UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2023

OR

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

For the transition period from _____ to _____

Commission File Number 001-36288

Akari Therapeutics, Plc

(Exact name of Registrant as specified in its Charter)

England and Wales	**98-1034922**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
22 Boston Wharf Road, FL 7 Boston, Massachusetts	**02210**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (929) 274-7510

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
American Depository Shares, each representing 2,000 Ordinary Shares, par value $0.0001 per share	**AKTX**	**The Nasdaq Capital Market**
Ordinary Shares, $0.0001 par value per share*		**The Nasdaq Capital Market**

* Trading, but only in connection with the American Depository Shares.

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☐ NO ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES ☐ NO ☒

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☒ NO ☐

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files). YES ☒ NO ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☐		

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ☐ NO ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, based on the closing price of the Registrant's American Depository Shares, as reported on the Nasdaq Capital Market on June 30, 2023, was $13.6 million.

The number of shares of Registrant's Ordinary Shares outstanding as of March 29, 2024 was 15,847,391,523.

DOCUMENTS INCORPORATED BY REFERENCE

None.

TABLE OF CONTENTS

GENERAL INFORMATION

Unless otherwise stated or the context requires otherwise, references in this Annual Report on Form 10-K to "Akari," the "company," the "Company," "we," "us," "our" or similar designations refer to Akari Therapeutics, Plc and its subsidiaries, taken together. All trademarks, service marks, trade names and registered marks used in this report are trademarks, trade names or registered marks of their respective owners.

Website addresses referenced in this Annual Report on Form 10-K are provided for convenience only, and the content on the referenced websites does not constitute a part of, and are specifically not incorporated by reference into, this Annual Report on Form 10-K.

Statements made in this Annual Report on Form 10-K concerning the contents of any agreement, contract or other document are summaries of such agreements, contracts or documents and are not complete description of all of their terms. If we filed any of these agreements, contracts or documents as exhibits to this Annual Report on Form 10-K or to any previous filing with the Securities and Exchange Commission ("SEC"), you may read the document itself for a complete understanding of its terms.

NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K ("Form 10-K") and the documents we incorporate by reference contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements, other than statements of historical fact, included or incorporated in this report regarding, among other things, our cash resources and projected cash runway, financial position, our strategy, strategic alternatives, future operations, clinical trials (including, without limitation, the anticipated timing enrollment, and results thereof), collaborations, intellectual property, future revenues, projected costs, fundraising and/or financing plans, prospects, developments relating to our competitors and our industry, the timing or likelihood of regulatory actions, filings and approvals for our current and future drug candidates, and the benefits related to the Merger Agreement (as defined below) and the plans and objectives of management are forward-looking statements. The words "believes," "anticipates," "estimates," "plans," "expects," "intends," "may," "could," "should," "potential," "likely," "projects," "intend," "continue," "will," "schedule," "would," "aim," "contemplate," "estimate," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We cannot guarantee that we will actually achieve the plans, intentions, or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. These forward-looking statements involve known and unknown risks, uncertainties, and other factors, which may be beyond our control, and which may cause the actual results, performance, or achievements of the Company to be materially different from future results, performance, or achievements expressed or implied by such forward-looking statements.

There are a number of important factors that could cause our actual results to differ materially from those indicated or implied by forward-looking statements. These important factors include those set forth below under Part I, Item 1A "Risk Factors" and in our other disclosures and filings with the Securities and Exchange Commission ("SEC"). These factors and the other cautionary statements made in this Form 10-K and the documents we incorporate by reference should be read as being applicable to all related forward-looking statements whenever they appear in this Form 10-K and the documents we incorporate by reference.

In addition, any forward-looking statements represent our estimates only as of the date that this Form 10-K is filed with the SEC and should not be relied upon as representing our estimates as of any subsequent date. All forward-looking statements included in this Form 10-K are made as of the date hereof and are expressly qualified in their entirety by this cautionary notice. We disclaim any intention or obligation to update or revise any forward-looking statement, whether as a result of new information, future events, or otherwise, except as may be required by law.

SUMMARY OF PRINCIPAL RISK FACTORS

Below is a summary of material factors that make an investment in our common stock speculative or risky. Importantly, this summary does not address all the risks and uncertainties that we face. Additional discussion of the risks and uncertainties summarized in this risk factor summary, as well as other risks and uncertainties that we face, can be found within Part I, Item 1A, "Risk Factors" in this Annual Report on Form 10-K. The below summary is qualified in its entirety by those more complete discussions of such risks and uncertainties. You should consider carefully the risks and uncertainties described under Part I, Item 1A, "Risk Factors" in this Annual Report on Form 10-K as part of your evaluation of an investment in our common stock.

- We have a history of operating losses and cannot give assurance of future revenues or operating profits; investors may lose their entire investment.
- Our auditor's report on our consolidated financial statements states that our recurring operating losses, negative cash flows and dependence on additional financial support raises substantial doubt about our ability to continue as a going concern, which may have a detrimental effect on our ability to obtain additional funding.
- We will require additional capital to fund our operations, and if we are unable to obtain such capital, we will be unable to successfully develop and commercialize any product candidates.
- Our business depends on the success of nomacopan, which is still under development. If we are unable to obtain marketing authorization for or successfully commercialize nomacopan, our business could be materially harmed.
- If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.
- If clinical trials or marketing authorization processes for nomacopan are prolonged, delayed or suspended, we may be unable to commercialize nomacopan on a timely basis.
- We may not receive a Priority Review Voucher ("PRV") in connection with the approval of nomacopan for the treatment of hematopoietic stem cell transplant-associated thrombotic microangiopathy ("HSCT-TMA"), which would permit priority review for a subsequent marketing application for a different product or may be sold to a third party.
- The efficacy of nomacopan may not be known until advanced stages of testing, after we have incurred significant product development costs which may not be recoverable.
- Results of earlier preclinical studies or clinical trials may not be predictive of advancement to the next phase of development.
- Long-term animal toxicity and long-term human safety studies of nomacopan could demonstrate that the administration of nomacopan results in serious adverse events.
- Chronic dosing of patients with nomacopan could lead to an immune response that causes adverse reactions or impairs the activity of the drug.
- Because nomacopan has not yet received marketing authorization, it is difficult to predict the time and cost of development and our ability to successfully complete clinical development and obtain the necessary marketing authorizations for commercialization.
- We have obtained orphan drug designation for nomacopan in the United States for the use in bullous pemphigoid ("BP"), HSCT-TMA, paroxysmal nocturnal hemoglobinuria ("PNH"), Guillain-Barré syndrome ("GBS"), and in the EU for HSCT-TMA, GBS, PNH, and BP, but we may be unable to

maintain the benefits associated with orphan drug designation or obtain orphan drug exclusivity upon potential approval of nomacopan in one or more of these orphan indications.

- We have obtained fast track designation from the FDA for the treatment of HSCT-TMA, and may seek such designation in other indications. Such designation or a similar designation from other national or international regulatory agencies, may not lead to a faster development or regulatory review or approval process, and may not result in nomacopan or any other product candidates receiving marketing approval.

- Even if we obtain FDA approval of nomacopan, we or our partners may never obtain approval or commercialize our product candidates outside of the United States and, conversely, even if we obtain marketing authorization of nomacopan in the EU, we or our partners may never obtain approval or commercialize our product candidates outside the EU.

- If we or our partners market products in a manner that violates fraud and abuse and other healthcare laws, or if we or they violate government price reporting laws, we or our partners may be subject to administrative civil and/or criminal penalties.

- Our success depends in part on our ability to protect our intellectual property and our proprietary technologies.

- We currently have no marketing, sales or distribution infrastructure with respect to nomacopan. If we are unable to develop our sales, marketing and distribution capability on our own or through collaborations with partners, we may not be successful in commercializing any approved drugs.

- If physicians and patients do not adopt our products, if approved, or if the market size for indications for which any product candidate is approved is smaller than expected, we may be unable to achieve forecasted revenues, if any.

- If product liability lawsuits are successfully brought against us or any of our collaborative partners, we may incur substantial liabilities and may be required to limit commercialization of our products.

- If we fail to develop and commercialize other product candidates, we may be unable to generate revenues.

- We seek to partner with third-party collaborators with respect to aspects of the development and commercialization of our product candidates and we may not succeed in establishing and maintaining collaborative relationships, which may significantly limit our ability to develop and commercialize our product candidates successfully, if at all.

- If our third-party manufacturer of nomacopan is unable to increase the scale of its production of nomacopan, and/or increase the product yield of its manufacturing, then our costs to manufacture the product may increase and potential future commercialization may be slowed.

- Ownership of our ADSs and/or ordinary shares involves a high degree of risk.

- The rights of our shareholders may differ from the rights typically offered to shareholders of a U.S. corporation.

PART I

Item 1. Business.

Overview

We are a clinical-stage biotechnology company focused on developing advanced therapies for autoimmune and inflammatory diseases involving the complement component 5 ("C5") and leukotriene B4 ("LTB4") pathways. Each of these pathways has scientifically well-supported causative roles in the diseases we are targeting. We believe that blocking early mediators of inflammation will prevent initiation and continual amplification of the processes that cause certain diseases. Our activities since inception have consisted of performing research and development activities and raising capital.

Our lead product candidate, nomacopan, is a recombinant small protein (16,769 Da) derived from a protein originally discovered in the saliva of the *Ornithodoros moubata* tick, which modulates the host immune system to allow the parasite to feed without alerting the host to its presence or provoking an immune response. Nomacopan is a second-generation complement inhibitor which has been shown to act on complement C5, preventing release of C5a and formation of C5b–9 (also known as the membrane attack complex ("MAC")), and also independently and specifically inhibit LTB4 activity, both elements that are often co-located as part of the immune/inflammatory response. We believe the importance of nomacopan's therapeutic potential is twofold. First, its dual inhibitory action may be able to prevent inflammatory and prothrombotic activities of two key pathways, and second, nomacopan's bio-physical properties may allow it to be used in a variety of formulations and routes of administration, including subcutaneous, intravenous, topical to eye, inhaled and intravitreous.

We are currently conducting a clinical trial of subcutaneous nomacopan for the treatment of hematopoietic stem cell transplant-related thrombotic microangiopathy ("HSCT-TMA") in pediatrics. We are planning for potential registrational Phase 3 trials of nomacopan in adult and pediatric HSCT-TMA. We are also investigating long-acting PASylated-nomacopan ("PAS-nomacopan") for treatment of geographic atrophy ("GA") secondary to dry age-related macular degeneration ("dry AMD") in preclinical studies.

The U.S. Food and Drug Administration ("FDA") has granted Rare Pediatric Disease, Orphan Drug, and Fast Track designations to nomacopan for the treatment of pediatric HSCT-TMA. If the nomacopan marketing application is ultimately determined to meet the FDA's criteria to be a rare pediatric disease application, nomacopan may be eligible for a Rare Pediatric Disease priority review voucher ("PRV") upon FDA approval. A PRV is valuable because it can be redeemed to obtain priority review for a subsequent marketing application for a different product or may be sold to a third party. Additionally, nomacopan has been granted Orphan Drug designation by the European Commission as a treatment for hematopoietic stem cell transplantation ("HSCT").

Following the anticipated closing of the Merger (as defined below) late in the second quarter of 2024, we expect to have an expanded pipeline of assets spanning early and late development stages with the addition of Peak Bio Inc.'s Phase 2-ready PHP-303 program targeting alpha-1 antitrypsin deficiency ("AATD"). The program was licensed from Bayer Healthcare and is a 5th generation neutrophil elastase inhibitor ("NEI") targeting the inflammatory aspects of AATD, a rare condition. Additionally, the combined company will feature a robust antibody drug conjugate ("ADC") toolkit with novel payload and linker technologies. The program includes a novel pre-clinical ADC candidate targeting TROP-2. By combining chemotherapy with immunotherapy strategies, we aim to develop cutting-edge solutions for cancer patients. Further, we expect to emphasize business development and licensing opportunities with broad potential impact on patients.

In connection with the Merger, an assessment of the combined pipeline is planned, including program prioritization, updated timelines, near-term value creation opportunities, and other considerations.

Merger Agreement

As previously disclosed in our Form 8-K filed with the SEC on March 11, 2024, we entered into an Agreement and Plan of Merger (the "Merger Agreement") with Peak Bio, Inc. ("Peak Bio") and Pegasus Merger Sub, Inc., a Delaware corporation and a wholly-owned subsidiary of Akari ("Merger Sub"), pursuant to which, upon the terms and subject to the conditions thereof, Merger Sub will be merged with and into Peak Bio (the "Merger"), with Peak Bio surviving the Merger as a wholly-owned subsidiary of Akari.

Pursuant to the Merger Agreement, and upon the terms and subject to the conditions thereof, at the effective time of the Merger (the "Effective Time"), each issued and outstanding share of Peak Bio common stock, par value $0.0001 per share (the "Peak Common Stock") (other than (x) shares of Peak Common Stock held by Peak Bio as treasury stock, or shares of Peak Common Stock owned by Akari, Merger Sub or any direct or indirect wholly-owned subsidiaries of Akari and (y) Dissenting Shares (as defined in the Merger Agreement)), will be converted into the right to receive Akari American Depositary Shares ("Akari ADSs") representing a number of Akari ordinary shares, par value $0.0001 per share (the "Akari Ordinary Shares") equal to an exchange ratio calculated in accordance with the Merger Agreement (the "Exchange Ratio"), each such share duly and validly issued against the deposit of the requisite number of Akari Ordinary Shares in accordance with the Deposit Agreement (as defined in the Merger Agreement). The Exchange Ratio will be calculated such that the total number of shares of Akari ADSs to be issued as merger consideration for the Peak Common Stock will be expected to be, upon issuance, approximately 50% of the outstanding shares of Akari ADSs (provided, certain adjustments to this ratio will be made in respect of the net cash, as determined in accordance with the Merger Agreement, of each of Akari and Peak Bio at the close of business one business day prior to the anticipated consummation of the Merger). The Merger Agreement provides that, under certain circumstances, additional Akari ADSs may be issued to the holders of shares of Peak Common Stock following the consummation of the Merger equal to an exchange ratio calculated in accordance with the Merger Agreement (the "Additional Exchange Ratio").

At the Effective Time, each warrant to purchase capital stock of Peak Bio ("Peak Warrant") outstanding immediately prior to the Effective Time will be converted into and exchangeable for warrants to purchase a number of Akari Ordinary Shares or Akari ADSs, as determined by Akari (each, an "Adjusted Warrant"), on substantially similar terms and subject to substantially similar conditions as were applicable to such Peak Warrant immediately prior to the Effective Time, except (i) for terms rendered inoperative by reason of the transactions contemplated by the Merger Agreement, (ii) as provided in the following sentence and (iii) such amendments to the terms of the Adjusted Warrants as are necessary to comply with applicable Law (as defined in the Merger Agreement). The number of Akari Ordinary Shares (or the number of Akari Ordinary Shares underlying Akari ADSs, as applicable) subject to each Adjusted Warrant will be equal to the number of shares of Peak Common Stock issuable upon exercise of such Peak Warrant immediately prior to the Effective Time multiplied by the Exchange Ratio, with any fractional Akari Ordinary Shares or Akari ADSs rounded down to the nearest whole Akari Ordinary Share or Akari ADS, as applicable, and the exercise price with respect to each Akari Ordinary Share (or each Akari Ordinary Share underlying Akari ADSs, as applicable) underlying such Adjusted Warrant will be equal to the exercise price of such Peak Warrant immediately prior to the Effective Time divided by the Exchange Ratio. The grant of the Adjusted Warrants will be effected as of the Effective Time, or as soon thereafter as is reasonably practicable, taking into account Akari's administrative procedures. The Adjusted Warrants will be further adjusted, if applicable, to give effect to the impact of the Additional Exchange Ratio.

Each option to acquire shares of Peak Common Stock ("Peak Option") that is outstanding and unexercised immediately prior to the Effective Time, whether or not vested, will be assumed and converted into an option to purchase a number of Akari ordinary shares or Akari ADSs, as determined by Akari (each, an "Adjusted Option"). The number of Akari Ordinary Shares (or the number of Akari Ordinary Shares underlying Akari ADSs, as applicable) subject to the Adjusted Option will be equal to the product of (i) the total number of shares of Peak Common Stock subject to such Peak Option immediately prior to the Effective Time multiplied by (ii) the Exchange Ratio, with any fractional Akari Ordinary Shares or Akari ADSs rounded down to the nearest whole Akari Ordinary Share or Akari ADS, as applicable, and the exercise price per share of each Adjusted Option will be equal to the exercise price of such Peak Option immediately prior to the Effective Time divided by the Exchange Ratio. The Adjusted Options will be further adjusted, if applicable, to give effect to the impact of the Additional Exchange Ratio.

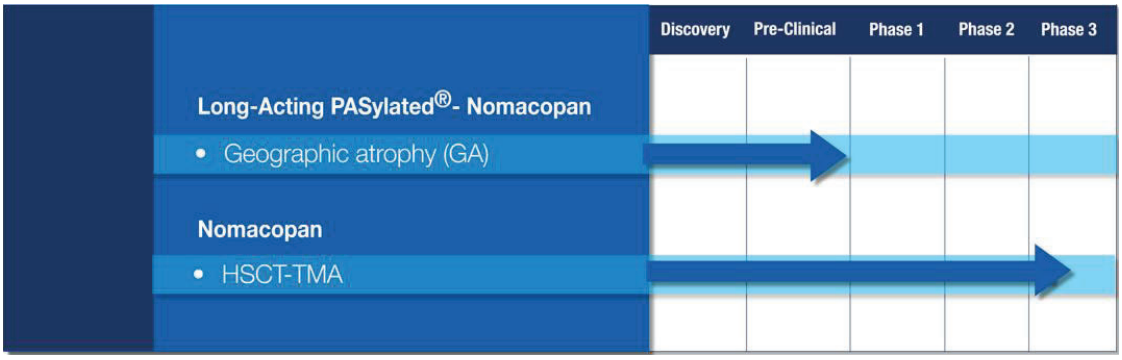
Consummation of the Merger is subject to various conditions, including, among others, (i) approval of the Merger Agreement and Merger by Peak Bio stockholders, (ii) Akari's shareholders authorizing Akari's board of directors to allot all Akari ordinary shares to be issued in connection with the Merger (to be represented by Akari ADSs), (iii) the absence of any law or order prohibiting consummation of the Merger, (iv) Akari's Registration Statement on Form S-4 (to be issued in connection with the Merger) having been declared effective, (v) the Akari ADSs issuable to Peak Bio stockholders having been authorized for listing on Nasdaq, (vi) accuracy of the other party's representations and warranties (subject to certain materiality standards set forth in the Merger Agreement), (vii) compliance by the other party in all material respects with such other party's obligations under the Merger Agreement; (viii) the absence of a material adverse effect on the other party, (ix) the other party's net cash being greater than negative $13,500,000 and (x) the PIPE Investment (as defined in the Merger Agreement) shall have been consummated simultaneously with, and conditioned only upon, the occurrence of the closing, and shall result in net proceeds to Akari of at least $10,000,000.

Either Akari or Peak Bio may terminate the Merger Agreement under certain circumstances, including if (i) the Merger is not completed by September 4, 2024, (ii) the other party's board of directors withdraws, modifies or qualifies its recommendation in favor of the transactions contemplated by the Merger Agreement or approves or recommends an alternative transaction or (iii) Akari's or Peak Bio's board of directors, as applicable, resolves to enter into a definitive agreement with respect to a superior proposal prior to obtaining approval of the Akari ADS issuance or Merger, as applicable, from Akari's shareholders or Peak Bio's stockholders, as applicable. The Merger Agreement also provides that under certain specified circumstances of termination described in the Merger Agreement, Akari or Peak Bio, as applicable, will be required to pay a termination fee equal to $300,000 and reimburse the other party for expenses related to the transaction up to $1.5 million.

Research and Development

Our Pipeline

We are currently developing potentially life-transforming treatments for autoinflammatory and orphan diseases involving the complement component 5 ("C5") and leukotriene B4 ("LTB4") pathways. Our current pipeline is set forth below:



In connection with the Merger, an assessment of our pipeline, as depicted above, in combination with Peak Bio's pipeline is planned, including program prioritization, updated timelines, near-term value creation opportunities, and other considerations.

