, *dupilumab*, developed by Sanofi S.A. and Regeneron Pharmaceuticals, Inc., is approved for the treatment of moderate-to-severe atopic dermatitis and moderate-to-severe asthma.

Many of our competitors have significantly greater financial, clinical and human resources. Additionally, small and early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. As a result, our competitors may discover, develop, license or commercialize products before or more successfully than we do. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis drug products or drug delivery technologies that are more effective or less costly than our product candidates that we are currently developing or that we may develop.

We believe that our ability to successfully compete will depend on, among other things:

- the efficacy and safety of our product candidates, especially as compared to marketed products and product candidates in development by third parties;
- the time it takes for our product candidates to complete clinical development and receive marketing approval;
- the ability to commercialize and market any of our product candidates that receive regulatory approval;
- the price of our products;
- whether coverage and adequate levels of reimbursement are available from third-party payors, such as private and governmental health insurance plans, including Medicare;
- the ability to protect intellectual property rights related to our product candidates;
- the ability to manufacture on a cost-effective basis and sell commercial quantities of any of our product candidates that receive regulatory approval; and
- acceptance of any of our product candidates that receive regulatory approval by physicians and other healthcare providers.

If our competitors market products that are more effective, safer or less expensive than our future products, if any, or that reach the market sooner than our future products, if any, we may not achieve commercial success. Because we have limited research and development capabilities, it may be difficult for us to stay abreast of the rapid changes in technology. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our technologies or product candidates obsolete, less competitive or not economical.

Price controls may adversely affect our future profitability.

In certain countries, prescription drug pricing and reimbursement is subject to governmental control. In those countries that impose price controls, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we or our strategic partners may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidates to other available therapies.

Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In certain markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we or our strategic partners might obtain marketing approval for a product candidate in a particular country, but then be subject to price regulations that delay commercial launch of the product candidate, possibly for lengthy time periods, and negatively impact the revenue that we generate from the sale of the product in that country. If reimbursement of such product candidates is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, or if there is competition from lower priced cross-border sales, our profitability will be negatively affected.

Legislative or regulatory healthcare reforms may make it more difficult and costly for us to obtain regulatory clearance or approval of our product candidates and to produce, market and distribute our products after clearance or approval is obtained.

From time to time, legislation is drafted and introduced that could significantly change the statutory provisions governing the regulatory clearance or approval, manufacture and marketing of regulated products or the reimbursement thereof. In addition, U.S. FDA regulations and guidance are often revised or reinterpreted by the U.S. FDA in ways that may significantly affect our business and our products. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of our product candidates. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require:

- changes to manufacturing methods;
- change in clinical trial design, including additional treatment arm (control);
- recall, replacement or discontinuance of one or more of our products; and
- additional recordkeeping.

Each of these would likely entail substantial time and cost and could harm our business and our financial results.

In addition, in the United States, there have been a number of legislative and regulatory proposals to change the health care system in ways that could affect our ability to sell our products profitably. The pharmaceutical industry in the United States, as an example, has been affected by the passage of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively PPACA, which, among other things, imposed new fees on entities that manufacture or import certain branded prescription drugs and expanded pharmaceutical manufacturer obligations to provide discounts and rebates to certain government programs. There have been executive, judicial and Congressional challenges to certain aspects of PPACA. For example, during his term in office, President Trump signed Executive Orders and other directives designed to delay the implementation of certain provisions of PPACA or otherwise circumvent some of the requirements for health insurance mandated by PPACA. In addition, The Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services, or HHS, published a final rule to give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the PPACA marketplaces. Further, Congress considered legislation that would repeal or repeal and replace all or part of the PPACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the PPACA have been signed into law. The Tax Cuts and Jobs Act of 2017, or the Tax Act, includes a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the PPACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". In addition, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the PPACA-mandated "Cadillac" tax high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminated the health insurer tax. The Bipartisan Budget Act of 2018, or BBA, among other things, amended the PPACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, or Texas District Court, ruled that the individual mandate is a critical and inseverable feature of the PPACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the PPACA are invalid as well. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the Texas District Court ruling that the individual mandate was unconstitutional and remanded the case back to the Texas District Court to determine whether the remaining provisions of the PPACA are invalid as well. The United States Supreme Court is currently reviewing this case, but it is unknown when a decision will be reached. Although the U.S. Supreme Court has not yet ruled on the constitutionality of the PPACA, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the PPACA marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the PPACA. It is unclear how the Supreme Court ruling, other such litigation and the healthcare reform measures of the Biden administration will impact the PPACA and our business.