Clinical Development Programs — Past and Current

Phase 1a Single Ascending Dose Trial

Nomacopan entered clinical development in 2013 when a Phase 1a clinical trial was initiated under a Clinical Trials Authorization ("CTA") issued by the Medicines and Healthcare products Regulatory Agency ("MHRA"), an executive agency of the Department of Health and Social Care in the United Kingdom. The primary objective of this single ascending dose, first-in-man study was to explore the safety profile of nomacopan in 24 subjects. The drug was well tolerated, and no serious or drug-related serious adverse events were reported. The secondary objective of this Phase 1a clinical trial was to examine the effect of nomacopan on complement activity at the highest therapeutic dose. These results showed that the peak onset of action was about nine hours after injection, and that the effect of a single dose was detectable for more than 96 hours. This was consistent between all subjects and showed 100% inhibition of the complement system within 12 hours.

Phase 1b Dose Range Finding Trial

A Phase 1b repeat dose study was initiated in the first quarter of 2016. In this double-blind, randomized Phase 1b trial, each cohort of six normal healthy volunteers was given either a loading dose of subcutaneous placebo twice a day for two days followed by five days of a single daily placebo dose (n=2) or a loading dose of 30 mg of subcutaneous nomacopan twice a day for two days followed by five days of a single daily subcutaneous maintenance dose (n=4) of either 15 mg, 22.5 mg or 30 mg.

Data from the 22.5 mg once daily maintenance cohort and 30 mg once daily maintenance cohort demonstrated that subcutaneous nomacopan achieved complete complement inhibition (ELISA CH50 < 8 Eq/ml, lower limit of quantification) within the first day, and demonstrated complete complement inhibition at the end of dosing on day 7 whether measured using the ELISA or lytic CH50 assays.

The data from the 15 mg once daily maintenance cohort demonstrated that subcutaneous nomacopan achieved complete complement inhibition (ELISA CH50 < 8 Eq/ml, lower limit of quantification) within the first day

following an ablating dose but by day three was unable to maintain complete complement inhibition at the 24-hour trough measurement. A final cohort of 4 healthy volunteers was given 22.5 mg of nomacopan as a maintenance dose for 21 days. Complete complement inhibition was demonstrated at the end of the 21 day period of once daily dosing and there were no neutralizing antibodies detected. One volunteer receiving the nomacopan in the 30 mg 7 day cohort stopped dosing on day three due to a non-serious adverse event possibly related to antibiotics administered for meningitis prophylaxis. The trial was conducted at Hammersmith Medicines Research Ltd, in London.

HSCT-TMA Clinical Program

HSCT-TMA is an orphan condition with severe cases having an estimated fatality rate of more than 80% patients with the disease. Complement activity is known to be implicated in HSCT-TMA with sC5b-9 (the soluble form of the membrane attack complex) and CH50 identified as key markers of disease progression; LTB4, which is also inhibited by nomacopan, may also be implicated by causing uncontrolled functioning of certain immune cells, such as neutrophils, that may lead to inflammation, tissue damage, and development of thrombosis. Currently, there are no approved treatment options for adult or pediatric patients with HSCT-TMA in the U.S. or Europe.

In December 2019, we opened a two-part, multi-center Phase 3 study for the treatment of pediatric HSCT-TMA with nomacopan, based upon guidance from our end-of-phase 2 meeting with the FDA. Part A of the trial is a dose confirmation study. The pivotal Part B of the trial is a responder-based safety and efficacy study. Part A of the clinical trial was designed to include three age cohorts: ages 0.5 to <2 years, ≥2 to <9 years and ≥9 to <18 years. As a result of the COVID-19 pandemic, we experienced delays in site openings and study subject enrollment, but to date, we have enrolled 10 patients into the three age cohorts.

In November 2022, the FDA granted the Rare Pediatric Disease Designation to nomacopan for the treatment of pediatric HSCT-TMA. Rare Pediatric Disease Designation recognizes the unmet need for treatments in rare pediatric diseases and is intended to encourage development of these treatments. Under this program, a sponsor who receives an approval of a new drug application ("NDA") or biologics license application ("BLA") for a rare pediatric disease may be eligible for a Priority Review Voucher ("PRV"). A PRV is valuable because it can be redeemed to obtain priority review for a subsequent marketing application for a different product or may be sold to a third party.

In February 2023, based on guidance from a Type C meeting with the FDA, we announced our plans to move forward into design and planning for pivotal Part B of the Phase 3 clinical trial of nomacopan for treatment of pediatric HSCT-TMA in patients between 2 years and <18 years of age. We participated in the FDA Model-Informed Drug Development (MIDD) program to refine our pharmacokinetic/pharmacodynamic ("PK/PD") model suitability and doses for the Phase 3 clinical trial of nomacopan in pediatric HSCT-TMA. Clinical data from 38 subjects (in previous clinical studies and healthy volunteers) were included in the PK/PD model, which was used to predict dosing for pediatric HSCT-TMA patients through 10,000 virtual patient simulations. These simulations informed FDA MIDD interactions that confirmed PK/PD model suitability and doses selected for the nomacopan Phase 3 Part A clinical trial in pediatric HSCT-TMA. An expanded PK/PD model using data from 55 subjects treated with nomacopan was reviewed in a Type C meeting with the FDA along with PK/PD data from the Part A study.

In addition, in February 2023, we announced we added a new pipeline program that will develop nomacopan as a potential treatment for adult HSCT-TMA, which will include a study that will serve as supportive evidence for the pediatric program.

In March 2023, we presented a case study of the first patient to complete treatment in the Part A portion of the Phase 3 clinical study of nomacopan in pediatric HSCT-TMA at the late-breaker at the Transplantation & Cellular Therapy Tandem Meetings and as a poster presentation at the European Society for Blood and Marrow Transplantation 49th Annual Meeting. A 6-year-old male patient at Royal Manchester Children's Hospital, Manchester University NHS Foundation Trust in Manchester, UK received a 6/8 HLA-mismatched unrelated cord blood HSCT conditioned with fludarabine, treosulfan and thiotepa, for relapsed refractory acute myelogenous leukemia ("AML"). The patient received 7 granulocyte infusions peri-transplant as part of an experimental protocol to augment the graft-versus-leukemia effect. His immediate post-transplant course was complicated by engraftment syndrome, acute gut graft-versus-host disease ("GVHD") grade 3 and cytomegalovirus ("CMV) viraemia. At day +66 after transplant, the patient developed features consistent with TMA, was enrolled in the clinical trial, and began treatment with

nomacopan on day +74. A single age- and weight-based ablating dose was followed by maintenance dosing for 21 days. After initial PD analysis at day 14 of treatment, the patient was found to have pre-dose terminal complement activity ("TCA") slightly higher (value 14.4) than the LLOQ (CH50 >10 U Eq/ml). Although his TCA had been reduced by 95% from a high baseline CH50 of 299.6U Eq/ml and sC5b9 had normalized, dose was increased in line with the study protocol. A few days later the patient developed neurological symptoms following a period of hypertension and was diagnosed with posterior reversible encephalopathy syndrome ("PRES"). Nomacopan was stopped for 3 days and restarted after the diagnosis was deemed to be unrelated to nomacopan treatment. Treatment continued for 46 days until the patient's urine protein creatinine ratio was corrected for ≥28 days. Gut pathology and thrombocytopenia were resolved. The patient was discharged from the hospital and remains well and in remission. No adverse events related to nomacopan were experienced during the 72-day treatment period.

In July 2023, we received Orphan Drug designation from the European Commission for nomacopan as a treatment for HSCT.

In November 2023, we had a Type C meeting with the FDA to discuss the clinical and nonclinical development plan for nomacopan for the treatment of HSCT-TMA in adult and pediatric patients. To incorporate the FDA's guidance from this meeting in our development plans, and in light of the planned pipeline assessment in connection with the Merger and other factors, we expect to make decisions in 2024 about initiating Part B of the Phase 3 clinical trial for pediatric HSCT-TMA and the clinical trial for adult HSCT-TMA.

Front And Back Of The Eye Programs

Results in a rodent model of Experimental Immune Conjunctivitis ("EIC"), undertaken at Moorfields Hospital Institute of Ophthalmology, showed that nomacopan demonstrated significant anti-inflammatory activity. In this preclinical model of severe eye surface inflammation, nomacopan, applied topically, resulted in a statistically significant reduction (64%, $p<0.001$) in late phase inflammation versus placebo.

During the third quarter of 2018, we commenced a Phase 1/2 trial to evaluate the safety and efficacy of nomacopan in patients with the inflammatory mediated eye disorder aopic keratoconjunctivitis ("AKC"). In Part A of the Phase 1/2 study, three patients were treated with twice daily nomacopan eye drops in addition to standard of care for up to 56 days in order to establish the safety and tolerability of the drops in preparation for Part B, a randomized, double-masked placebo-controlled comparison in 16 patients. The drops were observed to be comfortable, based on a comfort score measured after each eye drop, and well-tolerated throughout the trial for all three patients. There were no serious adverse events reported. On that basis, the independent safety committee gave permission for the trial to proceed to Part B. Enrollment in the Part B placebo-controlled efficacy arm of the study was halted in H1 2020 due to the COVID-19 outbreak. Of the 12 patients recruited, a complete data set was available on 10 patients – two from Part A and eight from Part B. In Part B, of the eight patients recruited, six were in the placebo arm (four AKC patients and two other surface of the eye diagnosis) and two were treated with nomacopan (two AKC patients). As a first-in-eye Phase 1/2 study, the primary endpoint measure was safety. Aggregating data from the eight AKC patients from Part A and Part B showed no ocular treatment emergent serious adverse events during the eight-week treatment period. Nomacopan is pH neutral and was delivered topically as eye drops without preservatives and was comfortable and well tolerated. Although the four nomacopan treated AKC patients achieved a higher improved mean efficacy score than the four placebo AKC patients, the patient numbers were too small to evaluate statistical significance on efficacy measures between the two treatment groups.

During 2020 and 2021, we announced preclinical data comparing the therapeutic efficacy of nomacopan, long acting PAS-nomacopan, and a monoclonal anti-VEGF antibody all administered intravitreally. PAS-nomacopan was found to reduce intraocular VEGF levels by as much as the anti-VEGF antibody with 74% ($p=0.04$) and 68% ($p=0.05$) reductions respectively, compared to saline control. Furthermore, based on a preclinical score measurement, inflammation increased in both the control and anti-VEGF groups by 49% and 33%, respectively, PAS-nomacopan treatment showed a 9% reduction in inflammation assessed by retinal fundoscopy ($p=0.02$). This therapeutic activity across multiple pathogenic pathways (VEGF, inflammation and complement) supports the potential for nomacopan as a new mode of action for the treatment of back of the eye diseases.

During the fourth quarter of 2020, we announced the publication of the results of a two-year research collaboration with the UCL Institute of Ophthalmology. The results showed that the therapeutic intravitreal ("IVT") administration of long-acting PAS-nomacopan mitigated both the severity and progress of retinal damage in two

retinal tissue models of autoimmune uveitis, a severe inflammatory eye disease where steroids are the primary treatment option. In addition, results showed the presence of inflammatory cells expressing both complement C5 and LTB4 receptors in retinal tissue from donor patients with uveitis as compared to healthy donor eyes.

During the second quarter of 2022, we announced positive results from two preclinical studies of PAS-nomacopan administered intravitreally. These preclinical results confirm the bioavailability of PAS-nomacopan in the retina and suggested that a clinical dose interval of three months or more may be possible and indicate that PAS-nomacopan may be able to inhibit neovascularization. Studies have shown that due to adverse effects, such as infection, increase in intraocular pressure and discomfort and anxiety, IVT injection presents a heavy burden on patients therefore a longer dosing interval may be beneficial.

During the third quarter of 2022, we announced further positive results from these recent pre-clinical studies on the tolerability and extended dose interval of long-acting PAS-nomacopan, which, together with data previously presented, suggest PAS-nomacopan has the potential to be a novel treatment option for GA, a chronic progressive degeneration of the macula in the aging eye leading to lesions on the outer retina that can cause irreversible vision loss. There is currently two FDA-approved therapies for treatment of GA. Both are complement inhibitors; that are administered to patients through monthly or every-other-month needle injections into the eye (IVTs). Frequent needle injections into the eye are a source of fear, discomfort, disruption for patients and have been shown to decrease patient compliance with optimal dosing regimens.

Our preclinical results show that PAS-nomacopan has the potential to make IVT injection long-lasting in the back of the eye and may provide a more than three-month dosing interval that could be less burdensome and more attractive for patients. Sight-threatening choroidal neovascularization (“CNV”) is a safety risk associated with approved and late-stage complement-only inhibitors used for the treatment of GA. CNV is typically treated with anti-VEGF injections. Currently approved and late-stage GA treatments have shown increased risks of developing CNV in clinical trials 4X and 2X compared to sham, respectively. Dual-action PAS-nomacopan may offer the well-understood benefits of complement C5 inhibition in slowing the progression of GA lesions, while LTB4 inhibition also has the potential to help prevent VEGF-A over-expression, a key driver of CNV. We believe the positive results in preclinical studies of long-acting PAS-nomacopan support the potential to submit an investigational new drug application (“IND”) for clinical trials in GA.

In July 2023, we announced completion of our evaluation of PAS-nomacopan candidates and selected a single drug candidate to move forward into clinical trials for treatment of GA, pending IND clearance.

In November 2023, we presented a poster on our progress in pre-clinical development of long-acting PAS-nomacopan as a potential treatment for GA at the 4th Annual Dry AMD Therapeutic Development conference. We believe positive pre-clinical results and an advanced high yielding manufacturing process support the potential submission of an IND to begin clinical development with Phase 1 single and multiple ascending dose (“SAD/MAD”) testing to evaluate safety and pharmacokinetics/pharmacodynamics (“PK/PD”) of long-acting PAS-nomacopan. PK/PD data show PAS-nomacopan has extended half-life in the eye after intravitreal injection (7.4 to 8.4 days), suggesting the dose interval may be 3 months or longer.

Immunogenicity

A chronic (28 day) dosing experiment in mice investigated whether daily subcutaneous administration of the expected therapeutic dose of nomacopan induces an antibody response, and whether the antibodies neutralize complement inhibition by nomacopan. The data from this chronic dosing experiment showed nomacopan was well-tolerated with no injection site allergic reactions or behavioral changes. Nomacopan can induce formation of low titre anti-drug IgG antibodies in mice after four weeks of daily inoculation, which is not uncommon, but these antibodies were not neutralizing and had no effect on nomacopan’s ability to inhibit complement.

No neutralizing antibodies have been detected to date in clinical studies, including in the healthy volunteers in the Phase 1a and 1b trials, and the PNH studies. Pharmacokinetic analysis in PNH patients show that nomacopan serum drug levels do not fall in the presence of anti-drug antibodies and pharmacodynamic analyses show that terminal complement activity was fully inhibited (ELISA CH50 <10 U Eq/mL) throughout nomacopan dosing.

PAS-Nomacopan

Using PASylation®, a proprietary technology licensed from of XL-protein GmbH ("XL-protein"), nomacopan can be modified with XL-protein by adding a 600 amino acid proline/alanine/ serine ("PAS") N-terminal fusion tag to generate PAS-nomacopan (68kDa). The unstructured and uncharged PAS polypeptide increases the apparent molecular size to approximately 600kDa, slowing kidney clearance and extending the systemic half-life of nomacopan.

Data from mouse, rat and dog studies of PAS-nomacopan demonstrated that the expected terminal half-life in humans may be approximately 4 days. Based on these data, PK modeling supports that a once weekly subcutaneous dosing regimen in human may be feasible. In addition, work in a rabbit eye model has demonstrated the potential for an IVT dosing interval of once every three months or more using PAS-nomacopan.

Target Indications

Hemopoietic Stem Cell Transplant - Thrombotic Microangiopathy (HSCT-TMA)

TMAs are a group of diseases in which thrombosis occurs in small blood vessels as a result of damage to the endothelium (lining) of the vessels. This leads to hemolytic anemia, low platelet count (thrombocytopenia), end organ damage which may result in complications including renal failure, stroke and pulmonary hypertension. The major varieties of TMA are hemolytic uremic syndrome ("HUS"), atypical hemolytic uremic syndrome ("aHUS"), thrombotic thrombocytopenic purpura ("TTP"), antiphospholipid syndrome ("APS"), disseminated intravascular coagulation ("DIC"), malignant hypertension, scleroderma renal failure and TMA associated with hemopoietic stem cell transplant ("HSCT"). The latter is often linked to toxicity of calcineurin inhibitors which are used to protect against graft versus host disease ("GvHD"). There are no currently approved drugs for the treatment of HSCT-TMA and, untreated, the condition in its more severe forms has a high risk of death.

Geographic Atrophy (GA) Secondary to dry Age-Related Macular Degeneration (dry AMD)

GA secondary to dry age-related macular degeneration ("dAMD") is a degenerative disease of the retina that leads to progressive loss of retinal pigment epithelium ("RPE") and ultimately to photoreceptors. These areas of loss manifest as atrophic lesions on the macula, which reduce photosensitivity and if they overlap the fovea impair vision and ultimately lead to blindness. The pathogenesis of GA is multifactorial and is generally thought to be triggered by intrinsic and extrinsic stress acting on the poorly regenerative retinal pigment epithelium as people age. The stress results in the appearance of drusen and lipofuscin deposits. Components of drusen and lipofuscin, include complement, as well as products of oxidative stress such as advanced glycation end products, and may trigger inflammation via multiple pathways. The resulting inflammation can ultimately lead to the retinal cell death characteristic of GA. Development of AMD, including dAMD, is associated with polymorphisms in various complement proteins and recently a complement inhibitor against C3 has become the first FDA-approved drug for treatment of GA.

Market Opportunity in Complement Mediated Diseases

The NIH estimates that approximately 23.5 million Americans may suffer from an autoimmune disorder, although this number is almost certainly an underestimate of the actual prevalence as it includes only 24 diseases for which good epidemiology studies were available. It is estimated that an additional 1.18 million people in the U.S. will acquire/develop an autoimmune disease every five years. Women are more than two times more likely than men to develop an autoimmune disease. Researchers have identified 80 – 100 different autoimmune diseases and suspect at least 40 additional diseases of having an autoimmune basis. Patients with one autoimmune disease are at increased risk of other diseases with an autoimmune basis. These diseases are chronic and can be life-threatening. Autoimmune disease is one of the top 10 leading causes of death in female children and women in all age groups up to 64 years of age. The NIH estimates annual direct health care costs for autoimmune diseases to be in the range of $100 billion.

Both the complement and leukotriene pathways work as part of the immune system to disable and clear out foreign invaders and unwanted cells, and as such, plays an important role in the pathology of many autoimmune diseases. The term “Complement Mediated Diseases” applies to diseases and conditions where a patient’s immune system attacks and destroys healthy body tissue by mistake, causing direct damage mediated by complement and via a plethora of mediators induced by complement activation. In addition to those conditions where complement activity is believed to be the primary driver of disease, there are many other poorly treated diseases where in addition to complement activation other inflammatory pathways are implicated. These diseases, such as HSCT-TMA, GA, PNH, aHUS, GBS, Myasthenia Gravis, NMOSD, BP and AKC, are potential targets for bi-specific nomacopan.

Based on internally conducted market research, mortality in patients who develop severe transplant-related TMAs is estimated to be 80%. There are no approved therapeutics for HSCT-TMA. We believe the size of the potential patient population for moderate to severe complement mediated HSCT-TMA is approximately 200-300 in the pediatric population and 3,100-3,200 in the adult population in the U.S. alone. With respect to GA, we believe over 5 million patients worldwide are estimated to be affected, with approximately 1 million in the U.S. alone.

Competition in Complement and Leukotriene Mediated Diseases

The development and commercialization of new drugs is highly competitive. We expect to face competition with respect to all product candidates that we may develop or commercialize in the future from pharmaceutical and biotechnology companies worldwide. The key factors affecting the success of any approved product will be its efficacy, safety profile, drug interactions, method of administration, pricing, reimbursement and level of promotional activity relative to those of competing drugs.