Other legislative changes have been proposed and adopted in the United States since the PPACA was enacted. For example, in August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by U.S. Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2012 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute, including the BBA, will remain in effect through 2030 unless additional Congressional action is taken. However, COVID-19 relief support legislation suspended the 2% Medicare sequester from May 1, 2020 through March 31, 2021. In January 2013, the American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to certain providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Further, there has been particular and increasing legislative and enforcement interest in the United States with respect to drug pricing practices in recent years, particularly with respect to drugs that have been subject to relatively large price increases over relatively short time periods. There have been several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that attempt to implement several of the administration's proposals. The FDA also released a final rule, effective November 30, 2020, implementing a portion of the importation executive order providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed pending review by the Biden administration until March 22, 2021. On November 20, 2020, CMS issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. On December 28, 2020, the United States District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. However, it is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

In the future, there will likely continue to be proposals relating to the reform of the U.S. healthcare system, some of which could further limit coverage and reimbursement of drug products, including our product candidates.

Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. Our results of operations could be adversely affected by PPACA and by other health care reforms that may be enacted or adopted in the future. Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic.

It may be difficult for us to profitably sell any future products that may be approved if coverage and reimbursement for these products is limited by government authorities and/or third-party payor policies.

In addition to any healthcare reform measures which may affect reimbursement, market acceptance and sales of our product candidates, if approved, will depend on, in part, the extent to which our products, and the procedures which utilize our products, will be covered by third-party payors, such as government health care programs, commercial insurance and managed care organizations. These third-party payors determine the extent to which new drugs, and the procedures which utilize new drugs, will be covered as a benefit under their plans and the level of reimbursement for any covered product and procedures utilizing such products. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates, and the procedures which utilize our product candidates.

A primary trend in the healthcare industry has been cost containment, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products and/or biosimilars. Third-party payors decide which drugs, and procedures using such drugs, they will pay for and establish reimbursement and co-payment levels. Government and other third-party payors are increasingly challenging the prices charged for health care products and services, examining the cost effectiveness of drugs in addition to their safety and efficacy, and limiting or attempting to limit both coverage and the level of reimbursement for prescription drugs and the procedures which utilize prescription drugs. We cannot be sure that coverage will be available for our product candidates, and the procedures which utilize our product candidates, if approved, or, if coverage is available, the level of reimbursement.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products, and the procedures which utilize such products. In the United States, the principal decisions about reimbursement for new medicines, and the procedures which utilize new medicines, are typically made by CMS, as CMS decides whether and to what extent a new medicine, and procedures which utilize a new medicine, will be covered and reimbursed under Medicare. Private payors may follow CMS, but have their own methods and approval processes for determining reimbursement for new medicines, and the procedures that utilize new medicines. It is difficult to predict what CMS or other payors will decide with respect to reimbursement for fundamentally novel products such as ours, as there is no body of established practices and precedents for these new products.

Reimbursement may impact the demand for, and/or the price of, any product for which we obtain marketing approval. Assuming we obtain coverage for a given product, or a procedure which utilizes a given product, by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. Patients who are prescribed medications and procedures for the treatment of their conditions, and their prescribing physicians, generally rely on third-party payors to reimburse all or part of the costs associated with those prescription drugs and procedures. Patients are unlikely to use our products, or agree to procedures utilizing our products, unless coverage is provided and reimbursement is adequate to cover all or a significant portion of the associated costs. Therefore, coverage and adequate reimbursement is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and the procedures which utilize newly approved drugs, and coverage may be more limited than the purposes for which such drug is approved by the U.S. FDA or comparable foreign regulatory authorities.

Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs, medical devices and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the successful commercialization of new products. Further, the adoption and implementation of any future governmental cost containment or other health reform initiative may result in additional downward pressure on the price that we may receive for any approved product. Reimbursement by a third-party payor may depend upon a number of factors including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining coverage and reimbursement approval for a product, or a procedure which utilizes a product, from a government or other third-party payor is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost effectiveness data for the use of our products, and the procedures which utilize our products, to the payor. Further, no uniform policy requirement for coverage and reimbursement for drug products, and procedures which utilize drug products, exists among third-party payors in the United States. Therefore, coverage and reimbursement for drug products, and the procedures which utilize drug products, can differ significantly from payor to payor. As a result, the coverage determination process may require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. We may not be able to provide data sufficient to gain acceptance with respect to coverage and/or sufficient reimbursement levels. We cannot be sure that coverage or adequate reimbursement will be available for our product candidates, or the procedures which utilize our product candidates, if approved. Also, we cannot be sure that reimbursement amounts will not reduce the demand for, or the price of, our future products. If reimbursement is not available, or is available only to limited levels, we may not be able to commercialize our product candidates, or achieve profitably at all, even if approved.

Reimbursement may not be immediately available for our product candidates in China, which could diminish our sales or affect our profitability.

In China, the Ministry of Human Resources and Social Security of China or provincial or local human resources and social security authorities, together with other government authorities, review the inclusion or removal of drugs from China's National Drug Catalog for Basic Medical Insurance, Work-related Injury Insurance and Maternity Insurance, or the National Reimbursement Drug List, or NRDL, or provincial or local medical insurance catalogues for the National Medical Insurance Program regularly, and the tier under which a drug will be classified, both of which affect the amounts reimbursable to program participants for their purchases of those drugs. These determinations are made based on a number of factors, including price and efficacy.