Our potential competitors may have substantially greater financial, technical, and personnel resources than we do. In addition, many of these competitors have significantly greater commercial infrastructures. Our ability to compete successfully will depend largely on our ability to leverage our collective experience in drug discovery, development and commercialization to:

- discover and develop drugs that are differentiated from other products in the market;
- obtain patent and/or proprietary protection for our product candidates and technologies;
- obtain required marketing authorizations;
- commercialize our product candidates ourselves and/or through partners, if approved; and
- attract and retain high-quality personnel, including those with research, development and commercial skills.

There has been a broad research effort in complement-based therapy to date, with eculizumab being the first therapy approved that directly inhibits C5. Although there is currently less research and development effort in the leukotriene field there are approved leukotriene inhibitors used as a treatment for severe asthma. However, we are aware of certain other companies and academic institutions that are continuing their efforts to discover and develop alternate complement and/or C5 inhibitors, including, but not limited to, Alexion Pharmaceuticals, a subsidiary of AstraZeneca, Annexon, Inc., Apellis Pharmaceuticals, Inc., Omeros Corporation, Amgen, Inc., IVERIC bio, Inc., Novartis AG, Roche Pharmaceuticals, and UCB, Inc.

Sales and Marketing

Because we have been focused on discovery and development of drugs, we currently have limited sales, marketing and distribution capabilities in order to commercialize nomacopan or any other product candidates that may be approved in the future. If our lead product candidate nomacopan is approved, we intend either to establish a sales and marketing organization with technical expertise and supporting distribution capabilities to commercialize nomacopan, or to outsource some or all of these functions to third parties. We may take different approaches to commercialization in different geographies. We will adopt a similar strategy for the other compounds in our pipeline.

Manufacturing

We currently employ third-party contract development and manufacturing organizations ("CDMOs"), which manufacture in accordance with current good manufacturing practice ("GMP") requirements, for our investigational medical products, including active pharmaceutical ingredients, drug substance and drug product for our preclinical research and clinical studies for nomacopan. Analytical methods, compliant with GMP requirements, have been established and qualified for release and stability testing of drug substance and drug products. Since 2016, we have successfully manufactured multiple lots of GMP nomacopan drug substance and drug product batches, which have been used in clinical trials in the U.S. and Europe.

In January 2021, we announced that the FDA agreed in a Type C meeting that nomacopan derived from a next generation manufacturing process was acceptable for use in clinical trials. This process increased the final yield of nomacopan at least 5-fold compared to the previous manufacturing process, which may significantly decrease future commercial cost of goods and reduce the cost of ongoing Phase 3 and future clinical development programs for nomacopan. GMP nomacopan has been manufactured with this new process and used in clinical trials in the U.S. and Europe.

Since 2018 we have engaged a CDMO to develop a manufacturing process for a long acting PASylated form of nomacopan ("PAS-nomacopan"). Two development batches of drug substance and a development batch of drug product were successfully manufactured in 2023.

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We currently rely, and expect to continue to rely, on CDMOs for the manufacture of nomacopan and PAS-nomacopan and any other product candidates that we may develop for larger scale preclinical and clinical testing, as well as for commercial quantities of any product candidates that are approved.

In the future we may encounter disruptions in the supply chain of nomacopan or PAS-nomacopan which could negatively impact our ability to supply our drug product to clinical trial sites, delaying clinical studies.

Intellectual Property

We will be able to protect our technology and products from unauthorized use by third parties only to the extent it is covered by valid and enforceable patents or is effectively maintained as trade secrets. Patents and other proprietary rights are thus an essential element of our business.

Our success will depend in part on our ability to obtain and maintain proprietary protection for our product candidates, technology, and know-how, to operate without infringing on the proprietary rights of others, and to prevent others from infringing our proprietary rights. Our policy is to seek to protect our proprietary position by, among other methods, filing U.S. and foreign patent applications related to our proprietary technology, inventions, and improvements that are important to the development of our business and defending our patent applications and patents if they are subjected to challenge by a third party. We also rely on trade secrets, know-how, continuing technological innovation, and in-licensing opportunities to develop and maintain our proprietary position.

As of March 1, 2024, we own or have exclusive rights to patents and patent applications based on 16 international patent applications. This includes nine issued United States patents, nine patents granted by the European Patent Office and foreign issued patents in other jurisdictions. This further includes pending patent applications in the United States and other jurisdictions. Our patents and patent applications relate to the complement C5 inhibitor protein nomacopan and to its use in the treatment of key disease indications, as well as to nomacopan variants, and histamine binding proteins. As of March 1, 2024, our current patent portfolio includes granted patents in the jurisdictions of United States, Canada, major European countries, Japan, China, Brazil, Israel, Hong Kong, Mexico, Russia, Australia, New Zealand and pending applications in the jurisdictions of United States, Canada, Europe, Japan, China, Brazil, Israel, Republic of Korea, Australia and New Zealand.

Issued patents in the US and other countries which cover our product candidate nomacopan and its uses will expire between 2024 and 2038, excluding any patent term adjustment that might be available in certain countries, or any patent term extensions that might be available following the grant of marketing authorizations. We have pending patent applications for our product candidate nomacopan and its uses that, if issued, would expire in the United States and in countries outside of the United States between 2024 and 2040, excluding any patent term adjustment that might be available following the grant of the patent and any patent term extensions that might be available following the grant of marketing authorizations. These patent and patent applications relate to subject matters including: complement inhibitor molecule; methods for treating myasthenia gravis; methods for treating peripheral nerve disorders; methods for treating respiratory disorders; methods for treating viral infections of the respiratory tract; methods of treating complement-mediated diseases in patients with C5 polymorphisms, methods of treating acute graft versus host disease; methods of treating cicatrizing eye inflammatory disorders; methods of treating autoimmune blistering diseases; methods of treating rheumatic diseases; methods of treating proliferative retinal diseases; methods of treating HSCT-TMA, and nomacopan variants lacking C5 or LTB4 binding.

We have licensed rights to patents and patent applications relating to PAS polypeptides and nucleic acids encoding PAS polypeptides, which include patents/applications which cover PAS-nomacopan fusion proteins. We also own a pending PCT patent application directed to certain PAS-nomacopan fusion proteins and their use in the treatment of key disease indications, including GA. If granted, national/regional patents derived from this PCT application would expire in 2043.

If we are unable to obtain, maintain, defend and enforce patent and other intellectual property rights for our technologies and product candidate nomacopan, or if the scope of the patent and other intellectual property rights obtained is not sufficiently broad, our competitors and other third parties could develop and commercialize technology, biologics and/or biosimilars similar or identical to ours, and erode or negate any competitive advantage that we may have, which could harm our business and ability to achieve profitability.

We can provide no assurance that our patent applications or those of our licensors will result in additional patents being issued or that issued patents will afford sufficient protection against competitors with similar technologies, nor can there be any assurance that the patents issued will not be infringed, designed around or invalidated by third parties. Even issued patents may later be found unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. The degree of future protection for our

proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep competitive advantage. Composition-of-matter patents on the biological or chemical active pharmaceutical ingredients are generally considered to offer the strongest protection of intellectual property and provide the broadest scope of patent protection for pharmaceutical products, as such patents provide protection without regard to any method of use or any method of manufacturing. While we have issued composition-of-matter patents in the United States and other countries for nomacopan, we cannot be certain that the claims in our issued composition-of-matter patents will not be found invalid or unenforceable if challenged. We cannot be certain that the claims in any patent applications covering composition-of-matter or formulations of our product candidates that are pending, or that we may file, will be considered patentable by the United States Patent and Trademark Office ("USPTO"), and courts in the United States or by the patent offices and courts in foreign countries, nor can we be certain that the claims in our issued composition-of-matter patents will not be found invalid or unenforceable if challenged. Even if any patent applications that we may file relating to specific formulations of our product candidates issue as patents, formulation patents protect a specific formulation of a product and may not be enforced against competitors making and marketing a product that has the same active pharmaceutical ingredient in a different formulation. Method-of-use patents protect the use of a product for the specified method or for treatment of a particular indication. This type of patent may not be enforced against competitors making and marketing a product that has the same active pharmaceutical ingredient for use in a method not claimed by the patent. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products "off-label." Although off-label prescriptions may infringe or contribute to the infringement of method-of-use patents, the practice is common and such infringement may be difficult to prevent or prosecute. Also, as is the case for composition-of-matter patents, we cannot be certain that the claims in our issued method-of-use patents will not be found invalid or unenforceable if challenged. We cannot be certain that the claims in any patent applications covering methods of using our product candidates that are pending, or that we may file, will be considered patentable by the USPTO and courts in the United States or by the patent offices and courts in foreign countries, nor can we be certain that the claims in our issued method-of-use patents will not be found invalid or unenforceable if challenged.

Government Regulation

Government Regulation and Product Approval

Government authorities in the U.S., at the federal, state and local level, and in other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing and export and import of products such as those that we are developing. A new drug must be approved by the FDA, generally through the new drug application ("NDA") process and a new biologic must be approved by the FDA through the biologics license application ("BLA") process before it may be legally marketed in the U.S. The animal and other non-clinical data and the results of human clinical trials performed under an Investigational New Drug application ("IND") and under similar foreign applications will become part of the NDA or BLA.

U.S. Drug Development Process

In the U.S., the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act ("FDCA") and in the case of biologics, also under the Public Health Service Act ("PHSA") and the implementing regulations for both statutes. The process of obtaining marketing authorizations and the subsequent compliance with applicable federal, state, local, and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, requesting product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement, or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us. The process required by the FDA before a drug or biologic may be marketed in the U.S. generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies according to Good Laboratory Practices ("GLP") and relevant provisions of the Animal Welfare Act, where applicable, or other applicable laws and regulations;
- submission to the FDA of an IND which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials according to Good Clinical Practices ("GCP") to establish the safety and efficacy of the proposed drug for its intended use;
- submission to the FDA of an NDA or BLA;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with current good manufacturing practice ("cGMP") to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity; and
- FDA review and approval of the NDA or BLA.

Once a product candidate is identified for development, it enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information and analytical data, to the FDA as part of the IND. The sponsor will also include a protocol detailing, among other things, the objectives of the first phase of the clinical trials, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated, if the first phase lends itself to an efficacy evaluation. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Clinical holds also may be imposed by the FDA at any time before or during studies due to safety concerns or non-compliance.

All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with GCP. They must be conducted under protocols detailing the objectives of the trial, dosing procedures, subject

selection and exclusion criteria and the safety and effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND, and progress reports detailing the results of the clinical trials must be submitted at least annually. In addition, timely safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse events. An institutional review board ("IRB") responsible for the research conducted at each institution participating in the clinical trial must review and approve each protocol before a clinical trial commences at that institution and must also approve the information regarding the trial and the consent form that must be provided to each trial subject or his or her legal representative, monitor the study until completed and otherwise comply with IRB regulations.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- ***Phase 1:*** The product candidate is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case of some products for severe or life-threatening diseases, such as cancer, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing may be conducted in patients.

- ***Phase 2***: This phase involves studies in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.

- ***Phase 3***: Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical study sites. These studies are intended to establish the overall risk-benefit ratio of the product candidate and provide, if appropriate, an adequate basis for product labeling.

The FDA or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. Phase 1, Phase 2, and Phase 3 testing may not be completed successfully within any specified period, if at all.

During the development of a new drug, sponsors are given opportunities to meet with the FDA at certain points. These points may include prior to submission of an IND, at the end of Phase 2, and before an NDA or BLA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and FDA to reach agreement on the next phase of development. Sponsors typically use the end of Phase 2 meeting to discuss their Phase 2 clinical results and seek feedback on their plans for the pivotal Phase 3 clinical trial that they believe will support approval of the new drug.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA. Safety reports must be submitted to the FDA and the investigators 15 calendar days after the trial sponsor determines that the adverse event information qualifies for reporting. The sponsor also must notify FDA of any unexpected fatal or life-threatening suspected adverse reaction as soon as possible but in no case later than 7 calendar days after the sponsor's initial receipt of the information. Sponsors of clinical trials of drugs and biologics are required to register and disclose certain clinical trial information on a registry maintained by the National Institutes of Health, at www.clinicaltrials.gov.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

U.S. Review and Approval Processes

The results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling, and other relevant information are submitted to the FDA as part of an NDA or BLA requesting approval to market the product. The submission of an NDA or BLA is subject to the payment of substantial user fees; a waiver of such fees may be obtained under certain limited circumstances. Within sixty days of receipt, the FDA initially reviews all NDAs and BLAs submitted to ensure that they are sufficiently complete for substantive review before it accepts them for filing. The FDA may request additional information rather than accept a NDA or BLA for filing. In this event, the NDA or BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. FDA may refer an NDA or BLA that is novel or that presents difficult questions of safety or efficacy to an advisory committee for review, evaluation and recommendation on questions presented by the FDA, which may include questions related to whether the application should be approved and under what conditions. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving an NDA or BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the product is manufactured to assess compliance with cGMP.

The FDA may also place other conditions on approval, including the requirement for a Risk Evaluation and Mitigation Strategy ("REMS") to assure the safe use of the product. If the FDA concludes a REMS is needed, the sponsor of the NDA or BLA must submit a proposed REMS, and the FDA will not approve the application without an approved REMS. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products.

The approval process is lengthy and often difficult, and the FDA may refuse to approve an NDA or BLA if the applicable regulatory criteria are not satisfied or may require additional clinical or other data and information. Even if such data and information are submitted, the FDA may ultimately decide that the NDA or BLA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than how we interpret the same data. The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant to assure and preserve the product's identity, strength, quality and purity. The FDA reviews a BLA to determine, among other things whether the product is safe, pure and potent and the facility in which it is manufactured, processed, packed or held meets standards designed to assure the product's continued safety, purity and potency. The FDA may issue a complete response letter ("CRL"), which may require additional clinical or other data or impose other conditions that must be met in order to secure final approval of the NDA or BLA, or an approval letter following satisfactory completion of all aspects of the review process. The applicant may either resubmit the NDA or BLA, addressing all of the deficiencies identified in the letter, withdraw the application, or, in the case of an NDA, request an opportunity for a hearing. The applicant also may request resolution of any dispute concerning the CRL. If the FDA denies approval of a BLA, the applicant may request, and FDA must issue, a notice of opportunity for hearing.

NDAs or BLAs may receive either standard or priority review. Under current FDA review goals, standard review of an NDA for a new molecular entity ("NME") or original BLA will be ten months from the date that the NDA or BLA is filed. A drug representing a significant improvement in treatment, prevention or diagnosis of a serious disease or condition may receive a priority review of six months. Priority review does not change the standards for approval, but may expedite the approval process.

If a product receives marketing authorization, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. In addition, the FDA may require a sponsor to conduct Phase IV testing, such as clinical trials designed to further assess a drug's safety and/or effectiveness after NDA or BLA approval, and may require testing and surveillance programs to monitor the safety of approved products which have been commercialized.

The Pediatric Research Equity Act ("PREA") requires a sponsor to conduct pediatric studies for most drugs and biologics with a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under PREA, original NDAs and BLAs and certain supplemental applications must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The sponsor or FDA may request a deferral of pediatric studies for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug or biologic is ready for approval for use in adults before pediatric studies are complete or that additional safety or effectiveness data needs to be collected before pediatric studies can begin.

The Best Pharmaceuticals for Children Act ("BPCA") provides NDA holders a six-month period of exclusivity attached to any patent or regulatory exclusivity listed in the Orange Book, and BLA holders a six-month period of exclusivity attached to any unexpired regulatory exclusivity, if certain conditions are met. Conditions for pediatric exclusivity include a determination by the FDA that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, a written request by the FDA for pediatric studies, completion of the studies in accordance with the written request, and submission of reports from the requested studies to the FDA. The issuance of a written request does not require the sponsor to undertake the described studies.

Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of FDA approval of our product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as partial compensation for effective patent term lost due to time spent during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND, and the submission date of an NDA or BLA, plus the time between the submission date of an NDA or BLA and the approval of that application, except that the period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved drug may be extended, and the extension must be applied for prior to expiration of the patent. The United States Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration.

Biologics Price Competition and Innovation Act of 2009 (BPCIA)

The BPCIA amended the PHSA to create an abbreviated approval pathway for biosimilar and interchangeable biosimilar products and provide for a twelve-year exclusivity period for the first approved biological product, or reference product, against which a biosimilar or interchangeable biosimilar application is evaluated. A biosimilar product is defined as one that is highly similar to a reference product notwithstanding minor differences in clinically inactive components and for which there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity and potency of the product. An interchangeable biosimilar product is a biosimilar product that, subject to state pharmacy laws, may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.

The biosimilar applicant must demonstrate that the product is biosimilar based on data from: (1) analytical studies showing that the biosimilar product is highly similar to the reference product; (2) animal studies (including toxicity); and (3) as applicable, one or more clinical studies to demonstrate safety, purity and potency in one or more appropriate conditions of use for which the reference product is approved. In addition, the applicant must show that the biosimilar and reference products have the same mechanism of action for the conditions of use on the label, route of administration, dosage and strength, and the production facility must meet standards designed to assure product safety, purity and potency.

An application for a biosimilar product may not be submitted until four years after the date on which the reference product was first approved. The first approved interchangeable biosimilar product will be granted an exclusivity

period of up to one year after it is first commercially marketed, but the exclusivity period may be shortened under certain circumstances.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the U.S., or more than 200,000 individuals in the U.S. and for which there is no reasonable expectation that the cost of developing and making available in the U.S. a drug for this type of disease or condition will be recovered from sales in the U.S. for that drug. Orphan drug designation must be requested before submitting an NDA or BLA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not itself convey any advantage in or shorten the duration of the regulatory review and approval process. If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication, except in very limited circumstances, for seven years. Orphan drug exclusivity, however, also could block the approval of one of our product candidates for seven years if a competitor obtains approval of the same drug, for the same designated orphan indication or if our product candidate is determined to be contained within the competitor's product for the same indication or disease.

Rare Pediatric Disease Priority Review Vouchers

With enactment of the Food and Drug Administration Safety and Innovation Act of 2012 ("FDASIA"), Congress authorized the FDA under Section 529 of the FDCA to award priority review vouchers ("PRVs"), to sponsors of certain rare pediatric disease product applications. This provision, which was further amended by the Advancing Hope Act of 2016, is designed to encourage development of new drug and biological products for prevention and treatment of certain rare pediatric diseases.

Under this program, a sponsor who receives approval for a new drug or biologic for a rare pediatric disease may qualify for a PRV, which can be redeemed for priority review of a subsequent marketing application for a different product. The sponsor of a rare pediatric disease drug product that receives a PRV may transfer, including by sale, the PRV to another sponsor and that PRV may be further transferred any number of times before it is used. A PRV entitles the holder to designate a single human drug application submitted under Section 505(b)(1) of the FDCA or Section 351 of the PHSA as qualifying for a priority review. An FDA priority review may expedite the review process of a marketing application reducing the review time from ten months after formal acceptance of the file to six months after formal acceptance of the file.

In order for a sponsor to receive a PRV in connection with approval of a BLA or NDA, the investigational product must be designated by the FDA as a product for a rare pediatric disease prior to submission of the marketing application. A rare pediatric disease is a disease that is serious or life-threatening and which primarily affects individuals aged from birth to 18 years and fewer than 200,000 people in the United States. Alternatively, the disease may affect more than 200,000 people in the United States if there is no reasonable expectation that the cost of developing and making available in the United States a product for such disease or condition will be recovered from sales in the United States of such product. In addition, to qualify for a PRV, the sponsor must request the voucher and the BLA or NDA must itself be given priority review, rely on clinical data derived from studies examining a pediatric population and dosages of the product intended for that population, not seek approval for a different adult indication in the original rare pediatric disease product application and be for a product that does not include a previously approved active ingredient.

The Rare Pediatric Disease PRV program was originally set to expire in October 2020 but was extended for an additional six years with passage of the Coronavirus Response and Relief Supplemental Consolidated Appropriations Act of 2021. Under the current statutory sunset provisions, the FDA may only award a rare pediatric disease PRV if a sponsor has a rare pediatric disease designation for the drug or biologic before September 30, 2024, and the NDA or BLA for the product is approved before September 30, 2026

Fast Track Designation and Accelerated Approval

The FDA has established programs to facilitate the development, and expedite the review of, drugs that are intended for the treatment of a serious or life-threatening disease or condition for which there is no effective treatment and which demonstrate the potential to address unmet medical needs for the condition. Under the fast track program, the sponsor of a product candidate may request that the FDA designate the product candidate for a specific indication as a fast track drug concurrent with, or after, the filing of the IND for the product candidate. The FDA determines if the product candidate qualifies for fast track designation within 60 days of receipt of the sponsor's request.

The FDA may designate a drug for fast-track status if it is intended to treat a serious or life-threatening illness and nonclinical or clinical data demonstrate the potential to address an unmet medical need. If so designated, the FDA takes steps to expedite the development and review of the product's marketing application, including by meeting with the sponsor more frequently to provide timely advice so that the development program is as efficient as possible. Another benefit of fast-track designation is that the FDA may initiate review of sections of an NDA or BLA before the application is complete. This rolling review is available if the applicant provides, and the FDA approves, a schedule for the submission of the remaining information and the applicant pays applicable user fees. The FDA's review goal date does not begin until the last section of the application is submitted, however. Fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in clinical trials.

The agency may determine that an accelerated approval pathway is appropriate if a product candidate is intended to treat a serious condition and provide meaningful therapeutic benefit to patients over existing treatments based upon a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments.

In clinical trials, a surrogate endpoint is a measurement of laboratory or clinical signs of a disease or condition that substitutes for a direct measurement of how a patient feels, functions, or survives. Surrogate endpoints can often be measured more easily or more rapidly than other clinical endpoints. As a condition of accelerated approval, the FDA generally requires that the sponsor perform adequate and well-controlled post-marketing clinical trials with due diligence to confirm clinical benefit and, under the Food and Drug Omnibus Reform Act of 2022 ("FDORA"), the FDA is now permitted to require, as appropriate, that such trials be underway prior to approval or within a specific time period after the date accelerated approval is granted. Failure to conduct required post-approval studies or to confirm clinical benefit through post-marketing studies allows the FDA to withdraw the drug from the market on an expedited basis. In addition, for products under accelerated approval, FDA generally requires all promotional materials, including launch materials, to be submitted for prior review.

Post-Approval Requirements

Once approval of an NDA or BLA is granted, the FDA may withdraw the approval if compliance with regulatory standards is not maintained or if problems are identified after the product reaches the market. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures, including a REMS or the conduct of post-marketing studies to assess a newly discovered safety issue. Later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further FDA review and approval. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws and regulations. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products. Future inspections by the FDA and other regulatory agencies may identify compliance issues at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct.

Any drug products manufactured or distributed by us pursuant to FDA approvals are subject to continuing regulation by the FDA, including, among other things, requirements related to record-keeping, reporting of adverse experiences, submitting periodic reports, updating safety and efficacy information, drug sampling and distribution, and electronic records and signatures. The FDA also closely regulates labeling, advertising, promotion and other types of information that may be disseminated about products that are placed on the market. Drugs may be promoted only for the approved indications and in a manner that is consistent with the approved label.

From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the development, approval, manufacturing and marketing of products regulated by the FDA. It is impossible to predict whether further legislative changes will be enacted, or FDA regulations, guidance or interpretations changed or what the impact of such changes, if any, may be.

Regulation and Marketing Authorization in the European Union

Preclinical Studies

Preclinical tests include laboratory evaluations of product chemistry, formulation and stability, as well as studies to evaluate toxicity in animal studies, in order to assess the potential safety and efficacy of the product. The conduct of the preclinical tests and formulation of the compounds for testing must comply with the relevant EU regulations and requirements. The results of the preclinical tests, together with relevant manufacturing information and analytical data, are submitted as part of the CTA and MAA.

Clinical Trial Approval

Clinical trials in the EU are governed by the Clinical Trials Regulation, (EU) No 536/2014, or the CT Regulation. The CT Regulation was adopted in 2014 and replaces the Clinical Trials Directive 2001/20/EC, or the CT Directive. To ensure that the rules for clinical trials are identical throughout the EU, the EU clinical trials legislation was passed as a "regulation" that is directly applicable in all EU Member States. All clinical trials performed in the EU are required to be conducted in accordance with the CT Regulation.

The CT Regulation aims to harmonize, simplify and streamline the approval of clinical trials in the EU. The main characteristics of the CT Regulation include:

- A streamlined application procedure via a single-entry point, the EU portal.
- A single set of documents to be prepared and submitted for the application as well as simplified reporting procedures that will spare sponsors from submitting broadly identical information separately to various bodies and different EU Member States.
- A harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts. Part I is assessed jointly by all Member States Concerned. Part II is assessed separately by each Member State Concerned.
- Strictly defined deadlines for the assessment of clinical trial application.
- The involvement of the ethics committees in the assessment procedure in accordance with the national law of the Member State Concerned but within the overall timelines defined by the CT Regulation.

The transitory provisions of the CT Regulation provide that ongoing clinical trials previously authorized under the CT Directive, can remain under the CT Directive, or they can transition to the CTR. By January 31, 2025, all ongoing clinical trials must have transitioned to the CTR.

Marketing Authorization

Authorization to market a product in the Member States of the EU proceeds under one of four procedures: a centralized authorization procedure, a mutual recognition procedure, a decentralized procedure or a national procedure.

Centralized Authorization Procedure

The centralized procedure enables applicants to obtain a marketing authorization that is valid in all EU Member States based on a single application. Certain medicinal products, including products developed by means of biotechnological processes, must undergo the centralized authorization procedure to obtain marketing authorization, which, if granted by the European Commission, is automatically valid in all 27 EU Member States.

The centralized authorization procedure is mandatory for:

- medicinal products developed by means of biotechnological processes such as genetic engineering;
- advanced therapy medicinal products as defined in Article 2 of Regulation (EC) No. 1394/2007 on advanced therapy medicinal products (such as, gene-therapy, somatic cell-therapy or tissue-engineered medicines);
- human immunodeficiency virus;
- acquired immune deficiency syndrome;
- cancer;
- neurodegenerative disorder;
- diabetes;
- auto-immune diseases and other immune dysfunctions;
- viral diseases; and
- medicinal products that are designated as orphan medicinal products pursuant to Regulation (EC) No 141/2000.

The centralized authorization procedure is optional for other medicinal products if they contain a new active substance or if the applicant shows that the medicinal product concerned constitutes a significant therapeutic, scientific or technical innovation or that the granting of authorization is in the interest of patients in the EU.

Administrative Procedure

Under the centralized authorization procedure, the European Medicines Agency's ("EMA") Committee for Medicinal Products for Human Use ("CHMP") serves as the scientific committee that renders opinions about the safety, efficacy and quality of medicinal products for human use on behalf of the EMA. The CHMP has 210 days to adopt an opinion as to whether a marketing authorization should be granted. The process usually takes longer in case additional information is requested, which triggers clock-stops in the procedural timelines. The process is complex and involves extensive consultation with the regulatory authorities of EU Member States and a number of experts. When an application is submitted for a marketing authorization in respect of a product that is of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation, the applicant may pursuant to Article 14(9) Regulation (EC) No 726/2004 request an accelerated assessment procedure. If the CHMP accepts such request, the time-limit of 210 days will be reduced to 150 days but it is possible that the CHMP can

revert to the standard time limit for the centralized procedure if it considers that it is no longer appropriate to conduct an accelerated assessment. If the opinion is negative, information is given as to the grounds on which this conclusion was reached. After the adoption of the CHMP opinion, a decision on the MAA must be adopted by the European Commission, after consulting the EU Member States, which in total can take more than 60 days.

Conditional Approval

In specific circumstances, EU legislation (Article 14(7) Regulation (EC) No 726/2004 and Regulation (EC) No 507/2006 on Conditional Marketing Authorizations for Medicinal Products for Human Use) enables applicants to obtain a conditional marketing authorization prior to obtaining the comprehensive clinical data required for an application for a full marketing authorization. Such conditional approvals may be granted for product candidates (including medicines designated as orphan medicinal products) if (1) the risk-benefit balance of the product candidate is positive, (2) it is likely that the applicant will be in a position to provide the required comprehensive clinical trial data, (3) the product fulfills unmet medical needs and (4) the benefit to public health of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data are still required. A conditional marketing authorization may contain specific obligations to be fulfilled by the marketing authorization holder, including obligations with respect to the completion of ongoing or new studies, and with respect to the collection of pharmacovigilance data. Conditional marketing authorizations are valid for one year, and may be renewed annually, if the risk-benefit balance remains positive, and after an assessment of the need for additional or modified conditions and/or specific obligations. The timelines for the centralized procedure described above also apply with respect to the review by the CHMP of applications for a conditional marketing authorization.

Marketing Authorization under Exceptional Circumstances

Under Article 14(8) Regulation (EC) No 726/2004, products for which the applicant can demonstrate that comprehensive data (in line with the requirements laid down in Annex I of Directive 2001/83/EC, as amended) cannot be provided (due to specific reasons foreseen in the legislation) might be eligible for marketing authorization under exceptional circumstances. This type of authorization is reviewed annually to reassess the risk-benefit balance. The fulfillment of any specific procedures/obligations imposed as part of the marketing authorization under exceptional circumstances is aimed at the provision of information on the safe and effective use of the product and will normally not lead to the completion of a full dossier/approval.

Enhanced Pathways

Enhanced pathways including a potential rolling review of clinical data by EMA have become more common as a result of the COVID-19 pandemic, but significant requirements have to be met to benefit from such enhanced or facilitated pathways to approval.

Market Authorizations Granted by Authorities of EU Member States

In general, if the centralized procedure is not followed, there are three alternative procedures as prescribed in Directive 2001/83/EC:

- The decentralized procedure allows applicants to file identical applications to several EU Member States and receive simultaneous national approvals based on the recognition by EU Member States of an assessment by a reference member state.

- The mutual recognition procedure is based on the acceptance by the competent authorities of the EU Member States of the marketing authorization of a medicinal product by the competent authorities of another EU Member State.

- The national procedure is only available for products intended to be authorized in a single EU Member State.

A marketing authorization may be granted only to an applicant established in the EU.

Pediatric Studies

Prior to obtaining a marketing authorization in the EU, applicants have to demonstrate compliance with all measures included in an EMA-approved Pediatric Investigation Plan ("PIP") covering all subsets of the pediatric population, unless the EMA has granted a product-specific waiver, a class waiver, or a deferral for one or more of the measures included in the PIP. The respective requirements for all marketing authorization procedures are set forth in Regulation (EC) No 1901/2006, which is referred to as the Pediatric Regulation. This requirement also applies when a company wants to add a new indication, pharmaceutical form or route of administration for a medicine that is already authorized. The Pediatric Committee of the EMA ("PDCO") may grant deferrals for some medicines, allowing a company to delay development of the medicine in children until there is enough information to demonstrate its effectiveness and safety in adults. The PDCO may also grant waivers when development of a medicine in children is not needed or is not appropriate, such as for diseases that only affect the elderly population.

Before a marketing authorization application can be filed, or an existing marketing authorization can be amended, the EMA determines that companies actually comply with the agreed studies and measures listed in each relevant PIP.

Periods of Authorization and Renewals

A marketing authorization is valid for five years in principle and the marketing authorization may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the competent authority of the authorizing EU Member State. To this end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least six months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization is valid for an unlimited period, unless the European Commission or the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal. Any authorization which is not followed by the actual placing of the product on the EU market (in case of centralized procedure) or on the market of the authorizing EU Member State within three years after authorization ceases to be valid (the so-called sunset clause).

Orphan Designation and Exclusivity

Pursuant to Regulation (EC) No 141/2000 and Regulation (EC) No. 847/2000, the European Commission can grant such orphan medicinal product designation to products for which the sponsor can establish that it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 people in the EU when the application is made, or a life threatening, seriously debilitating or serious and chronic condition in the EU and that without incentives it is unlikely that the product would generate a sufficient return in the EU to justify the necessary investment in its development. In addition, the sponsor must establish that there is no other satisfactory method approved in the EU of diagnosing, preventing or treating the condition, or if such a method exists, the proposed orphan product will be of significant benefit to patients.

Orphan designation is not a marketing authorization. It is a designation that provides a number of benefits, including fee reductions, regulatory assistance, and the possibility to apply for a centralized EU marketing authorization, as well as ten years of market exclusivity following a marketing authorization. During this market exclusivity period, neither the EMA, the European Commission nor the EU Member States can accept an application or grant a marketing authorization for a "similar medicinal product." A "similar medicinal product" is defined as a medicinal product containing a similar active substance or substances as those contained in an authorized orphan medicinal product and that is intended for the same therapeutic indication. The market exclusivity period for the authorized therapeutic indication may be reduced to six years if, at the end of the fifth year, it is established that the orphan designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity. In addition, a competing similar medicinal product may, in limited circumstances, be authorized prior to the expiration of the market exclusivity period, including if it is shown to be safer, more effective or otherwise clinically superior to the already approved orphan product. Furthermore, a product

can lose orphan designation, and the related benefits, prior to obtaining a marketing authorization if it is demonstrated that the orphan designation criteria are no longer met.

Regulatory Data Protection

EU legislation also provides for a system of regulatory data and market exclusivity. According to Article 14(11) of Regulation (EC) No 726/2004, as amended, and Article 10(1) of Directive 2001/83/EC, as amended, upon receiving marketing authorization, new chemical entities approved on the basis of complete and independent data package benefit from eight years of data exclusivity and an additional two years of market exclusivity. Data exclusivity prevents regulatory authorities in the EU from referencing the innovator's data to assess a generic (abbreviated) application. During the additional two-year period of market exclusivity, a generic marketing authorization can be submitted, and the innovator's data may be referenced, but no generic medicinal product can be marketed until the expiration of the market exclusivity. The overall ten-year period will be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder ("MAH") obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. Even if a compound is considered to be a new chemical entity and the innovator is able to gain the period of data exclusivity, another company nevertheless could also market another version of the product if such company obtained marketing authorization based on an MAA with a complete and independent data package of pharmaceutical tests, preclinical tests and clinical trials. However, products designated as orphan medicinal products enjoy, upon receiving marketing authorization, a period of ten years of orphan market exclusivity—see also *Orphan Designation and Exclusivity*. Depending upon the timing and duration of the EU marketing authorization process, products may be eligible for up to five years' supplementary protection certificates ("SPCs") pursuant to Regulation (EC) No 469/2009. Such SPCs extend the rights under the basic patent for the product.

Regulatory Requirements after a Marketing Authorization Has Been Obtained

If we obtain authorization for a medicinal product in the EU, we will be required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products.

Pharmacovigilance and Other Requirements

We will, for example, have to comply with the EU's stringent pharmacovigilance or safety reporting rules, pursuant to which post-authorization studies and additional monitoring obligations can be imposed. Other requirements relate, for example, to the manufacturing of products and APIs in accordance with good manufacturing practice standards. EU regulators may conduct inspections to verify our compliance with applicable requirements, and we will have to continue to expend time, money and effort to remain compliant. Non-compliance with EU requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, can also result in significant financial penalties in the EU. Similarly, failure to comply with the EU's requirements regarding the protection of individual personal data can also lead to significant penalties and sanctions. Individual EU Member States may also impose various sanctions and penalties in case we do not comply with locally applicable requirements.

Manufacturing

The manufacturing of authorized product, for which a separate manufacturer's license is mandatory, must be conducted in strict compliance with the EMA's Good Manufacturing Practices ("GMP") requirements and comparable requirements of other regulatory bodies in the EU, which mandate the methods, facilities and controls used in manufacturing, processing and packing of products to assure their safety and identity. The EMA enforces its current GMP requirements through mandatory registration of facilities and inspections of those facilities. The EMA may have a coordinating role for these inspections while the responsibility for carrying them out rests with the EU Member States competent authority under whose responsibility the manufacturer falls. Failure to comply with these requirements could interrupt supply and result in delays, unanticipated costs and lost revenues, and could subject the applicant to potential legal or regulatory action, including but not limited to warning letters, suspension of manufacturing, seizure of product, injunctive action or possible civil and criminal penalties.

Marketing and Promotion

The marketing and promotion of authorized products, including industry-sponsored continuing medical education and advertising directed toward the prescribers of drugs and/or the general public, are strictly regulated in the EU under Directive 2001/83/EC and EU Member States' national law implementing it. The applicable regulations aim to ensure that information provided by holders of marketing authorizations regarding their products is truthful, balanced and accurately reflects the safety and efficacy claims authorized by the EMA or by the competent authority of the authorizing EU Member State. Failure to comply with these requirements can result in adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties.

Patent Term Extension

In order to compensate the patentee for delays in obtaining a marketing authorization for a patented product, a supplementary protection certificate ("SPC") may be granted extending the exclusivity period for that specific product by up to five years.

A six-month pediatric extension of an SPC may be obtained where the patentee has carried out an agreed pediatric investigation plan, the authorized product information includes information on the results of the studies and the product is authorized in all Member States of the EU. The six-month pediatric extension of SPCs is not available for medicinal products that are designated as orphan medicinal products, as such products benefit from a separate two-year pediatric extension of orphan status and exclusivity. The six-month pediatric extension of SPCs is, however, available for medicinal products which were originally designated as orphan medicinal products but were subsequently (voluntarily) removed from the EU's Register of Orphan Medicinal Products.

The aforementioned EU rules are generally applicable in the European Economic Area which includes the EU Member States, Iceland, Liechtenstein and Norway.

Reform of the Regulatory Framework in the European Union

The European Commission introduced legislative proposals in April 2023 that, if implemented, will replace the current regulatory framework in the EU for all medicines (including those for rare diseases and for children). The European Commission has provided the legislative proposals to the European Parliament and the European Council for their review and approval. In October 2023, the European Parliament published draft reports proposing amendments to the legislative proposals, which will be debated by the European Parliament. Once the European Commission's legislative proposals are approved (with or without amendment), they will be adopted into EU law.

UK Regulation

The UK ceased being a Member State of the EU on January 31, 2020, and the EU and the UK have concluded a trade and cooperation agreement ("TCA"), which was provisionally applicable since January 1, 2021 and has been formally applicable since May 1, 2021. The TCA includes specific provisions concerning pharmaceuticals, which include the mutual recognition of GMP, inspections of manufacturing facilities for medicinal products and GMP documents issued, but does not provide for wholesale mutual recognition of UK and EU pharmaceutical regulations. At present, Great Britain has implemented previous EU legislation on the marketing, promotion and sale of medicinal products through the Human Medicines Regulations 2012 (as amended) (under the Northern Ireland Protocol, the EU regulatory framework currently continues to apply in Northern Ireland). Except in respect of the EU Clinical Trials Regulation, the regulatory regime in Great Britain therefore aligns in many ways with current EU medicines regulations, however it is possible that these regimes will diverge more significantly in the future now that Great Britain's regulatory system is independent from the EU and the TCA does not provide for mutual recognition of UK and EU pharmaceutical legislation. However, notwithstanding that there is no wholesale recognition of EU pharmaceutical legislation under the TCA, under a new international recognition framework mentioned below which was put in place by the MHRA on January 1, 2024, the MHRA may take into account decisions on the approval of marketing authorizations from the EMA (and certain other regulators) when considering an application for a Great Britain or UK marketing authorization.

On February 27, 2023, the UK government and the European Commission announced a political agreement in principle to replace the Northern Ireland Protocol with a new set of arrangements, known as the "Windsor Framework". This new framework fundamentally changes the existing system under the Northern Ireland Protocol, including with respect to the regulation of medicinal products in the UK. In particular, the MHRA will be responsible for approving all medicinal products destined for the UK market (i.e., Great Britain and Northern Ireland), and the EMA will no longer have any role in approving medicinal products destined for Northern Ireland. A single UK-wide marketing authorization will be granted by the MHRA for all medicinal products to be sold in the UK, enabling products to be sold in a single pack and under a single authorization throughout the UK. The Windsor Framework was approved by the EU-UK Joint Committee on March 24, 2023, so the UK government and the EU will enact legislative measures to bring it into law. On June 9, 2023, the MHRA announced that the medicines aspects of the Windsor Framework will apply from January 1, 2025.