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Our current and future operations may be directly or indirectly through our relationships with healthcare providers, patients and other persons and entities, subject to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research, market, sell and distribute our products. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

The U.S. Anti-Kickback Statute prohibits, among other things, any person or entity from knowingly and willfully offering, paying, soliciting, receiving or providing any remuneration, directly or indirectly, overtly or covertly, to induce or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any item or service reimbursable, in whole or in part, under Medicare, Medicaid or other U.S. federal healthcare programs. The U.S. Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers, among others, on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution.

The U.S. federal false claims laws, including the False Claims Act, or FCA, and civil monetary penalties laws, which prohibit any person or entity from, among other things, knowingly presenting, or causing to be presented, a false, fictitious or fraudulent claim for payment to, or approval by, the U.S. federal government or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to the U.S. federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the U.S. government. In addition, manufacturers can be held liable under the FCA even when they do not submit claims directly to government third-party payors if they are deemed to "cause" the submission of false or fraudulent claims. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery. FCA liability is potentially significant in the healthcare industry because the statute provides for treble damages and mandatory penalties per false claim or statement. Government enforcement agencies and private whistleblowers have investigated pharmaceutical companies for or asserted liability under the FCA for a variety of alleged promotional and marketing activities, such as providing free product to customers with the expectation that the customers would bill federal programs for the product; providing consulting fees and other benefits to physicians to induce them to prescribe products; engaging in promotion for "off-label" uses; and submitting inflated best price information to the Medicaid Rebate Program.

HIPAA prohibits, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

The Physician Payments Sunshine Act, enacted as part of PPACA, imposes, among other things, annual reporting requirements for covered manufacturers for certain payments and "transfers of value" provided to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report such information regarding their payments and other transfers of value to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives during the previous year.

HIPAA, as amended by HITECH, and their respective implementing regulations, impose, among other things, specified requirements relating to the privacy, security and transmission of individually identifiable health information held by covered entities, which include certain healthcare providers, health plans and healthcare clearinghouses, and their business associates, which include individuals or entities that perform services for covered entities that involve the creation, use, maintenance or disclosure of, individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in U.S. federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Many U.S. states and other foreign jurisdictions have analogous laws and regulations, such as state anti-kickback and false claims laws, that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers. In addition, certain states require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and certain states and local jurisdictions require the registration of pharmaceutical sales representatives.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent health care reform legislation has strengthened these laws. For example, recent health care reform legislation, has among other things, amended the intent requirement of the U.S. Anti-Kickback Statute and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. Moreover, recent health care reform legislation provides that the government may assert that a claim including items or services resulting from a violation of the U.S. Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA.

Ensuring that our business arrangements with third parties comply with applicable healthcare laws and regulations will likely be costly. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations were found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, possible exclusion from government funded healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and curtailment of our operations, any of which could substantially disrupt our operations. If the physicians or other providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

We are subject to U.S. and foreign anti-corruption and anti-money laundering laws with respect to our operations and non-compliance with such laws can subject us to criminal and/or civil liability and harm our business.

We are subject to the U.S. Foreign Corrupt Practices Act of 1977, as amended, or the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and possibly other state and national anti-bribery and anti-money laundering laws in countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, third-party intermediaries, joint venture partners and collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or benefits to recipients in the public or private sector. We engage third-party investigators, CROs, and other consultants to design and perform preclinical studies of our product candidates, and will do the same for any clinical trials. Also, once a product candidate has been approved and commercialized, we may engage third-party intermediaries to promote and sell our products abroad and/or to obtain necessary permits, licenses, and other regulatory approvals. We or our third-party intermediaries may have direct or indirect interactions with officials and employees of government agencies or state-owned or affiliated entities. We can be held liable for the corrupt or other illegal activities of these third-party intermediaries, our employees, representatives, contractors, collaborators, partners, and agents, even if we do not explicitly authorize or have actual knowledge of such activities.

Noncompliance with anti-corruption and anti-money laundering laws could subject us to whistleblower complaints, investigations, sanctions, settlements, prosecution, other enforcement actions, disgorgement of profits, significant fines, damages, other civil and criminal penalties or injunctions, suspension and/or debarment from contracting with certain persons, the loss of export privileges, reputational harm, adverse media coverage, and other collateral consequences. If any subpoenas, investigations, or other enforcement actions are launched, or governmental or other sanctions are imposed, or if we do not prevail in any possible civil or criminal litigation, our business, results of operations and financial condition could be materially harmed. In addition, responding to any action will likely result in a materially significant diversion of management's attention and resources and significant defense and compliance costs and other professional fees. In certain cases, enforcement authorities may even cause us to appoint an independent compliance monitor which can result in added costs and administrative burdens.

The incidence and prevalence for target patient populations of our product candidates are based on estimates and third-party sources. If the market opportunities for our product candidates are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, our revenue and ability to achieve profitability might be materially and adversely affected.

Periodically, we make estimates regarding the incidence and prevalence of target patient populations for particular diseases based on various third-party sources and internally generated analysis and use such estimates in making decisions regarding our drug development strategy, including acquiring or in-licensing product candidates and determining indications on which to focus in preclinical or clinical trials.

These estimates may be inaccurate or based on imprecise data. For example, the total addressable market opportunity will depend on, among other things, acceptance of our drugs by the medical community and patient access, drug pricing and reimbursement. The number of patients in the addressable markets may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our drugs, or new patients may become increasingly difficult to identify or gain access to, all of which may significantly harm our business, financial condition, results of operations and prospects.

Risks Related to our ADSs

The price of our ADSs has been, and may continue to be, volatile and may fluctuate due to factors beyond our control.

The trading market for publicly traded emerging biopharmaceutical and drug discovery and development companies has been highly volatile and is likely to remain highly volatile in the future. The stock market in general and the market for biopharmaceutical and drug discovery and development companies in particular, has experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The COVID-19 pandemic, for example, has negatively affected the stock market and investor sentiment and has resulted in significant volatility. The market price of our ADSs may fluctuate significantly due to a variety of factors, including:

- positive or negative results from, or delays in, testing and clinical trials by us, collaborators or competitors;
- technological innovations or commercial product introductions by us or competitors;
- changes in government regulations;
- changes in the structure of healthcare payment systems;
- developments concerning proprietary rights, including patents and litigation matters;
- public concern relating to the commercial value or safety of our product candidates;
- financing, collaborations or other corporate transactions;
- publication of research reports or comments by securities or industry analysts;
- general market conditions in the pharmaceutical industry or in the economy as a whole;
- the loss of any of our key scientific or senior management personnel;

- sales of our ADSs or ordinary shares by us, our senior management and board members or holders of our ADSs or our ordinary shares in the future; or
- other events and factors, many of which are beyond our control.

These and other market and industry factors may cause the market price and demand for our ADSs to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from readily selling their ADSs and may otherwise negatively affect the liquidity of our ADSs. In addition, the stock market in general, and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. In the past, when the market price of a security has been volatile, holders of that security have sometimes instituted securities class action litigation against the issuer. If any of the holders of our ADSs were to bring such a lawsuit against us, we could incur substantial costs defending the lawsuit and the attention of our senior management would be diverted from the operation of our business. Any adverse determination in litigation could also subject us to significant liabilities.

You may face difficulties in protecting your interests, and your ability to protect your rights through U.S. courts may be limited, because we are incorporated under Cayman Islands law, we conduct substantially all of our operations and all of our directors and executive officers reside outside of the United States.

We are an exempted company incorporated under the laws of the Cayman Islands. Our corporate affairs are governed by our Tenth Amended and Restated Memorandum and Articles of Association, or Articles, the Companies Law (as amended) of the Cayman Islands, or the Companies Law, and the common law of the Cayman Islands. The rights of shareholders to take action against the directors, actions by minority shareholders and the fiduciary duties of our directors to us under Cayman Islands law are to a large extent governed by the common law of the Cayman Islands. The common law of the Cayman Islands is derived in part from comparatively limited judicial precedent in the Cayman Islands as well as from the common law of England and Wales, the decisions of whose courts are of persuasive authority, but are not binding, on a court in the Cayman Islands. Similarly, the rights of our shareholders and the fiduciary duties of our directors under Cayman Islands law are not as clearly established as they would be under statutes or judicial precedent in some jurisdictions in the United States. In particular, the Cayman Islands has a less developed body of securities laws than the United States, and some U.S. states, such as Delaware, have more fully developed and judicially interpreted bodies of corporate law than the Cayman Islands. In addition, Cayman Islands companies do not have standing to sue before the federal court of the United States.

Shareholders of Cayman Islands exempted companies like us have no general rights under Cayman Islands law to inspect corporate records or to obtain copies of lists of shareholders of these companies. Although our shareholders are permitted by our Articles to request access to our books and records, our directors have discretion under our Articles to determine whether or not, and under what conditions, our corporate records may be inspected by our shareholders, but are not obliged to make them available to our shareholders. This may make it more difficult for you to obtain the information needed to establish any facts necessary for a shareholder motion or to solicit proxies from other shareholders in connection with a proxy contest.

Certain corporate governance practices in the Cayman Islands, which is our home country, differ significantly from requirements for companies incorporated in other jurisdictions such as the United States. To the extent we choose to follow home country practice with respect to corporate governance matters, our shareholders may be afforded less protection than they otherwise would under rules and regulations applicable to U.S. domestic issuers.

As a result of all of the above, our public shareholders may have more difficulty in protecting their interests in the face of actions taken by management, members of the board of directors or controlling shareholders than they would as public shareholders of a company incorporated in the United States. For a discussion of significant differences between the provisions of the Companies Law and the laws applicable to companies incorporated in the United States and their shareholders, see “Description of Share Capital–Material Differences in Corporate Law” in Exhibit 99.2 to the form 6-K filed with the SEC on January 29, 2021.