Great Britain is no longer covered by the EU's procedures for the grant of marketing authorizations (Northern Ireland is currently covered by the centralized authorization procedure and can be covered as a concerned member state under the decentralized or mutual recognition procedures). A separate marketing authorization will be required to market products in Great Britain. On January 1, 2024, a new international recognition framework was put in place by the MHRA, under which the MHRA may have regard to decisions on the approval of marketing authorizations made by the EMA and certain other regulators. Various national procedures are now available to place a product on the market in the UK, Great Britain, or Northern Ireland. The MHRA offers a 150-day assessment timeline for all high quality applications for a UK, Great Britain or Northern Ireland marketing authorization. The 150 day timeline does not, however, include a "clock-stop" period which may occur if issues arise or points require clarification following an initial assessment of the application. Such issues should be addressed within a 60-day period, although extensions may be granted in exceptional cases.

Foreign Regulation

In addition to regulations in the United States, the European Union and the UK, we will be subject to a variety of other foreign regulations governing clinical trials and commercial sales and distribution of our products. Whether or not we obtain FDA, EMA or MHRA approval for a product, we must obtain approval by the comparable regulatory authorities of other countries or areas before we may commence clinical trials or market products in those countries or areas. The approval process and requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from place to place, and the time may be longer or shorter than that required for FDA, EMA or MHRA approval.

Pharmaceutical Pricing and Reimbursement

Sales of pharmaceutical products depend in significant part on the extent of coverage and reimbursement from government programs, including Medicare and Medicaid in the U.S., and other third party payers. Third party payers are sensitive to the cost of drugs and are increasingly seeking to implement cost containment measures to control, restrict access to, or influence the purchase of drugs, biologicals, and other health care products and services. Governments may regulate reimbursement, pricing, and coverage of products in order to control costs or to affect levels of use of certain products. Payers may restrict coverage of some products due to cost concerns, by various means such as using payer formularies under which only selected drugs are covered, variable co-payments that make drugs that are not preferred by the payer more expensive in terms of higher out-of-pocket expenses for patients, and by employing utilization management controls, such as discouraging patients' use of copay coupons and discount cards and imposing requirements for prior authorization before a prescription can be billed or prior clinical failure on another type of treatment before a new product can be prescribed. Payers may especially impose these obstacles to coverage for higher-priced drugs in order to limit the payer's cost for treatment of the disease. Consequently, any future products may be subject to payer-driven restrictions, rendering patients responsible for a higher percentage of the total cost of drugs in the outpatient setting. This could lower the demand for any future products if the increased patient out-of-pocket cost-sharing obligations are more than they can afford.

Medicare is a U.S. federal government insurance program that covers individuals aged 65 years or older, as well as individuals of any age with certain disabilities, and individuals with End-Stage Renal Disease. The primary Medicare programs that may affect reimbursement for Akari are Medicare Part B, which covers physician services and outpatient care, and Medicare Part D, which provides a voluntary outpatient prescription drug benefit. Medicare

Part B provides limited coverage of certain outpatient drugs and biologicals that are reasonable and necessary for diagnosis or treatment of an illness or injury. Under Medicare Part B, reimbursement for most drugs is based on a fixed percentage above the applicable product's average sales price ("ASP"). Manufacturers calculate ASP based on a statutory formula and must report ASP information on a quarterly basis to the Centers for Medicare and Medicaid Services ("CMS"), the federal agency that administers Medicare and the Medicaid Drug Rebate Program. The current reimbursement rate for drugs and biologicals in both the hospital outpatient department setting and the physician office setting is ASP + 6%. The rate for the physician clinic setting is set by statute, but CMS has the authority to adjust the rate for the hospital outpatient setting on an annual basis. This reimbursement rate may decrease in the future. In both settings, the amount of reimbursement for a product's usage is updated quarterly based on the manufacturer's submission of new ASP information about its product or based on the submission of ASP information of each manufacturer that sells a product for which there are multiple competitors in that product market.

Medicare Part D is a prescription drug benefit available to all Medicare beneficiaries. It is a voluntary benefit that is implemented through private plans under contractual arrangements with the federal government. Similar to pharmaceutical coverage through private health insurance, Part D plans negotiate discounts from drug manufacturers. Medicare Part D coverage is available through private plans, and the list of prescription drugs covered by Part D plans varies by plan. However, individual plans are required by statute to cover certain therapeutic categories and classes of drugs or biologicals and to have at least two drugs in each unique therapeutic category or class, with certain exceptions. As further described below under "U.S. Healthcare Reform and Other U.S. Healthcare Laws," the Inflation Reduction Act of 2022 ("IRA") has made significant changes to the Medicare Part B and Medicare Part D prescription drug benefit are structured.

Beginning April 1, 2013, the Budget Control Act of 2011, Pub. L. No. 112-25, as amended by the American Taxpayer Relief Act of 2012, Pub. L. 112-240, required Medicare payments for all items and services, including drugs and biologicals, to be reduced by 2% under sequestration (i.e., automatic spending reductions). Subsequent legislation extended the 2% reduction, on average, through 2031. This 2% reduction in Medicare payments affects all parts of the Medicare program and could impact any future sales of any future products.

Various states, such as California, have also taken steps to consider and enact laws or regulations that are intended to increase the visibility of the pricing of pharmaceutical products with the goal of reducing the prices at which we are able to sell our products. Because these various actual and proposed legislative changes are intended to operate on a state-by-state level rather than a national one, we cannot predict what the full effect of these legislative activities may be on our business in the future. Medicaid is a government health insurance program for low-income children, families, pregnant women, and people with disabilities. It is jointly funded by the federal and state governments, and it is administered by individual states within parameters established by the federal government. Coverage and reimbursement for drugs and biologics thus varies by state. Drugs and biologics may be covered under the medical or pharmacy benefit. State Medicaid programs may impose utilization management controls, such as prior authorization, step therapy, or quantity limits on drugs and biologics. Medicaid also includes the Medicaid Drug Rebate Program, under which, as a condition of coverage for our future products by the individual state Medicaid programs, we will be required to pay a retrospective rebate to each state Medicaid program for the quarterly utilization of our products by those respective state Medicaid programs we would be required to pay a rebate to each state Medicaid program for quantities of any future products that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available to the states for any future products under Medicaid and Medicare Part B. Those rebates are based on pricing data that would be reported by us on a monthly and quarterly basis to CMS. These data include the average manufacturer price and the best price for each product we sell. As further described below under "U.S. Healthcare Reform and Other U.S. Healthcare Laws," the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the "PPACA") made significant changes to how the Medicaid Drug Rebate Program operates.

Federal law requires that any company that participates in the Medicaid Drug Rebate Program also participate in the Public Health Service's 340B drug discounted pricing program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B pricing program requires participating manufacturers to agree to charge statutorily-defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. These 340B covered entities include a variety of community health clinics

and other entities that receive health services grants from the Public Health Service as well as hospitals that serve a disproportionate share of low-income patients. The 340B ceiling price is calculated using a statutory formula, which is based on the average manufacturer price and rebate amount for the covered outpatient drug as calculated under the Medicaid Drug Rebate Program. Changes to the definition of average manufacturer price and the Medicaid rebate amount under PPACA and CMS's issuance of final regulations implementing those changes also could affect the 340B ceiling price calculation for any future products and could negatively impact our results of operations. As described below under "U.S. Healthcare Reform and Other U.S. Healthcare Laws," PPACA expanded the 340B program to include additional types of covered entities but exempts "orphan drugs" designated under section 526 of the FDCA from the ceiling price requirements for these newly-eligible entities. CMS has also implemented new regulations that further define and further expand which health care provider entities are eligible to purchase approved drugs at the discounted 340B prices.

In order to be eligible to have products paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by certain federal agencies and grantees, manufacturers must participate in the Department of Veterans Affairs Federal Supply Schedule ("FSS") pricing program, established by Section 603 of the Veterans Health Care Act of 1992 ("VHCA"). Under this program, we would be obligated to make our innovator "covered drugs" available for procurement on an FSS contract and charge a price to four federal agencies, Department of Veterans Affairs, Department of Defense, Public Health Service and Coast Guard, the so-called "Big Four" government purchasers, that is no higher than the statutory Federal Ceiling Price ("FCP"). The FCP is based on the non-federal average manufacturer price ("Non-FAMP"), which we would calculate and report to the Department of Veterans Affairs on a quarterly and annual basis. Under the Tricare Retail Pharmacy program, established by Section 703 of the National Defense Authorization Act, participating manufacturers pay quarterly rebates on utilization of innovator products that are dispensed through the Tricare Retail Pharmacy network to Tricare beneficiaries. The rebates are calculated as the difference between Annual Non-FAMP and FCP. The FCP is based on a weighted average Non-FAMP, which manufacturers are required to report on a quarterly and annual basis to the VA. If a company misstates Non-FAMPs or FCPs it must restate these figures and potentially refund to the government purchasers any overcharges that occurred.

Pursuant to the VHCA, knowing provision of false information in connection with a Non-FAMP filing can subject a manufacturer to significant civil monetary penalties for each item of false information.

FSS contracts are federal procurement contracts that include standard government terms and conditions, separate pricing for each product, and extensive disclosure and certification requirements. All items on FSS contracts are subject to a standard FSS contract clause that requires FSS contract price reductions under certain circumstances where pricing is reduced to an agreed "tracking customer." Further, in addition to the "Big Four" agencies, all other federal agencies and some non-federal entities are authorized to access FSS contracts. FSS contractors are permitted to charge FSS purchasers other than the Big Four agencies "negotiated pricing" for covered drugs that is not capped by the FCP; instead, such pricing is negotiated based on a mandatory disclosure of the contractor's commercial "most favored customer" pricing.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. Moreover, the requirements governing drug pricing and reimbursement vary widely from country to country. For example, in the EU, the national authorities of the individual EU Member States are free to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices and/or reimbursement of medicinal products for human use. Some individual EU Member States adopt policies according to which a specific price or level of reimbursement is approved for the medicinal product. Other EU Member States adopt a system of reference pricing, basing the price or reimbursement level in their territory either, on the pricing and reimbursement levels in other countries, or on the pricing and reimbursement levels of medicinal products intended for the same therapeutic indication. Some EU Member States may require the completion of additional studies that compare the cost effectiveness of a particular product candidate to currently available therapies (so called health technology assessments) in order to obtain reimbursement or pricing approval. Furthermore, some EU Member States impose direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our product candidates. Historically, products launched in the EU do not follow price structures of the U.S. and generally prices tend to be significantly lower.

U.S. Healthcare Reform and Other U.S. Healthcare Laws

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal healthcare laws, including those commonly referred to as "fraud and abuse" laws have been applied in recent years to restrict certain marketing practices in the pharmaceutical industry. These laws may impact, among other things, our proposed sales, marketing and education programs. In addition, we may be subject to patient privacy regulation by both the U.S. federal government and the states in which we conduct our business. The laws that may affect our ability to operate include the following:

- The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully soliciting, offering, receiving, or paying any remuneration, directly or indirectly, in cash or in kind, to induce or reward purchasing, ordering or arranging for or recommending the purchase or order of any item or service for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. Liability may be established without a person or entity having actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it. This statute has been interpreted to apply broadly to arrangements between pharmaceutical manufacturers on the one hand and prescribers, patients, purchasers and formulary managers on the other. In addition, PPACA amended the Social Security Act to provide that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. A conviction for violation of the Anti-Kickback Statute requires mandatory exclusion from participation in federal health care programs. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and those activities may be subject to scrutiny or penalty if they do not qualify for an exemption or safe harbor.

- The federal civil False Claims Act ("FCA") prohibits, among other things, knowingly presenting, or causing to be presented claims for payment of government funds that are false or fraudulent, or knowingly making, using or causing to be made or used a false record or statement material to such a false or fraudulent claim, or knowingly concealing or knowingly and improperly avoiding, decreasing, or concealing an obligation to pay money to the federal government. This statute 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. The FCA prohibits anyone from knowingly presenting, conspiring to present, making a false statement in order to present, or causing to be presented, for payment to federal programs (including Medicare and Medicaid) claims for items or services, including drugs, that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. This law also prohibits anyone from knowingly underpaying an obligation owed to a federal program. Increasingly, U.S. federal agencies are requiring nonmonetary remedial measures, such as corporate integrity agreements in FCA settlements. FCA liability is potentially significant in the healthcare industry because the statute provides for treble damages and mandatory penalties of $13,946 to $27,894 per false claim or statement for penalties assessed after January 15, 2024. 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; among other reasons.

- The federal False Statements Statute prohibits knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry, in connection with the delivery of or payment for healthcare benefits, items, or services.

- The federal Civil Monetary Penalties Law authorizes the imposition of substantial civil monetary penalties against an entity, such as a pharmaceutical manufacturer, that engages in activities including,

among others (1) knowingly presenting, or causing to be presented, a claim for services not provided as claimed or that is otherwise false or fraudulent in any way; (2) arranging for or contracting with an individual or entity that is excluded from participation in federal healthcare programs to provide items or services reimbursable by a federal healthcare program; (3) violations of the federal Anti-Kickback Statute; or (4) failing to report and return a known overpayment.

- The federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") imposes criminal and civil liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of, or payment for, healthcare benefits, items or services; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

- The majority of states also have statutes similar to the federal anti-kickback law and false claims laws that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, that apply regardless of whether the payer is a government entity or a private commercial entity.

- The federal Open Payments (Physician Payments Sunshine Act) program requires manufacturers of products for which payment is available under Medicare, Medicaid or the State Children's Health Insurance Program, to track and report annually to the federal government (for disclosure to the public) certain payments and other transfers of value made to physicians and other licensed practitioners (such as nurse practitioners, certified nurse anesthetists, physician assistants, and others) as well as teaching hospitals and ownership and investment interests held by physicians and their immediate family members. In addition, several U.S. states and localities have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, file periodic reports with the state, and/or make periodic public disclosures on sales, marketing, pricing, clinical trials, and other activities. Other state laws prohibit certain marketing-related activities including the provision of gifts, meals or other items to certain healthcare providers. Many of these laws and regulations contain ambiguous requirements that government officials have not yet clarified. Given the lack of clarity in the laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent federal and state laws and regulations.

- Federal price reporting laws require manufacturers to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/or discounts on approved products.

- Federal consumer protection and unfair competition laws broadly regulate marketplace activities and activities that potentially harm consumers.

Sanctions under these federal and state healthcare laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, monetary damages, criminal fines, disgorgement, additional reporting obligations and oversight if the manufacture becomes subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and individual imprisonment.

Federal and state authorities are continuing to devote significant attention and resources to enforcement of fraud and abuse laws within the pharmaceutical industry, and private individuals have been active in alleging violations of the law and bringing suits on behalf of the government under the FCA. For example, federal enforcement agencies recently have investigated certain pharmaceutical companies' product and patient assistance programs, including manufacturer reimbursement support services, relationships with specialty pharmacies, and grants to independent charitable foundations.

The PPACA was adopted in the U.S. in March 2010. This law substantially changes the way healthcare is financed by both governmental and private insurers in the U.S., and significantly impacts the pharmaceutical industry. PPACA contains a number of provisions that are expected to impact our business and operations. Changes that may affect our business include those governing enrollment in federal healthcare programs, reimbursement changes, rules

regarding prescription drug benefits under the health insurance exchanges, expansion of the 340B program, expansion of state Medicaid programs, and fraud and abuse and enforcement. These changes will impact existing government healthcare programs and will result in the development of new programs, including Medicare payment for performance initiatives and improvements to the physician quality reporting system and feedback program.

PPACA contains several provisions that have or could potentially impact our business. PPACA made significant changes to the Medicaid Drug Rebate Program. For example, under PPACA, rebate liability expanded from fee-for-service Medicaid utilization to include the utilization of Medicaid managed care organizations as well. With regard to the amount of the rebates owed, PPACA increased the minimum Medicaid rebate from 15.1% to 23.1% of the average manufacturer price for most innovator products; extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations; changed the calculation of the rebate for certain innovator products that qualify as line extensions of existing drugs; and capped the total rebate amount for innovator drugs at 100% of the average manufacturer price. In addition, PPACA and subsequent legislation changed the definition of average manufacturer price; subjected manufacturers to new annual fees and taxes for certain branded prescription drugs; created the Medicare Part D coverage gap discount program, in which manufacturers must agree to 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; and provided incentives to programs that increase the federal government's comparative effectiveness research.

PPACA requires pharmaceutical manufacturers of branded prescription drugs to pay a branded prescription drug fee to the federal government. Generally, a fee is imposed by the IRS on each manufacturer or importer of branded prescription drug sales of over $5 million to specific government programs, such as Medicare and Medicaid. Sales of "orphan drugs" are excluded from this fee. "Orphan drugs" are specifically defined for purposes of the fee. For each indication approved by the FDA for the drug, such indication must have been designated as orphan by the FDA under section 526 of the FDCA, an orphan drug tax credit under section 45C of the Internal Revenue Code must have been claimed with respect to such indication, and such tax credit must not have been disallowed by the IRS. Finally, the FDA must not have approved the drug for any indication other than an orphan indication for which a section 45C orphan drug tax credit was claimed (and not disallowed).

Additional provisions of PPACA may negatively affect manufacturer's revenues in the future. For example, PPACA created the Medicare Part D coverage gap discount program, which manufacturers of branded prescription drugs are required to provide a 50% discount (extended by subsequent legislation to 70%) on branded prescription drugs at the point-of-sale dispensed to beneficiaries when they are in the coverage gap for out-of-pocket spending (commonly known as the "donut hole").

PPACA also expanded the Public Health Service's 340B drug pricing discount program. The 340B pricing program requires participating manufacturers to agree to charge statutorily-defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. PPACA expanded the 340B program to include additional types of covered entities: certain free-standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals, each as defined by PPACA. PPACA exempts "orphan drugs" designated under section 526 of the FDCA, from the ceiling price requirements for these newly-eligible entities.

In addition to PPACA, the Inflation Reduction Act of 2022 ("IRA") includes several provisions that may impact our business to varying degrees, including provisions that reduce the out-of-pocket spending cap for Medicare Part D beneficiaries from $7,050 to $2,000 starting in 2025, thereby effectively eliminating the coverage gap; impose new manufacturer financial liability on certain drugs under Medicare Part D, allow the U.S. government to negotiate Medicare Part B and Part D price caps for certain high-cost drugs and biologics without generic or biosimilar competition; require companies to pay rebates to Medicare for certain drug prices that increase faster than inflation; and delay until January 1, 2032 the implementation of the HHS rebate rule that would have limited the fees that pharmacy benefit managers can charge. Further, under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one orphan designation and for which the only approved indication is for that disease or condition. If a product receives multiple orphan designations or has multiple approved indications, it may not qualify for the orphan drug exemption. The implementation of the IRA is currently subject to ongoing litigation that challenges the constitutionality of the IRA's Medicare drug price negotiation program. The effects of the IRA on our business and the healthcare industry in general is not yet known.

Finally, numerous federal and state laws, including state security breach notification laws, state health information privacy laws, and federal and state consumer protection laws govern the collection, use, and disclosure of personal information. In addition, most healthcare providers and research institutions with whom we collaborate are subject to privacy and security requirements under HIPAA, as amended by HITECH, and its implementing regulations. Although we are currently neither a "covered entity" nor a "business associate" under HIPAA, and these privacy and security requirements do not apply to us, the regulations may affect our interactions with healthcare providers, health plans, and research institutions from whom we obtain patient health information. Further, we could be subject to criminal penalties if we knowingly obtain individually identifiable health information from a HIPAA covered entity in a manner that is not authorized or permitted by HIPAA or for aiding and abetting the violation of HIPAA.

There is significant interest in the United States in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access, including increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices, particularly with respect to drugs that have been subject to relatively large price increases over relatively short time periods. There have been several recent U.S. Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing and reform government program reimbursement methodologies for drugs. Although multiple efforts to repeal or replace portions of the PPACA have been introduced, and multiple judicial challenges to the PPACA have also been attempted. Further, Executive Orders relating to the regulation of prescription drug pricing have also been introduced over time. We cannot predict the scope or impact of future legislative, judicial, or executive efforts to reform healthcare in the United States.

Other Regulations

We are also subject to the U.S. Foreign Corrupt Practices Act ("FCPA"), the U.K. Bribery Act ("Bribery Act"), and other anticorruption laws and regulations pertaining to our financial relationships with foreign government officials. The FCPA prohibits U.S. companies and their representatives from paying, offering to pay, promising, or authorizing the payment of anything of value to any foreign government official, government staff member, political party, or political candidate to obtain or retain business or to otherwise seek favorable treatment. In many countries in which we operate, the healthcare professionals with whom we interact may be deemed to be foreign government officials for purposes of the FCPA. The Bribery Act, which applies to any company incorporated or doing business in the UK, prohibits giving, offering, or promising bribes in the public and private sectors, bribing a foreign public official or private person, and failing to have adequate procedures to prevent bribery amongst employees and other agents. Penalties under the Bribery Act include potentially unlimited fines for companies and criminal sanctions for corporate officers under certain circumstances. Liability in relation to breaches of the Bribery Act is strict. This means that it is not necessary to demonstrate elements of a corrupt state of mind.

Recent years have seen a substantial increase in anti-bribery law enforcement activity by U.S. regulators, with more frequent and aggressive investigations and enforcement proceedings by both the DOJ and the SEC, increased enforcement activity by non-U.S. regulators, and increases in criminal and civil proceedings brought against companies and individuals. Increasing regulatory scrutiny of the promotional activities of pharmaceutical companies also has been observed in a number of EU member states. In Germany, a specific anti-corruption provision with regard to healthcare professionals was introduced in the Criminal Code in 2017.

Similar strict restrictions are imposed on the promotion and marketing of products in the EU, where a large portion of our non-U.S. business is conducted, and other territories. Laws in the EU, including in the individual EU Member States, require promotional materials and advertising for products to comply with the product's Summary of Product Characteristics ("SmPC"), which is approved by the competent authorities. Promotion of a medicinal product which does not comply with the SmPC is considered to constitute off-label promotion. The off-label promotion of medicinal products is prohibited in the EU and in other territories. The promotion of medicinal products that are not subject to a marketing authorization is also prohibited in the EU. Laws in the EU, including in the individual EU Member States, also prohibit the direct-to-consumer advertising of prescription-only medicinal products. Violations of the rules governing the promotion of medicinal products in the EU and in other territories could be penalized by administrative measures, fines and imprisonment. Furthermore, illegal advertising can be challenged by competitors, and as a result, can be prohibited by court and the responsible company can be obligated to pay damages to the competitor.

Interactions between pharmaceutical companies and physicians are also governed by strict laws, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct in the individual EU Member States. The provision of any inducements to physicians to prescribe, recommend, endorse, order, purchase, supply, use or administer a medicinal product is prohibited. A number of EU Member States have introduced additional rules requiring pharmaceutical companies to publicly disclose their interactions with physicians and to obtain approval from employers, professional organizations and/or competent authorities before entering into agreements with physicians. These rules have been supplemented by provisions of related industry codes, including the EFPIA Disclosure Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organizations and related codes developed at national level in individual EU Member States. Additional countries may consider or implement similar laws and regulations. Violations of these rules could lead to reputational risk, public reprimands, and/or the imposition of fines or imprisonment. Our present and future business has been and will continue to be subject to various other laws and regulations. Laws, regulations and recommendations relating to safe working conditions, laboratory practices, the experimental use of animals, and the purchase, storage, movement, import and export and use and disposal of hazardous or potentially hazardous substances, including radioactive compounds, used in connection with our research work are or may be applicable to our activities. We cannot predict the impact of government regulation, which may result from future legislation or administrative action, on our business.

Employees and Human Capital Resources

Our mission is to deliver advanced therapies to improve the lives of patients and families battling autoimmune and inflammatory diseases. Accordingly, we are a team who is passionate about and committed to our mission and establishing a culture where patients and their families are at the center of all we do, with core values that connect us to each other and our stakeholders, and define who we are, what we stand for, and how we work.

As of March 15, 2024, we had 12 employees, nine of which are full-time, including our Chief Executive Officer, Rachelle Jacques, our Chief Scientific Officer, Miles Nunn, Ph.D., our Chief Medical Officer, John Neylan III, M.D., our Chief Operating Officer, Melissa Bradford-Klug, and eight other individuals, five of whom are engaged in research and development. None of our employees are represented by labor unions or covered by collective bargaining agreements, and we consider our relationship with employees to be good. We also utilize the services of several independent consultants to support our research and development and general and administrative operations, including our Interim CFO, Wendy DiCicco.

We are focused on effective identification, recruitment, development, and retention of, and compensation and benefits to, human resource talent, including workforce and management development, diversity and inclusion initiatives, succession planning, and corporate culture and leadership quality, which are vital to our success. The principal purposes of our equity incentive plans are to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards and cash-based performance bonus awards.

Corporate Information

We were originally established as a private limited company under the laws of England and Wales on October 7, 2004 under the name Freshname No. 333 Limited. On January 19, 2005, we changed our name to Morria Biopharmaceuticals Limited and on February 3, 2005, we completed a reverse merger with Morria Biopharmaceuticals Inc., or Morria, a Delaware corporation, in which Morria became our wholly-owned subsidiary and we re-registered as a non-traded public limited company under the laws of England and Wales. On March 22, 2011, we incorporated an Israeli subsidiary, Morria Biopharma Ltd. On June 25, 2013, we changed our name to Celsus Therapeutics Plc and on October 13, 2013 Morria was renamed Celsus Therapeutics Inc. On September 18, 2015, we completed an acquisition of all of the capital stock of Volution Immuno Pharmaceuticals SA ("Volution"), a private Swiss company, from RPC Pharma Limited ("RPC"), Volution's sole shareholder, in exchange for our ordinary shares, in accordance with the terms of a Share Exchange Agreement, dated as of July 10, 2015. In connection with the acquisition, our name was changed to Akari Therapeutics, Plc. As such, our affairs are governed by our Articles of Association and the English law.

Our principal UK office is located at 75/76 Wimpole Street, London W1G 9RT, United Kingdom, and our telephone number is +44 20 8004 0270. Puglisi & Associates ("Puglisi") serves as our agent for service of process in the United States. Puglisi's address is 850 Library Avenue, Suite 204, Newark, Delaware 1971.

Our principal U.S. office is located at 22 Boston Wharf Road FL 7, Boston, Massachusetts 02210, and our telephone number is (929) 274-7510. Celsus Therapeutics, Inc. serves as our agent for service of process in the United States.

Information Available on the Internet

We use our website (www.akaritx.com), LinkedIn (https://www.linkedin.com/company/akaritx/) and Twitter (https://twitter.com/AkariTX) as distribution channels for Company information. The information contained on, or that can be accessed through our website, LinkedIn or Twitter, which may be deemed material, is not part of this Annual Report on Form 10-K and such internet addresses are included in this document solely as inactive textual references. We make available free of charge through our website our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and exhibits and amendments to these reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we electronically file or furnish such materials to the SEC. The SEC maintains an internet site at www.sec.gov containing reports, proxies and information statements and other information regarding issuers that file electronically with the SEC.

Item 1A. Risk Factors.

Investing in our securities involves a high degree of risk. You should carefully consider the risks and uncertainties described below in addition to the other information included or incorporated by reference in this Form 10-K before purchasing our American Depository Shares. Our business, financial condition and results of operations could be materially and adversely affected by any of these and currently unknown risks or uncertainties. In that case, the market price of our American Depository Shares could decline, and you may lose all or part of your investment in our securities.

Risks Relating to Our Financial Position and Our Business

We have a history of operating losses and cannot give assurance of future revenues or operating profits; investors may lose their entire investment.

We do not expect to generate revenue or profitability that is necessary to finance our operations in the short term. We incurred net losses of $10.0 million and $17.7 million for the years ended December 31, 2023 and 2022, respectively. In addition, our accumulated deficit as of December 31, 2023 and 2022 was $227.5 million and $217.5 million, respectively. Losses have principally resulted from costs incurred for manufacturing, clinical trial and preclinical activities and general and administrative expenses. We have funded our operations primarily through the private placement and public offering of equity securities.

To date, we have not commercialized any products or generated any revenues from the sale of products, and absent the realization of sufficient revenues from product sales, we may never attain profitability in the future. We expect to incur significant losses for the foreseeable future as we continue to conduct research and development, clinical testing, regulatory compliance activities and, if nomacopan or other future product candidates receive marketing authorization, sales and marketing activities.

Our failure to become and remain profitable could depress the market price of the ADS representing our ordinary shares, and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations. If we continue to suffer losses as we have in the past, investors may not receive any return on their investment and may lose their entire investment.

Our auditor's report on our consolidated financial statements states that our recurring operating losses, negative cash flows and dependence on additional financial support raises substantial doubt about our ability to continue as a going concern, which may have a detrimental effect on our ability to obtain additional funding.

The report of our U.S. independent registered public accounting firm on our consolidated financial statements for the period ended December 31, 2023, includes an explanatory paragraph raising substantial doubt about our ability to continue as a going concern as a result of our recurring losses from operations and net capital deficiency. Our future is dependent upon our ability to obtain financing in the future. This opinion could materially limit our ability to raise funds. If we fail to raise sufficient capital when needed, we will not be able to complete our business plan. As a result, we may have to liquidate our business and investors may lose their investment in our ADSs.

We will require additional capital to fund our operations, and if we are unable to obtain such capital, we will be unable to successfully develop and commercialize any product candidates.

As of December 31, 2023, we had cash of approximately $3.8 million. We believe we do not have sufficient funds to fund our operations for the next twelve months as of the filing of this Annual Report on Form 10-K. We will require additional capital in order to develop and commercialize our current product candidates or any product candidates that we acquire, if any. There is no assurance that additional funds will be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available on a timely basis, we may be required to terminate or delay development for one or more of our product candidates, which raises substantial

doubt about our ability to continue as a going concern. The report from our U.S. independent registered public accounting firm for our consolidated financial statements for the year ended December 31, 2023 included an emphasis of matter paragraph expressing substantial doubt about our ability to continue as a going concern. The inclusion of this going concern emphasis of matter paragraph could materially limit our ability to raise additional funds through the issuance of equity or debt securities or otherwise.

The amount and timing of any expenditure needed will depend on numerous factors, some of which are outside our control, including:

- the type, number, scope, progress, expansion costs, results of and timing of our ongoing or future clinical trials or the need for additional clinical trials of nomacopan in HSCT-TMA, GA, or any other indications or product candidates which we are pursuing or may choose to pursue in the future;
- the costs of obtaining, maintaining and enforcing our patents and other intellectual property rights;
- the costs and timing of obtaining or maintaining manufacturing for nomacopan for HSCT-TMA, GA, or any other indications or product candidates, including commercial manufacturing if any product candidate is approved;
- the costs and timing of establishing sales, marketing, and reimbursement capabilities;
- the costs and timing of enhanced internal controls over financial reporting;
- the terms and timing of establishing and maintaining collaborations, license agreements and other partnerships;
- costs associated with any new product candidates that we may develop, in-license or acquire;
- the effect of competing technological and market developments; and
- the costs associated with being a public company

We have not sold any products, and we do not expect to sell or derive revenue from any product sales for the foreseeable future. We may seek additional funding through future debt and equity financing, as well as potential additional collaborations or strategic partnerships with other companies or through non-dilutive financings. Additional funding may not be available to us on acceptable terms or at all. General market conditions may make it difficult for us to seek financing from the capital markets. We may be required to relinquish rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us, in order to raise additional funds through alliance, joint venture or licensing arrangements. In addition, the terms of any financing may adversely affect the holdings or the rights of our shareholders and the issuance of additional shares by us, or the possibility of such issuance, may cause the market price of our shares to decline.

If we are unable to obtain funding on a timely basis, we will be delayed or unable to complete ongoing and planned clinical trials for nomacopan and we may be required to significantly curtail some or all of our activities. We also could be required to seek funds through arrangements with collaborative partners or otherwise that may require us to relinquish rights to our product candidates or some of our technologies or otherwise agree to terms unfavorable to us.

Future sales and issuances of the ADSs or rights to purchase ADSs and any equity financing that we pursue, could result in significant dilution of the percentage ownership of our shareholders and could cause our ADS price to fall.

We will need to raise additional capital. In any financing transaction, we may sell ordinary shares or ADSs, convertible securities or other equity securities. To the extent that we raised additional funds by issuing equity securities, our shareholders may experience significant dilution. To the extent that we raise additional capital

through the sale of equity or convertible debt securities by any other means, existing ownership interests will be diluted. The sale of a substantial number of ADSs, or anticipation of such sales, could cause the trading price of our ADSs to decline or make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise desire.

Risks Related to the Clinical Development and Marketing Authorization of Our Product Candidates

Our business depends on the success of nomacopan, which is still under development. If we are unable to obtain marketing authorization for or successfully commercialize nomacopan, our business could be materially harmed.

Nomacopan has been the primary focus of our product development. Successful continued development and ultimate marketing authorization of nomacopan for at least one indication is critical to the future success of our business. We have invested, and will continue to invest, a significant portion of our time and financial resources in the development of nomacopan. We will need to raise sufficient funds for, and successfully enroll and complete, our ongoing clinical development programs for nomacopan and for our planned clinical development programs for nomacopan in other indications. The future regulatory and commercial success of this product candidate is subject to a number of risks, including the following:

- we may not have sufficient financial and other resources to complete the necessary clinical trials for nomacopan;
- we may not be able to obtain adequate evidence of efficacy and safety for nomacopan;
- we do not know the degree to which nomacopan will be adopted by the market, even if approved;
- in our clinical programs, we may experience difficulty in enrollment, adjustments to clinical trial protocols or the need for additional clinical trial sites, which could delay our clinical trial progress;
- our reliance on a sole manufacturer to supply drug substance and a sole manufacturer to provide drug product formulation of nomacopan that is being used in our clinical trials may negatively impact the availability of our drug product;
- we may encounter disruptions in the supply chain of nomacopan which could negatively impact our ability to supply our drug product to clinical trial sites, delaying clinical studies;
- the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA, MHRA, EMA or comparable foreign regulatory bodies for marketing approval;
- patients in our clinical trials may die or suffer other adverse effects for reasons that may or may not be related to nomacopan, which could delay or prevent further clinical development;
- the standards implemented by clinical or regulatory agencies may change at any time;
- the FDA, MHRA, EMA or comparable foreign regulatory agencies may require efficacy endpoints for a clinical trial that differ from the endpoints of our current or future trials, which may require us to conduct additional clinical trials;
- the mechanism of action of nomacopan is complex and we do not know the degree to which it will translate into a medical benefit in certain indications; and
- we may not be able to obtain, maintain or enforce our patents and other intellectual property rights.

Of the large number of drugs in development in the pharmaceutical industry, only a small percentage results in the submission of a new drug application ("NDA"), or biologics license application ("BLA") to the FDA, or a marketing authorization application ("MAA") to the EMA and even fewer are approved for commercialization. Furthermore, even if we do receive marketing authorization to market nomacopan, any such approval may be

subject to limitations on the indicated uses or patient populations for which we may market the product. Accordingly, even if we are able to obtain the requisite financing to continue to fund our development programs, we cannot assure that nomacopan will be successfully developed or commercialized. If we or any of our future development partners are unable to develop, or obtain marketing authorization for, or, if approved, successfully commercialize nomacopan, we may not be able to achieve forecasted revenues.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We may not be able to initiate or continue clinical trials required by the FDA, MHRA, EMA or other foreign regulatory agencies for nomacopan if we are unable to locate and enroll a sufficient number of eligible patients to participate in these clinical trials. We will be required to identify and enroll a sufficient number of patients with HSCT-TMA and other diseases for each of our ongoing and planned clinical trials of nomacopan in these indications. To date, we have experienced delays in enrollment of patients in our clinical trials and supply chain issues due in particular to the COVID-19 pandemic for certain of our past clinical trials, including, without limitation, in our discontinued bullous pemphigoid ("BP") clinical program, and, in the case of enrollment delays, the fact that we are targeting a small patient population with a rare disease or indication.

Patient enrollment is affected by other factors, including:

- design of the clinical trial protocol;
- size and nature of the patient population;
- eligibility criteria for the trial;
- perceived risks and benefits of the product candidate under trial;
- proximity and availability of clinical trial sites for prospective patients;
- availability of competing therapies and clinical trials;
- actual or threatened public health emergencies and outbreaks of disease (such as the COVID-19 pandemic);
- clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating;
- efforts to facilitate timely enrollment in clinical trials;
- number of specialist physicians that treat patients with these diseases;
- ability to identify and enroll such patients with a stage of disease appropriate for our ongoing or future clinical trials;
- the costs of finding and diagnosing patients;
- patient referral practices of physicians; and
- our ability to monitor patients adequately during and after treatment.

Our inability to enroll a sufficient number of patients for any of our clinical trials would result in significant delays or may require us to abandon one or more clinical trials.

If clinical trials or marketing authorization processes for nomacopan are prolonged, delayed or suspended, we may be unable to commercialize nomacopan on a timely basis.

We cannot predict whether we will encounter problems with any of our completed, ongoing or planned clinical trials that will cause us, an IRB, or any regulatory authority, to delay or suspend those clinical trials and may negatively impact our ability to obtain marketing authorization for, and to market and sell, a particular product candidate, including:

- conditions imposed on us by the FDA, MHRA, EMA or another foreign regulatory authority regarding the scope or design of our clinical trials;
- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- inspection of the clinical trial operations or trial site by the one or more regulatory authorities resulting in the imposition of a clinical hold;
- failure to demonstrate clinical benefit;
- changes in governmental regulations or administrative actions;
- lack of adequate funding to continue or complete the clinical trial;
- delays in reaching, or filing to reach, agreement on acceptable terms with prospective trial sites and prospective clinical research organizations ("CROs"), the terms of which can be extensively negotiated and may vary significant among different CROs and trial sites;
- insufficient supply of our product candidates or other materials necessary to conduct and complete our clinical trials;
- slow enrollment and retention rate of subjects in our clinical trials; and
- serious or unexpected drug-related side effects related to the product candidate being tested, including side effects that lead one or more regulatory authorities to impose a clinical hold.

Commercialization may be delayed by the imposition of additional conditions on our clinical trials by the FDA, MHRA, EMA or any other applicable foreign regulatory authority or the requirement of additional supportive studies by the FDA, MHRA, EMA or such foreign regulatory authority.

Public health epidemics or outbreaks could adversely impact our business as a result of disruptions, such as travel bans, quarantines, staffing shortages, and interruptions to access the trial sites and supply chains, which could result in material delays and complications with respect to our research and development programs and clinical trials.

We may not receive a Priority Review Voucher ("PRV") in connection with the approval of nomacopan for the treatment of HSCT-TMA, which would permit priority review for a subsequent marketing application for a different product or may be sold to a third party.

In November 2022, the FDA granted the Rare Pediatric Disease Designation to nomacopan for the treatment of pediatric HSCT-TMA. The FDA Rare Pediatric Disease Designation and Voucher Program recognizes the unmet need for approved treatments in rare pediatric diseases and is intended to encourage development of these treatments. Under this program, a sponsor who receives an approval of an NDA or BLA for a rare pediatric disease may be eligible for a PRV, which is received concurrently with marketing approval. A PRV is valuable because it can be redeemed to obtain priority review for a subsequent marketing application for a different product or may be sold to a third party. However, there can be no assurance that we will receive marketing approval for nomacopan for

the treatment of HSCT-TMA, and thereby receive a PRV that permits priority review of other product candidates, or if the PRV program will still exist at such time. The authority for the FDA to award rare pediatric disease PRVs is currently limited to drugs or biologics that receive Rare Pediatric Disease designation on or prior to September 30, 2024, and the FDA may only award such PRVs through September 30, 2026. Therefore if an application for nomacopan for HSCT-TMA is not approved on or prior to September 30, 2026, it will not be eligible for a PRV. However, it is possible the authority for the FDA to award rare pediatric disease PRVs will be further extended by Congress.

The efficacy of nomacopan may not be known until advanced stages of testing, after we have incurred significant product development costs which may not be recoverable.

Nomacopan may fail to show the desired safety and efficacy at any phase in the clinical development programs. Encouraging efficacy results in animal models of the target indication are no guarantee of success in human clinical trials. Often there is no adequate animal model of a human disease. If nomacopan does not demonstrate adequate efficacy, its development may be delayed or terminated, which could have a material adverse effect on our financial condition and results of operation.

Results of earlier preclinical studies or clinical trials may not be predictive of advancement to the next phase of development.