Future sales, or the possibility of future sales, of a substantial number of our ADSs or ordinary shares could adversely affect the price of our ADSs.

Future sales of a substantial number of our ADSs or ordinary shares, or the perception that such sales will occur, could cause a decline in the market price of our ADSs. If any of our large shareholders or members of our management team sell substantial amounts of our securities in the public markets, or the market perceives that such sales may occur, the market price of our ADSs and our ability to raise capital through an issue of equity securities in the future could be adversely affected.

We may sell additional equity or debt securities or enter into other financing arrangements to fund our operations, which may result in dilution to our shareholders and holders of our ADSs and impose restrictions on our business.

In order to raise additional funds to support our operations, we may sell additional equity or debt securities, which could adversely impact our existing shareholders and new investors, as well as our business. The sale of additional equity or debt securities, or a combination of both, would result in the issuance of additional shares capital and dilution to our shareholders and holders of our ADSs.

The incurrence of indebtedness would result in increased fixed payment obligations and could also result in certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. In the event that we enter into collaborations or licensing arrangements to raise capital, we may be required to accept unfavorable terms, including relinquishing or licensing to a third party on unfavorable terms our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves or potentially reserve for future potential arrangements when we might be able to achieve more favorable terms.

Because we do not anticipate paying any cash dividends on our ADSs or ordinary shares in the foreseeable future, capital appreciation, if any, will be your sole source of potential gains and you may never receive a return on your investment.

We have not paid cash dividends in the past on our ordinary shares. We intend to retain earnings, if any, for use in our business and do not anticipate paying any cash dividends in the foreseeable future. In addition, we are not permitted to pay cash dividends pursuant to the terms of the October/November 2019 Loan Facility without the prior consent of the lenders, and we are not permitted to dispose of a substantial part of our assets pursuant to the terms of the CSL Facility without the prior consent of CSL, and any future debt financing arrangement may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our ADSs or ordinary shares. As a result, capital appreciation, if any, on our ADSs or ordinary shares will be your sole source of potential gains for the foreseeable future, and you will suffer a loss on your investment if you are unable to sell your ADSs or the underlying ordinary shares at or above the price you pay for our ADSs or ordinary shares. Investors seeking cash dividends should not purchase our ADSs.

Purchasers of our ADSs may not have the same voting rights as the holders of our ordinary shares and may not receive voting materials in time to be able to exercise their right to vote.

As a holder of our ADSs, you will only be able to exercise the voting rights with respect to the underlying ordinary shares in accordance with the provisions of the deposit agreement. Under the deposit agreement, you must vote by giving voting instructions to the depositary. Upon receipt of your voting instructions, the depositary will try to vote the underlying ordinary shares in accordance with these instructions. You will not be able to directly exercise your right to vote with respect to the underlying shares unless you withdraw the shares. When a general meeting is convened, you may not receive sufficient advance notice to withdraw the shares underlying your ADSs to allow you to vote with respect to any specific matter. After we notify the depositary of the agenda for the shareholders' meeting, the depositary will notify you of the upcoming vote and will arrange to deliver our voting materials to you once they are available. We have agreed to give the depositary at least 35 days' prior notice of shareholder meetings. Nevertheless, we cannot assure you that you will receive the voting materials in time to ensure that you can instruct the depositary to vote your shares. In addition, the depositary and its agents are not responsible for failing to carry out voting instructions or for their manner of carrying out your voting instructions. This means that you may not be able to exercise your right to vote and you may have no legal remedy if the shares underlying your ADSs are not voted as you requested.

Except in limited circumstances, the depositary for our ADSs will give us a discretionary proxy to vote our ordinary shares underlying your ADSs if you do not vote at shareholders' meetings, which could adversely affect your interests.

Under the deposit agreement for our ADSs, to the extent we have provided the depositary with at least 35 days' notice of a proposed meeting, if voting instructions are not timely received by the depositary from you, you shall be deemed to have instructed the depositary to give a discretionary proxy to a person designated by us to vote the shares represented by your ADSs as desired. However, no such instruction shall be deemed given and no discretionary proxy shall be given (a) if we inform the depositary in writing that (i) we do not wish such proxy to be given, (ii) substantial opposition exists with respect to any agenda item for which the proxy would be given or (iii) the agenda item in question, if approved, would materially or adversely affect the rights of holders of shares and (b) unless we have provided the depositary with an opinion of our counsel to the effect that (a) the granting of such discretionary proxy does not subject the depositary to any reporting obligations in the Cayman Islands, (b) the granting of such proxy will not result in a violation of Cayman Islands laws, rules, regulations or permits, (c) the voting arrangement and deemed instruction will be given effect under Cayman Islands laws, rules, regulations and permits, and (d) the granting of such proxy will not under any circumstances result in the depositary being treated as the beneficial owner of ADSs under Cayman Islands laws, rules, regulations or permits.

The effect of this discretionary proxy is that, if you fail to give voting instructions to the depositary as to how to vote the ordinary shares underlying your ADSs at any particular shareholders' meeting, you cannot prevent our ordinary shares underlying your ADSs from being voted at that meeting, absent the situations described above, and it may make it more difficult for shareholders to influence our management. Holders of our ordinary shares are not subject to this discretionary proxy.

Purchasers of our ADSs may not receive distributions on our ordinary shares in the form of ADSs or any value for them if it is illegal or impractical to make them available to holders of ADSs.

The depositary for our ADSs has agreed to pay to purchasers of our ADSs the cash dividends or other distributions it or the custodian receives on our ordinary shares or other deposited securities after deducting its fees and expenses and certain taxes. Purchasers of our ADSs will receive these distributions in proportion to the number of our ordinary shares their ADSs represent. However, in accordance with the limitations set forth in the deposit agreement, it may be unlawful or impractical to make a distribution available to holders of ADSs. We have no obligation to take any other action to permit the distribution of our ADSs, ordinary shares, rights or anything else to holders of our ADSs. This means that purchasers of our ADSs may not receive the distributions we make on our ordinary shares or any value from them if it is unlawful or impractical to make them available to ADS holders. These restrictions may have a negative impact on the market value of our ADSs.

Purchasers of our ADSs may be subject to limitations on transfer of their ADSs.

ADSs are transferable on the books of the depositary. However, the depositary may close its transfer books at any time or from time to time when it deems expedient in connection with the performance of its duties. In addition, the depositary may refuse to deliver, transfer or register transfers of ADSs generally when our books or the books of the depositary are closed, or at any time if we or the depositary deems it advisable to do so because of any requirement of law or of any government or governmental body, or under any provision of the deposit agreement, or for any other reason in accordance with the terms of the deposit agreement. The rights of our shareholders may differ from the rights typically offered to shareholders of a U.S. corporation.

Our corporate affairs are governed by our Articles and by the laws governing Cayman Islands corporations and companies engaging in drug development, marketing and sales businesses, as well as by the common law of the Cayman Islands. Certain rights and responsibilities of our shareholders, ADS holders and members of our board of directors under Cayman law are different from those that apply to a Delaware corporation. For example, Directors of Cayman Islands exempted companies are required to observe certain fiduciary duties. These duties are owed to the Cayman Islands company and include the duty to act in the best interests of the company and the shareholders as a whole. However, the fiduciary duties of a director of a Cayman Islands exempted company may not be the same as the fiduciary duty of a director of a U.S. corporation. In addition, controlling shareholders of U.S. corporations owe fiduciary duties to minority shareholders, while shareholders (including controlling shareholders) of Cayman Islands companies owe no fiduciary duties either to the company or to other shareholders.

Further, the rights of our shareholders to bring shareholders' suits against us or our board of directors under Cayman Islands law are much more limited than those of shareholders of a U.S. corporation. For example, under Cayman Islands law, a shareholder who wishes to bring a claim against a director would generally need to obtain permission from the courts to bring a derivative action, in the name of the company, against the director. This is because the director of a Cayman Islands exempted company owes duties to the company and not to individual shareholders. As a result, our shareholders may have more difficulty protecting their rights in connection with actions taken by our directors than they would as shareholders of a U.S. corporation. In addition, minority shareholders in a Cayman Islands exempted company have more limited rights than minority shareholders in a U.S. corporation in relation to mergers and similar transactions that the company may carry out. For example, if a merger under the Companies Law involving a Cayman Islands exempted company is approved by the requisite majority of shareholders, a dissenting minority shareholder would have the right to be paid the fair value of their shares (which, if not agreed between the parties, will be determined by the Cayman Islands court) if they follow the required procedures, subject to certain exceptions. Such dissenter rights differ substantially from the appraisal rights, which would ordinarily be available to dissenting shareholders of Delaware corporations. Further, if a takeover offer is made to the shareholders of a Cayman Islands exempted company and accepted by holders of 90% of the shares affected, the offeror may require the holders of the remaining shares to transfer such shares on the terms of the offer. An objection can be made to the Grand Court of the Cayman Islands but this is unlikely to succeed in the case of an offer which has been so approved unless there is evidence of fraud, bad faith or collusion. A minority shareholder in this scenario would have no rights comparable to the appraisal rights which would generally be available to a dissenting shareholder of a U.S. corporation in similar circumstances. For a description of the principal differences between the provisions of Cayman law applicable to us and the U.S. Delaware General Corporate Law relating to shareholders' rights and protections, see "Description of Share Capital–Material Differences in Corporate Law" in Exhibit 99.2 to the form 6-K filed with the SEC on January 29, 2021.

We qualify as a foreign private issuer and, as a result, we are not subject to U.S. proxy rules and are subject to Exchange Act reporting obligations that permit less detailed and less frequent reporting than that of a U.S. domestic public company.