Completion of preclinical studies or clinical trials does not guarantee that we will initiate additional studies or trials for our product candidates. If further studies or trials are initiated, earlier preclinical studies or clinical trials may not predict the scope and phase of further trials, that these further studies or trials will be completed, or that if these further studies or trials are completed, that the design or results will provide a sufficient basis to apply for or receive marketing authorizations or to commercialize products. Results of clinical trials could be inconclusive, requiring additional or repeat trials. Data obtained from preclinical studies and clinical trials is subject to varying interpretations that could delay, limit or prevent marketing authorization. If the results achieved in our clinical trials are insufficient to proceed to further trials or to marketing authorization of our product candidates, we could be materially adversely affected. Failure of a clinical trial to achieve its pre-specified primary endpoint generally may require us to undertake additional studies or trials if we determine to continue development of the product candidate, may reduce the timely development of and marketing authorization to market the product candidate, and may decrease the chances for successfully achieving the primary endpoint in scientifically similar indications.

Interim, initial, or preliminary results from our clinical trials that we announce or publish from time to time may change (e.g. from positive safety or efficacy results to poor or negative safety or efficacy results) as more patient data become available and are subject to additional audit, validation and verification procedures that could result in material changes in the final data.

From time to time, we may publish or present interim, initial, or preliminary data, including interim top-line results or initial or preliminary results from our clinical trials. Any interim, initial or preliminary data and other results from our clinical trials may materially change as more patient data become available. Preliminary, initial, interim or top-line results also remain subject to audit, validation and verification procedures that may result in the final data being materially different from the interim, initial or preliminary data we previously published. As a result, interim, initial or preliminary data may not be predictive of final results and should be viewed with caution until the final data are available. We may also arrive at different conclusions, or considerations may qualify such results, once we have received and fully evaluated additional data. Differences between preliminary, initial or interim data and final data could adversely affect our business.

There is a high failure rate for drugs and biologics proceeding through clinical trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical development even after achieving promising results in earlier studies, and we cannot be certain that we will not face similar setbacks. Many drugs have failed to replicate efficacy and safety results in larger or more complex later stage trials. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain regulatory approval. If we fail to produce positive results in our ongoing and planned preclinical studies and clinical trials, the development timeline and regulatory approval and

commercialization prospects for our product candidates, and, correspondingly, our business and financial prospects, may be materially adversely affected.

Long-term animal toxicity and long-term human safety studies of nomacopan could demonstrate that the administration of nomacopan results in serious adverse events.

While we have conducted toxicity studies evaluating nomacopan in certain animals with no observed adverse effect at the highest dose tested, we intend to conduct further long-term animal toxicity studies, including reproductive and carcinogenicity studies, and will continue to collect safety data from ongoing and future clinical studies. Such studies may show that nomacopan results in serious adverse events or other adverse events. If animal toxicity and human safety studies do not yield favorable results, we may be required to abandon our development of nomacopan, which could have a material adverse effect on our financial condition, including our ability to generate forecasted revenues.

Chronic dosing of patients with nomacopan could lead to an immune response that causes adverse reactions or impairs the activity of the drug.

There is a risk that chronic dosing of patients with nomacopan may lead to an immune response that causes adverse reactions or impairs the activity of the drug. Patients may develop an allergic reaction to the drug and/or develop antibodies directed at the drug. Impaired drug activity could be caused by neutralization of the drug's inhibitory activity or by an increased rate of clearance of the drug from circulation.

One potential side effect of nomacopan that has occurred in patients receiving currently marketed C5 inhibitors and C3 inhibitors is an increased incidence of meningitis. As a result, we expect that patients receiving nomacopan may also require meningitis immunization and prophylactic antibiotics.

Nomacopan has a secondary binding site that sequesters leukotriene B4 ("LTB4"). LTB4 synthesis from arachidonic acid can be induced by a variety of triggers including terminal complement activation. LTB4 is a pro-inflammatory mediator that attracts and activates white blood cells at the area of inflammation. LTB4 inhibition may lead to positive anti-inflammatory benefits, but like other drugs with immune modulating properties may increase the risk of infection. However, a particular risk of infection associated with inhibition of LTB4 has not been identified and the only marketed drug which inhibits leukotrienes including LTB4, does not carry a warning of elevated infection risk on its label.

Any immune response that causes adverse reactions or impairs the activity of the drug could cause a delay in or termination of our development of nomacopan, which would have a material adverse effect on our financial condition and results of operation.

If nomacopan is not convenient for patients to use, then we might be prevented from successful commercialization.

Nomacopan may require cold storage prior to use and will likely require self-injection for certain indications. If the drug product is not stable at temperatures of between four and eight degrees Celsius, then the drug product may need to be defrosted before use, which patients could view as inconvenient, causing sales to not achieve forecasts. In addition, if nomacopan shows a lack of long-term stability at low storage temperatures, this may negatively impact our ability to manage the commercial supply chain, which could result in us having to refund customers or replace products that are unstable, which could materially increase our costs and have a material adverse effect on our financial condition and results of operation.

Because nomacopan has not yet received marketing authorization, it is difficult to predict the time and cost of development and our ability to successfully complete clinical development and obtain the necessary marketing authorizations for commercialization.

Nomacopan has not yet received marketing authorization for the treatment of any indications, and unexpected problems may arise that could cause us to delay, suspend or terminate our development efforts. To date,

only a limited number of patients have been enrolled in our clinical trials. Larger scale trials will be required to obtain marketing authorization and the long-term safety consequences of inhibition of C5 and/or LTB4 with nomacopan is not known. Marketing authorization of product candidates such as nomacopan can be more expensive and take longer than approval of previously approved products.

We have obtained orphan drug designation for nomacopan in the United States for the use in HSCT-TMA, BP, PNH and GBS, and in the EU for GBS, PNH, and BP, but we may be unable to maintain the benefits associated with orphan drug designation or obtain orphan drug exclusivity upon potential approval of nomacopan in one or more of these orphan indications.

In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Although we have received orphan drug designation for nomacopan in HSCT-TMA, GBS, PNH and BP and may in the future seek orphan product designation for nomacopan in further indications, we may never receive such additional designations and we are not currently pursuing a clinical development program targeting BP, GBS or PNH.

If a product that has orphan drug designation subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a BLA, to market the same biologic for the same indication for seven years, except in limited circumstances such as a showing of clinical superiority to the product with orphan product exclusivity or if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Even if we were to obtain orphan drug designation for nomacopan for a particular indication, we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing biological products. If we do obtain exclusive marketing rights in the United States, they may be limited if we seek approval for an indication broader than the orphan designated indication, and may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to assure sufficient quantities of the product to meet the needs of the relevant patients. Further, exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve a drug with the same active moiety for the same condition if the FDA concludes that the later drug is safer, more effective, or makes a major contribution to patient care.

In the EU, where a marketing authorization in respect of an orphan medicinal product is granted, the EMA and the EU Member States shall not, for a period of 10 years, accept another application for a marketing authorization, or grant a marketing authorization or accept an application to extend an existing marketing authorization, for the same therapeutic indication, in respect of a similar medicinal product. A marketing authorization may be granted, for the same therapeutic indication, to a similar medicinal product if: (i) the holder of the marketing authorization for the original orphan medicinal product has given his consent to the second applicant; (ii) the holder of the marketing authorization for the original orphan medicinal product is unable to supply sufficient quantities of the medicinal product; or (iii) the second applicant can establish in the application that the second medicinal product, although similar to the orphan medicinal product already authorized, is safer, more effective or otherwise clinically superior. The European Union's April 2023 draft legislative proposal is under review, including by the European Parliament and European Council but, if implemented in due course, may mean that orphan medicines have reduced marketing exclusivity.

The receipt of orphan drug designation status does not change the regulatory requirements or process for obtaining marketing approval and orphan drug designation does not mean that marketing approval will be granted.

We have obtained fast track designation from the FDA for the treatment of HSCT-TMA, and may seek such designation in other indications. Such designation or a similar designation from other national or international regulatory agencies, may not lead to a faster development or regulatory review or approval process, and may not result in nomacopan or any other product candidates receiving marketing approval.

In addition to the fast track designation we have received for HSCT-TMA, we may seek a breakthrough therapy or fast track designation for nomacopan in other indications. A breakthrough therapy is defined as a product that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. Designation as a breakthrough therapy is within the discretion of the FDA. Receipt of a breakthrough therapy designation for nomacopan may not result in a faster development process, review or approval compared to products considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if nomacopan qualifies as a breakthrough therapy, the FDA may later decide that it no longer meets the conditions for qualification.

Even if we obtain FDA approval of nomacopan, we or our partners may never obtain approval or commercialize our product candidates outside of the United States and, conversely, even if we obtain marketing authorization of nomacopan in the EU, we or our partners may never obtain approval or commercialize our product candidates outside the EU.

In order to market any products in a country, we must establish and comply with numerous and varying regulatory requirements regarding clinical trial design, safety and efficacy. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and marketing authorization in one country does not mean that marketing authorization will be obtained in any other country. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking marketing authorizations in other countries could result in significant delays, difficulties and costs for us, and may require additional preclinical studies or clinical trials, which could be costly and time consuming and could delay or prevent introduction of nomacopan in those countries. We rely on contract research organizations to run our clinical trials and on regulatory consultants for experience in obtaining marketing authorization in international markets. If we or our partners fail to comply with regulatory requirements or to obtain and maintain required approvals, our target market may be reduced and our ability to realize the forecasted revenues of nomacopan may be harmed.

If we or our partners market products in a manner that violates fraud and abuse and other healthcare laws, or if we or they violate government price reporting laws, we or our partners may be subject to administrative civil and/or criminal penalties.

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal healthcare laws, including those commonly referred to as “fraud and abuse” laws have been applied in recent years to restrict certain marketing practices in the pharmaceutical industry. These laws include, among others, false claims and anti-kickback statutes. At such time, if ever, as we or any of our partners market any of our future approved products, it is possible that some of the business activities of us and/or our partners could be subject to challenge under one or more of these laws.

Federal false claims, false statements and civil monetary penalties laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or to get a false claim paid. The federal healthcare program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Although there are several statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution, they are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor.

In addition, we and/or our partners may be subject to data privacy and security regulation, including HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (“HITECH”) and their respective implementing regulations, which impose specified requirements relating to the privacy, security and transmission of individually identifiable health information.

Most states also have statutes or regulations similar to these federal laws, which may apply to items such as pharmaceutical products and services reimbursed by private insurers. We and/or our partners may be subject to administrative, civil and criminal sanctions for violations of any of these federal and state laws.

Our employees, principal investigators, consultants, commercial partners or vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards.

We are also exposed to the risk of employees, independent contractors, principal investigators, consultants, commercial partners or vendors engaging in fraud or other misconduct. Misconduct by employees, independent contractors, principal investigators, consultants, commercial partners and vendors could include intentional failures to comply with United Kingdom ("UK") or European Union ("EU") regulations, to provide accurate information to the UK, EMA or EU Member States authorities or to comply with manufacturing or quality standards we have or will have established. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices such as promotion of products by medical practitioners. Of general application are the European Anti-Fraud Office Regulation 883/2013, and the UK Bribery Act 2010. Under the latter, a commercial organization can be guilty of the offence if the bribery is carried out by an employee, agent, subsidiary, or another third-party, and the location of the third-party is irrelevant to the prosecution. The advertising of medicinal products in the EU is regulated by Title VIII of European Directive 2001/83/EC. The corresponding UK legislation is Part 14 of the Human Medicines Regulations 2012 (S.I. 2012/1916 as amended). Such laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct could also involve the improper use of information obtained in the course of clinical studies, which could result in regulatory sanctions and serious and irreparable harm to our reputation.

This could also apply with respect to data privacy. In the EU, the General Data Protection Regulation (EU) 2016/679 ("GDPR") lays down the legal framework for data protection and privacy. The GDPR applies directly in EU Member States and applies to companies with an establishment in the EEA and to certain other companies not in the EEA that offer or provide goods or services to individuals located in the EEA or monitor the behavior of individuals located in the EEA. Since January 1, 2021, the UK is not part of the EU. In the UK, the GDPR has been converted into UK domestic law, pursuant to the Data Protection, Privacy and Electronic Communications (Amendments etc.) (EU Exit) Regulations 2019 (as amended), which makes some minor technical amendments to ensure the GDPR is operable in the UK ("UK GDPR"). The UK GDPR is also supplemented by the Data Protection Act 2018. UK and EU data protection law is therefore aligned. The GDPR and UK GDPR implement stringent operational requirements for controllers of personal data, including, for example, expanded disclosures about how personal information is to be used, limitations on retention of information, increased requirements pertaining to health data and pseudonymized (i.e., key-coded) data, increased cyber security requirements, mandatory data breach notification requirements and higher standards for controllers to demonstrate that they have obtained a valid legal basis for certain data processing activities. The activities of data processors are being regulated for the first time, and require companies undertaking processing activities to offer certain guarantees in relation to the security of such processing and the handling of personal data. Contracts with data processors will also need to be updated to include certain terms prescribed by the GDPR, and negotiating such updates may not be fully successful in all cases. The GDPR provides that EU Member States may make their own further laws and regulations in relation to the processing of genetic, biometric or health data, which could result in differences between Member States, limit our ability to use and share personal data or could cause our costs to increase, and harm our business and financial condition. We are also subject to evolving and strict rules on the transfer of personal data out of the EU and UK to the United States, under both the GDPR and the UK GDPR. Under the GDPR personal data cannot be transferred to a third country (i.e. outside of the EEA or UK, as applicable) unless certain safeguards are in place. These include, for example, where the transfer is to a country that the EU Commission has deemed "adequate" or where EU standard contractual clauses have been implemented. Further prospective revision of the Directive on privacy and electronic communications (Directive 2002/58/EC) ("ePrivacy Directive") may affect our marketing communications. Failure to comply with EU laws, including failure under the GDPR and UK GDPR, Data Protection Act 2018, ePrivacy Directive and other laws relating to the security of personal data may result in fines up to €20,000,000 (or £17,500,000 under the UK GDPR) or up to 4% of the total worldwide annual turnover of the preceding financial year, if greater, and other administrative penalties including criminal liability, which may be onerous and adversely affect our business, financial condition, results of operations and prospects. Failure to comply

with the GDPR and related laws may also give risk to increase risk of private actions from data subjects and consumer not-for-profit organizations, including a new form of class action that is available under the GDPR. Compliance with the GDPR and UK GDPR requires 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 the aforementioned fines and penalties, litigation, and reputational harm in connection with any European activities.

The UK is treated as a third country (for the purposes of data transfers). On June 28, 2021, the EU Commission published two adequacy decisions in respect of transfers under EU GDPR and the Law Enforcement Directive stating that the UK provides adequate protection for personal data transferred from the EU to the UK under EU GDPR. The adequacy decision is expected to last until June 27, 2025 but may end earlier, for example if an EU data subject or EU data protection authority challenges the adequacy decisions. In such a case, the Court of Justice of the European Union would need to determine whether the UK provides essentially equivalent protection.

The UK government has confirmed that the EEA is adequate, and so all transfers of personal data from the UK to the EEA will continue to be unrestricted after July 1, 2021.

The UK has issued a consultation with respect to future changes to data protection law. There is risk that in the event UK and EU data protection law diverges, that the adequacy decisions may come to an end. If this occurs, there will be cost implication due to dual compliance requirements and costs with respect to international data transfers.

It is not always possible to identify and deter misconduct by employees or other parties. The precautions we take to detect and prevent this activity may not protect us from legal or regulatory action resulting from a failure to comply with applicable laws or regulations. Misconduct by our employees, principal investigators, consultants, commercial partners or vendors could result in significant financial penalties, criminal sanctions and thus have a material adverse effect on our business, including through the imposition of significant fines or other sanctions, and our reputation.

Risks Related to our Intellectual Property

Our success depends in part on our ability to protect our intellectual property and our proprietary technologies.

Our commercial success depends in part on our ability to obtain and maintain patent protection and trade secret protection in the U.S. and other countries for our product candidates, proprietary technologies, and their uses as well as our ability to operate without infringing upon the proprietary rights of others. We can provide no assurance that our patent applications or those of our licensors will result in additional patents being issued or that issued patents will afford sufficient protection against competitors with similar technologies, nor can there be any assurance that the patents issued will not be infringed, designed around or invalidated by third parties. Even issued patents may later be found unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. The degree of future protection for our proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep competitive advantage. We have issued composition-of-matter patents in the United States and other countries for nomacopan, but we cannot be certain that the claims in our issued patents will not be found invalid or unenforceable if challenged. We cannot be certain that the claims in any patent applications covering our product candidates that are pending, or that we may file, will be considered patentable by the USPTO and courts in the United States or by the patent offices and courts in foreign countries, nor can we be certain that the claims in our issued patents will not be found invalid or unenforceable if challenged. Even if any patent applications that we may file relating to specific formulations of our product candidates issue as patents, formulation patents protect a specific formulation of a product and may not be enforced against competitors making and marketing a product that has the same active pharmaceutical ingredient in a different formulation. Method-of-use patents protect the use of a product for the specified method or for treatment of a particular indication. This type of patent may not be enforced against competitors making and marketing a product that has the same active pharmaceutical ingredient for use in a method not claimed by the patent. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products “off-label.” Although off-label prescriptions may infringe or contribute to the infringement of method-of-use patents, the practice is common and such infringement may be

difficult to prevent or prosecute. Also, as is the case for composition-of-matter patents, we cannot be certain that the claims in our issued method-of-use patents will not be found invalid or unenforceable if challenged. We cannot be certain that the claims in any patent applications covering methods of using our product candidates that are pending, or that we may file, will be considered patentable by the USPTO and courts in the United States or by the patent offices and courts in foreign countries, nor can we be certain that the claims in our issued method-of-use patents will not be found invalid or unenforceable if challenged.

Our issued patents for nomacopan and its uses are expected to expire between 2024 and 2035 (excluding any patent term adjustment or potential patent term extension). Our pending patent applications for nomacopan and its uses, if issued, are expected to expire at various times that range from 2024 to 2040 (excluding any potential patent term adjustment or extension).

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our future development partners will be successful in protecting our product candidates by obtaining and defending patents. These risks and uncertainties include the following:

- the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case;

- patent applications may not result in any patents being issued;

- patents that may be issued or in-licensed may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;

- patents have a finite term and thus may expire before the technologies they protect are approved or marketed and thus may not provide any competitive advantage. For example, issued composition-of-matter patents for the nomacopan product will expire in 2024 (excluding any patent term adjustment or extension);

- our competitors, many of whom have substantially greater resources and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use, and sell our potential product candidates;

- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns;

- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates; and

- some countries in Europe and China have compulsory licensing laws under which 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, are 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 and results of operations may be adversely affected.

In addition, we rely on the protection of our trade secrets and proprietary know-how. Although we have taken steps to protect our trade secrets and unpatented know-how, including entering into confidentiality agreements with third parties, and confidential information and inventions agreements with employees, consultants and advisors,

we cannot provide any assurances that all such agreements have been duly executed, and third parties may still obtain this information or may come upon this or similar information independently. Enforcing a claim that a third party obtained illegally and is using trade secrets and/or proprietary know-how is expensive, time consuming and unpredictable. The enforceability of confidentiality agreements may vary from jurisdiction to jurisdiction. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating its trade secrets. If any of these events occurs or if we otherwise lose protection for our trade secrets or proprietary know-how, our business may be harmed.

Others may claim an ownership interest in our intellectual property, which could expose it to litigation and have a significant adverse effect on its prospects.

A third party may claim an ownership interest in one or more of our patents or other intellectual property. A third party could bring legal actions against us and seek monetary damages and/or enjoin clinical testing, manufacturing and marketing of the affected product or products. We cannot guarantee that a third-party will not assert a claim or an interest in any of such patents or intellectual property. If we become involved in any litigation, it could consume a substantial portion of our resources, and cause a significant diversion of effort by our technical and management personnel. If any of these actions are successful, in addition to any potential liability for damages, we could be required to obtain a license to continue to manufacture or market the affected product, in which case we may be required to pay substantial royalties or grant cross-licenses to our patents. We cannot, however, assure you that any such license will be available on acceptable terms, if at all. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations as a result of claims of patent infringement or violation of other IP rights, Further, the outcome of IP litigation is subject to uncertainties that cannot be adequately quantified in advance, including the demeanor and credibility of witnesses and the identity of the adverse party. This is especially true in IP cases that may turn on the testimony of experts as to technical facts upon which experts may reasonably disagree. Ultimately, there is no guarantee that courts or patent offices in the U.S. and abroad will rule in our favor.