We report under the Exchange Act as a non-U.S. company with foreign private issuer status. Because we qualify as a foreign private issuer under the Exchange Act, we are exempt from certain provisions of the Exchange Act that are applicable to U.S. domestic public companies, including (i) the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations in respect of a security registered under the Exchange Act; (ii) the sections of the Exchange Act requiring insiders to file public reports of their stock ownership and trading activities and liability for insiders who profit from trades made in a short period of time; and (iii) the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q containing unaudited financial and other specified information, or current reports on Form 8-K upon the occurrence of specified significant events. In addition, our officers, directors and principal shareholders are exempt from the reporting and "short-swing" profit recovery provisions of Section 16 of the Exchange Act and the rules thereunder. Therefore, our shareholders may not know on a timely basis when our officers, directors and principal shareholders purchase or sell our ordinary shares or ADSs. In addition, foreign private issuers are not required to file their annual report on Form 20-F until the date that is four months after the end of each fiscal year, while U.S. domestic issuers that are accelerated filers are required to file their annual report on Form 10-K within 75 days after the end of each fiscal year. Foreign private issuers also are exempt from Regulation Fair Disclosure, aimed at preventing issuers from making selective disclosures of material information. As a result of the above, you may not have the same protections afforded to shareholders of companies that are not foreign private issuers.

As a foreign private issuer, we are permitted to adopt certain home country practices in relation to corporate governance matters that differ significantly from Nasdaq corporate governance listing standards. These practices may afford less protection to shareholders than they would enjoy if we complied fully with corporate governance listing standards.

As a foreign private issuer, we are permitted to take advantage of certain provisions in the Nasdaq listing rules that allow us to follow Cayman Islands law for certain governance matters. Certain corporate governance practices in the Cayman Islands may differ significantly from corporate governance listing standards. We intend to continue to follow Cayman Islands corporate governance practices in lieu of certain corporate governance requirements of Nasdaq. Therefore, our shareholders may be afforded less protection than they otherwise would have under corporate governance listing standards applicable to U.S. domestic issuers.

We may lose our foreign private issuer status in the future, which could result in significant additional costs and expenses.

As discussed above, we are a foreign private issuer, and therefore, we are not required to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act. The determination of foreign private issuer status is made annually on the last business day of an issuer's most recently completed second fiscal quarter. We would lose our foreign private issuer status if, for example, more than 50% of our ordinary shares are directly or indirectly held by residents of the United States and we fail to meet additional requirements necessary to maintain our foreign private issuer status. If we lose our foreign private issuer status on this date, we will be required to file with the SEC periodic reports and registration statements on U.S. domestic issuer forms, which are more detailed and extensive than the forms available to a foreign private issuer. We will also have to mandatorily comply with U.S. federal proxy requirements, and our officers, directors and principal shareholders will become subject to the short-swing profit disclosure and recovery provisions of Section 16 of the Exchange Act. In addition, we will lose our ability to rely upon exemptions from certain corporate governance requirements under the Nasdaq listing rules. As a U.S. listed public company that is not a foreign private issuer, we will incur significant additional legal, accounting and other expenses that we will not incur as a foreign private issuer, and accounting, reporting and other expenses in order to maintain a listing on a U.S. securities exchange. These rules and regulations could also make it more difficult for us to attract and retain qualified members of our board of directors and more expensive to procure director and officer liability insurance.

Our U.S. ADS Holders may suffer adverse tax consequences if we are characterized as a passive foreign investment company.

Generally, if for any taxable year (i) 75% or more of our gross income is passive income, or (ii) at least 50% of the average quarterly value of our assets are held for the production of, or produce, passive income, we would be characterized as a passive foreign investment company, or PFIC, for U.S. federal income tax purposes. For purposes of the above calculations, a non-U.S. corporation that directly or indirectly owns at least 25% by value of the shares of another corporation is treated as if it held its proportionate share of the assets of the other corporation and received directly its proportionate share of the income of the other corporation. Passive income generally includes dividends, interest, rents, royalties and capital gains. Based on estimates of our gross income and gross assets (including tangible assets and intangible assets based on the market value of our ordinary shares), and the nature of our business, we do not believe that we were a PFIC for the taxable year ended December 31, 2020; however we have not yet performed an analysis for our current taxable year. There can be no assurance regarding our PFIC status for any taxable year. If we are characterized as a PFIC, our U.S. shareholders may suffer adverse tax consequences, including having gains realized on the sale of our ordinary shares treated as ordinary income, rather than as capital gain, the loss of the preferential rate applicable to dividends received on our ordinary shares by individuals who are "U.S. Holders", and having interest charges apply to distributions by us and the proceeds of share sales and having to comply with certain reporting requirements. As used in this discussion, the term "U.S. Holder" means a beneficial owner of our ordinary shares or ADSs who is, for U.S. federal income tax purposes, (1) an individual who is a citizen or resident of the United States, (2) a corporation (or entity treated as a corporation for U.S. federal income tax purposes) created or organized in or under the laws of the United States, any state thereof, or the District of Columbia, (3) an estate the income of which is subject to U.S. federal income tax regardless of its source or (4) a trust (x) with respect to which a court within the United States is able to exercise primary supervision over its administration and one or more United States persons have the authority to control all of its substantial decisions or (y) that has elected under applicable U.S. Treasury regulations to be treated as a domestic trust for U.S. federal income tax purposes. Certain elections exist that may alleviate some of the adverse consequences of PFIC status and would result in an alternative treatment (such as mark-to-market treatment) of our ordinary shares; however, we do not intend to provide the information necessary for U.S. holders to make qualified electing fund elections if we are classified as a PFIC.

If a United States person is treated as owning at least 10% of our ordinary shares, such holder may be subject to adverse U.S. federal income tax consequences.

If a United States person is treated as owning (directly, indirectly, or constructively) at least 10% of the value or voting power of our ordinary shares (as a result of such person's ownership of ADSs), such person may be treated as a "United States shareholder" with respect to each "controlled foreign corporation" in our group. Because our group includes one or more U.S. subsidiaries, we expect that certain of our non-U.S. subsidiaries will be treated as controlled foreign corporations (regardless of whether or not we are treated as a controlled foreign corporation). A United States shareholder of a controlled foreign corporation may be required to report annually and include in its U.S. taxable income its pro rata share of "Subpart F income," "global intangible low-taxed income," and investments in U.S. property by controlled foreign corporations, regardless of whether we make any distributions. An individual that is a United States shareholder with respect to a controlled foreign corporation generally would not be allowed certain tax deductions or foreign tax credits that would be allowed to a United States shareholder that is a U.S. corporation. Failure to comply with these reporting obligations may subject a United States shareholder to significant monetary penalties and may prevent the statute of limitations with respect to such shareholder's U.S. federal income tax return for the year for which reporting was due from starting. We cannot provide any assurances that we will assist investors in determining whether any of our non-U.S. subsidiaries is treated as a controlled foreign corporation or whether any investor is treated as a United States shareholder with respect to any such controlled foreign corporation or furnish to any United States shareholders information that may be necessary to comply with the aforementioned reporting and tax paying obligations. A United States investor should consult its advisors regarding the potential application of these rules to an investment in our ADSs.

General Risk Factors

We have incurred and will incur increased costs as a result of operating as a public company in the United States, and our senior management will be required to devote substantial time to new compliance initiatives and corporate governance practices.

Our ADSs began trading on The Nasdaq Global Market on May 4, 2018 under the trading symbol "ASLN." As a U.S. public company, we have incurred significant legal, accounting and other expenses that we did not incur previously, and we will incur additional expenses after we no longer qualify as an emerging growth company, or EGC. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Stock Market LLC, or Nasdaq, and other applicable securities rules and regulations impose various requirements on non-U.S. reporting public companies, including the establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our senior management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified senior management personnel or members for our board of directors.

However, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we will be required to furnish a report by our senior management on our internal control over financial reporting and an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, while we remain an EGC we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants, adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented, and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

We are an EGC and we cannot be certain if the reduced reporting requirements applicable to "emerging growth companies" will make our ADSs less attractive to investors.

We are an EGC as defined in the Jumpstart Our Business Startups Act. For as long as we continue to be an EGC, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not EGCs, including not being required to comply with the auditor attestation requirements of Section 404, exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We may take advantage of these exemptions until we are no longer an EGC. We could be an EGC until December 31, 2023, although circumstances could cause us to lose that status earlier, including if the aggregate market value of our ADSs and ordinary shares held by non-affiliates exceeds $700 million as of the end of our second fiscal quarter before that time, in which case we would no longer be an EGC as of the following December 31st (the last day of our fiscal year). We cannot predict if investors will find our ADSs less attractive because we may rely on these exemptions. If some investors find our ADSs less attractive as a result, there may be a less active trading market for our ADSs and the price of our ADSs may be more volatile.

If we fail to maintain an effective system of internal controls over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, shareholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our ADSs.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inadequate internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our ADSs.

Management is required to assess the effectiveness of our internal controls annually. However, for as long as we are an EGC, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404. An independent assessment of the effectiveness of our internal controls could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls could lead to financial statement restatements requiring us to incur the expense of remediation and could also result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

If securities or industry analysts do not publish research, or publish inaccurate or unfavorable research, about our business, the price of our ADSs and our trading volume could decline.

The trading market for our ADSs depends in part on the research and reports that securities or industry analysts publish about us or our business. If no or too few securities or industry analysts provide coverage or if one or more of the analysts who cover us downgrade our ADSs or publish inaccurate or unfavorable research about our business, the price of our ADSs would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for our ADSs could decrease, which might cause the price of our ADSs and trading volume to decline.