Changes in patent laws or patent jurisprudence could diminish the value of our patents, thereby impairing our ability to protect our products or product candidates.

As is the case with other biopharmaceutical companies, our success if heavily dependent on intellectual property, particularly patents. Obtaining and exploiting patents in the biopharmaceutical industry involve both technological and legal complexity. Therefore, obtaining and exploiting biopharmaceutical patents is costly, time-consuming and inherently uncertain. For example, 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. These rulings have created uncertainty with respect to the validity and enforceability of patents, even once obtained. Depending on future actions and decisions by the U.S. Congress, the federal courts, and the U.S. Patent and Trademark Office, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we may obtain in the future.

Risks Related to our Business Operations

We currently have no marketing, sales or distribution infrastructure with respect to nomacopan. If we are unable to develop our sales, marketing and distribution capability on our own or through collaborations with partners, we may not be successful in commercializing any approved drugs.

We currently have no marketing, sales or distribution capabilities. If our product candidate nomacopan is approved, we intend either to establish a sales and marketing organization with technical expertise and supporting distribution capabilities to commercialize nomacopan, or to outsource this function to a third party. Either of these options could be expensive and time-consuming. Some of these costs may be incurred in advance of any approval of nomacopan. In addition, we may not be able to hire a commercial team in the United States or other target market that is sufficient in size or has adequate expertise in the medical institutions that we intend to target. Any failure or delay in the development of our or third parties' internal sales, marketing and distribution capabilities could adversely impact the commercialization of nomacopan and/or other future product candidates, if and when approved by the FDA.

With respect to our existing and future product candidates, we may choose to collaborate with third parties that have direct sales forces and established distribution systems, either to augment or to serve as an alternative to our own sales force and distribution capabilities. Any future product revenue may be lower than if we directly marketed or sold our approved products. In addition, any revenue we receive will depend in whole or in part upon the efforts of these third parties, which may not be successful. If we are unable to enter into these arrangements on acceptable terms or at all, we may not be able to successfully commercialize our approved products. If we are not successful in commercializing our approved products, our future product revenue will suffer and we may incur significant losses.

We only have a limited number of employees to manage and operate our business.

As of March 15, 2023, we had 12 employees, nine of which are full-time. Our limited financial resources have led us to focus on the development of nomacopan and to manage and operate our business in a highly efficient manner. We cannot make assurances that we will be able to hire and/or retain adequate staffing levels to develop nomacopan or run our operations and/or to accomplish all of the objectives that we otherwise would seek to accomplish.

Our industry is highly competitive, and our product candidates may become obsolete.

We are engaged in a rapidly evolving field. Competition from other pharmaceutical companies, biotechnology companies and research and academic institutions is intense and likely to increase. Many of those companies and institutions have substantially greater financial, technical and human resources than us. Those companies and institutions also have substantially greater experience in developing products, conducting clinical trials, obtaining marketing authorization and in manufacturing and marketing biologic products. Our competitors may succeed in obtaining marketing authorization for their products more rapidly than we do. Competitors have developed or are in the process of developing technologies that are, or in the future may be, the basis for competitive products. Our competitors may succeed in developing products that are more effective than those we are developing, or that would render our product candidates less competitive or even obsolete. In addition, one or more of our competitors may achieve product commercialization or patent protection, which could materially adversely affect our business.

If physicians and patients do not adopt our future products or if the market size for indications for which any product candidate is approved is smaller than expected, we may be unable to achieve forecasted revenues, if any.

Even if any of our product candidates obtain marketing authorization, they may not gain market acceptance among physicians, patients, or third-party payers. Physicians may decide not to recommend our treatments for a variety of reasons including:

- timing of market introduction of competitive products;
- demonstration of clinical safety and efficacy;
- cost-effectiveness;
- limited or no coverage by third-party payers;
- convenience and ease of administration;
- prevalence and severity of adverse side effects;
- restrictions in the label of the drug;
- availability of alternative treatments in clinical trials;
- understanding of the drug;

- other potential advantages of alternative treatment methods; and
- ineffective marketing and distribution capabilities.

If any of our product candidates are approved, but fail to achieve market acceptance or such market is smaller than anticipated, we may not be able to achieve forecasted revenues, if any.

We may be subject to healthcare laws and regulations, and health information privacy and security laws, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and others will play a primary role in the recommendation and prescription of our product candidates, if approved. Our future arrangements with third-party payors will expose us broadly to applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our product candidates, if we obtain marketing approval. In addition, we may be subject to patient privacy regulation by both the federal government and the states or other countries in which we conduct our business. For more information, see the section of this report titled "*Business – U.S. Healthcare Reform and Other Healthcare Laws*."

Ensuring that our future business arrangements with third parties comply with applicable healthcare laws and regulations could 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, including anticipated activities to be conducted by our sales team, 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 and exclusion from government funded healthcare programs, such as Medicare and Medicaid, any of which could substantially disrupt our operations and would materially adversely affect our business, financial condition and results of operations. If any of the physicians or other providers or entities with whom we expect to do business is 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, which could have a material adverse effect on our business, results of operations, financial condition and prospects.

Healthcare reform legislation, including potentially unfavorable pricing regulations or other healthcare reform initiatives may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates.

The commercial potential for our product candidates, if any, could be affected by changes in healthcare spending and policy in the United States and abroad. We operate in a highly regulated industry. New laws, regulations or judicial decisions or new interpretations of existing laws, regulations or decisions, related to healthcare availability, the method of delivery or payment for healthcare products and services could adversely affect our business, operations and financial condition. The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that may affect our ability to profitably sell our product and product candidates, if approved. The United States government, state legislatures and foreign governments also have shown significant interest in implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. The pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. Previously, in March 2010, the PPACA was enacted, which was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Healthcare reform initiatives recently culminated in the enactment of the IRA, which, among other things, allows HHS to directly negotiate the ceiling price of a statutorily specified number of drugs and biologic each year that receive reimbursement under Medicare Part B and Part D, requires the payment of rebates on Medicare Part B and Part D drugs whose prices have increased at a rate faster than the rate of inflation, and redesign the Medicare Part D cost sharing structure, including revising manufacturer

financial liability for covered products. For more information, see the section of this report titled "Business – U.S. Healthcare Reform and Other Healthcare Laws."

We expect that additional federal, state and foreign healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in limited coverage and reimbursement and reduced demand for our products, once approved, or additional pricing pressures.

Future changes associated with pharmaceutical product or drug reimbursement policies may adversely affect our business.

Market acceptance and sales of any one or more of our products will depend in part on reimbursement policies and may be affected by future healthcare reform measures in the United States and in foreign jurisdictions. Government authorities and third-party payers, such as private health insurers and health maintenance organizations, decide which drugs they will cover and establish payment levels. Obtaining coverage and reimbursement approval for 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 to the payor. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. We cannot be certain that reimbursement will be available for any of our approved drugs, if any. Also, we cannot be certain that reimbursement policies will not reduce the demand for, or the price paid for, any future products. The insurance coverage and reimbursement status of newly-approved products is particularly uncertain, and failure to obtain or maintain adequate coverage and reimbursement for nomacopan or any other product candidates could limit our ability to generate revenue.

The United States and several foreign jurisdictions are considering, or have already enacted, a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell future products profitably. There is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access to healthcare. In the United States, the pharmaceutical industry has been a particular focus of these efforts. We may experience pricing pressures in connection with the sale of any products that we develop due to the trend toward managed healthcare, increasing influence of health maintenance organizations and additional legislative proposals. See the section of this report titled, "Business – Pharmaceutical Pricing & Reimbursement."

If product liability lawsuits are successfully brought against us or any of our partners, we may incur substantial liabilities and may be required to limit commercialization of any approved products.

We face an inherent risk of product liability lawsuits related to the testing of our product candidates in seriously ill patients and may face an even greater risk if product candidates are approved by regulatory authorities and introduced commercially. Product liability claims may be brought against us or our partners by participants enrolled in our clinical trials, patients, health care providers or others using, administering or selling any of our future approved products. If we cannot successfully defend ourselves against any such claims, we may incur substantial liabilities, which may result in:

- decreased demand for any of our future approved products;
- injury to our reputation;
- withdrawal of clinical trial participants;
- termination of clinical trial sites or entire trial programs;
- significant litigation costs;
- substantial monetary awards to or costly settlements with patients or other claimants;

- product recalls or a change in the indications for which they may be used;
- loss of revenue;
- diversion of management and scientific resources from our business operations; and
- the inability to commercialize any approved drugs.

Although we currently carry clinical trial insurance, the amount of such insurance coverage may not be adequate. In addition, we will need to obtain more comprehensive insurance and increase our insurance coverage when we begin the commercialization of any approved drugs. Insurance coverage is becoming increasingly expensive. As a result, we may be unable to maintain or obtain sufficient insurance at a reasonable cost to protect us against losses that could have a material adverse effect on our business.

We enter into various contracts in the normal course of our business in which we indemnify the other party to the contract. In the event we have to perform under these indemnification provisions, it could have a material adverse effect on our business, financial condition and results of operations.

In the normal course of business, we periodically enter into academic, commercial, service, collaboration, licensing, consulting, investor relations and other agreements that contain indemnification provisions. With respect to our academic and other research agreements, we typically indemnify the institution and related parties from losses arising from claims relating to the products, processes or services made, used, sold or performed pursuant to the agreements for which we have secured licenses, and from claims arising from our or our sublicensees' exercise of rights under the agreement. With respect to our commercial agreements, we may be required to indemnify our vendors from any third-party product liability claims that could result from the production, use or consumption of the product, as well as for alleged infringements of any patent or other intellectual property right by a third party. With respect to investor relations agreements, we may indemnify the counterparty for losses resulting from our negligence or our supply of inaccurate information.

Should our obligation under an indemnification provision exceed applicable insurance coverage or if we were denied insurance coverage, our business, financial condition and results of operations could be adversely affected. Similarly, if we are relying on a collaborator to indemnify us and the collaborator is denied insurance coverage or the indemnification obligation exceeds the applicable insurance coverage and does not have other assets available to indemnify us, our business, financial condition and results of operations could be adversely affected.

Our business and operations could suffer in the event of computer system failures or security breaches.

Despite the implementation of security measures, our internal computer systems, and those of our contract research organizations ("CROs") and other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, cyber-attacks, natural disasters, fire, terrorism, war, and telecommunication and electrical failures. If such an event were to occur and interrupt our operations, it could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from ongoing or planned clinical trials could result in delays in our marketing authorization efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications, loss of trade secrets or inappropriate disclosure of confidential or proprietary information, including protected health information or personal data of employees or former employees, access to our clinical data, or disruption of the manufacturing process, we could incur liability and the further development of our drug candidates could be delayed. We may also be vulnerable to cyber-attacks by hackers or other malfeasance. This type of breach of our cybersecurity may compromise our confidential information and/or our financial information and adversely affect our business or result in legal proceedings. If security breaches result in the loss of clinical trial data or other confidential information, we may be the subject of legal proceedings and suffer financial and reputational damage. Further, these cybersecurity breaches may inflict reputational harm upon us that may result in decreased market value and erode public trust.

We or the third parties upon whom we depend may be adversely affected by natural disasters and/or health epidemics and pandemics, and our business continuity and disaster recovery plans may not adequately protect us from natural disasters and/or health epidemics and pandemics.

Natural disasters could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage, health epidemics or other event occurred that prevented us from using all or a significant portion of our office, that damaged critical infrastructure, such as the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. As the global supply chain continues to see disruptions, there is higher risk for continued labor shortages, reduced labor capacity at supplier and third-party manufacturers, increased raw material costs and delays in production of our clinical product and clinical trials that will adversely impact our business. The extent to which the global supply chain disruptions may continue to impact our results of operations, including the long-term nature of the impact, depends on numerous evolving factors, which are highly uncertain and difficult to predict.

Public health pandemics, epidemics or outbreaks could adversely impact our business. Pandemics can adversely impact our business as a result of disruptions, such as travel bans, quarantines, staffing shortages, and interruptions to access the trial sites and supply chains, which could result in material delays and complications with respect to our research and development programs and clinical trials.

If we fail to develop and commercialize other product candidates, we may be unable to generate revenues.

Although the development and commercialization of nomacopan is our primary focus, as part of our longer-term growth strategy, we may evaluate the development and commercialization of other therapies for the treatment of autoimmune, inflammatory or other diseases. We may from time to time evaluate internal opportunities from our current product candidates, and also may choose to in-license or acquire other product candidates as well as commercial products to treat patients suffering from immune-mediated, orphan or other disorders with high unmet medical needs and limited treatment options. These other product candidates may require additional, time-consuming development efforts prior to commercial sale, including preclinical studies, clinical trials and marketing approval by the FDA, MHRA, EMA and/or applicable foreign regulatory authorities. All product candidates are prone to the risks of failure that are inherent in pharmaceutical product development, including the possibility that the product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot assure you that any such products that are approved will be manufactured or produced economically, successfully commercialized or widely accepted in the marketplace or be more effective than commercially available alternatives, if any.

Our business could suffer if we are unable to attract and retain key employees.

Our success depends upon the continued service and performance of our senior management and other key personnel. The loss of the services of these personnel could delay or prevent the successful completion of our planned clinical trials or the commercialization of our therapeutic candidates or otherwise affect our ability to manage our company effectively and to carry out our business plan. We do not maintain key-man life insurance. Although we have entered into employment agreements with all of the members of our senior management team, members of our senior management team may resign at any time. High demand exists for senior management and other key personnel in the biopharmaceutical industry. There can be no assurance that we will be able to continue to attract and retain such personnel.

Our growth and success also depend on our ability to attract and retain additional highly qualified scientific, clinical, technical, sales, managerial and finance personnel. We experience intense competition for qualified personnel, and the existence of non-competition agreements between prospective employees and their former employers may prevent us from hiring those individuals or subject us to suit from their former employers. In addition, if we elect to independently commercialize any approved drug, we will need to expand our marketing and sales capabilities. While we attempt to provide competitive compensation packages to attract and retain key personnel, many of our competitors are likely to have greater resources and more experience than we have, making it difficult for us to compete successfully for key personnel. If we cannot attract and retain sufficiently qualified

technical employees on acceptable terms, we may not be able to develop and commercialize products. Further, any failure to effectively integrate new personnel could prevent us from successfully growing our company.

Environmental, social and corporate governance ("ESG") issues, including those related to climate change and sustainability, may have an adverse effect on our business, financial condition and results of operations and damage our reputation.

There is an increasing focus from certain investors, customers, consumers, employees and other stakeholders concerning ESG matters. Additionally, public interest and legislative pressure related to public companies' ESG practices continue to grow. If our ESG practices fail to meet regulatory requirements or investor, customer, consumer, employee or other stakeholders' evolving expectations and standards for responsible corporate citizenship in areas including environmental stewardship, support for local communities, board of director and employee diversity, human capital management, employee health and safety practices, product quality, supply chain management, corporate governance and transparency, our reputation, brand and employee retention may be negatively impacted, and our customers and suppliers may be unwilling to continue to do business with us.

Customers, consumers, investors and other stakeholders are increasingly focusing on environmental issues, including climate change, energy and water use, plastic waste and other sustainability concerns. Concern over climate change may result in new or increased legal and regulatory requirements to reduce or mitigate impacts to the environment. Changing customer and consumer preferences or increased regulatory requirements may result in increased demands or requirements regarding plastics and packaging materials, including single-use and non-recyclable plastic products and packaging, other components of our products and their environmental impact on sustainability, or increased customer and consumer concerns or perceptions (whether accurate or inaccurate) regarding the effects of substances present in certain of our products. Complying with these demands or requirements could cause us to incur additional manufacturing, operating or product development costs.

If we do not adapt to or comply with new regulations, including the SEC's published proposed rules that would require companies to provide significantly expanded climate-related disclosures in their periodic reporting, which may require us to incur significant additional costs to comply and impose increased oversight obligations on our management and board of directors, or fail to meet evolving investor, industry or stakeholder expectations and concerns regarding ESG issues, investors may reconsider their capital investment in our Company, we may become subject to penalties, and customers and consumers may choose to stop purchasing our products, if approved for commercialization, which could have a material adverse effect on our reputation, business or financial condition.

Any pandemic, epidemic, or outbreak of an infectious disease, may materially and adversely affect our business and our financial results and could cause a disruption to the development of our product candidates.

Public health crises, such as pandemics or similar outbreaks, could adversely impact our business. For example, we experienced delays in enrollment of patients in our clinical trials and supply chain issues due in particular to the COVID-19 pandemic for certain of our past clinical trials, including, without limitation, in our discontinued BP clinical program. Any future pandemic, epidemic or outbreak of an infectious disease could have similar effects. Furthermore, economic recessions, increased inflation and/or interest rates, and any disruptions to our operations or workforce availability, including those brought on by the effects of the COVID-19 pandemic or a similar health epidemic may have a negative effect on our operating results. The foregoing could result in an adverse effect on our business, results of operations, financial condition and cash flows.

Potential disruptions to our preclinical and clinical development efforts related to future outbreaks or pandemics may include, but are not limited to, disruptions in our supply chain and our ability to procure the components for each of our product candidates for use in preclinical studies and clinical trials and enrolling patients in clinical trials. We are unable to predict if a future outbreak or pandemic could have similar or different impacts on our preclinical studies, clinical trials, business, financial condition, and results of operations.

Risks Related to Our Reliance on Third Parties

We seek to partner with third-party collaborators with respect to aspects of the development and commercialization of our product candidates and we may not succeed in establishing and maintaining collaborative relationships, which may significantly limit our ability to develop and commercialize our product candidates successfully, if at all.

Our business strategy relies in part on partnering with pharmaceutical companies to supplement our internal development efforts. If we are not able to enter into collaboration arrangements, we may be required to undertake and fund further development, clinical trials, manufacturing and commercialization activities solely at our own expense and risk. If we are unable to finance and/or successfully execute those activities, or we delay such activities due to capital availability, our business could be materially and adversely affected, and potential future product launches could be materially delayed, be less successful, or we may be forced to discontinue clinical development of product candidates.

The process of establishing and maintaining collaborative relationships is difficult, time-consuming and involves significant uncertainty, including if a collaboration partner:

- may shift its priorities and resources away from our product candidates due to a change in business strategies, or a merger, acquisition, sale or downsizing;
- may seek to renegotiate or terminate their relationships with us due to unsatisfactory clinical results, manufacturing issues, a change in business strategy, a change of control or other reasons;
- may cease development in therapeutic areas which are the subject of our strategic collaboration;
- may not devote sufficient capital or resources towards our product candidates;
- may change the success criteria for a drug candidate thereby delaying or ceasing development of such candidate;
- experiences significant delays in initiating certain development activities, which will also delay payment of milestones tied to such activities, thereby impacting our ability to fund our own activities;
- develops a product that competes, either directly or indirectly, with our drug candidate;
- may not commit sufficient financial or human resources to the marketing, distribution or sale of our product;
- may encounter regulatory, resource or quality issues and be unable to meet demand requirements;
- may exercise a contractual right to terminate a strategic alliance;
- has a dispute arise concerning the research, development or commercialization of a drug candidate resulting in a delay in milestones, royalty payments or termination of an alliance and possibly resulting in costly litigation or arbitration which may divert management attention and resources; and
- may use our products or technology in such a way as to invite litigation from a third party.

If any collaborator fails to fulfill its responsibilities in a timely manner, or at all, our research, clinical development, manufacturing or commercialization efforts related 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 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 sources of additional capital.

If the third parties on which we rely for our clinical trials and results do not perform our clinical trial activities in accordance with good clinical practices and related regulatory requirements, we may be unable to obtain marketing authorization for or commercialize our product candidates.

We use and heavily rely on third-party contract research organizations to conduct and/or oversee the clinical trials of our product candidates and expect to continue to do so for the foreseeable future. Nonetheless, we are responsible for confirming that each of our clinical trials is conducted in accordance with the FDA's, MHRA's and/or EMA's requirements and its general investigational plan and protocol.

The FDA, MHRA and EMA require us and our contract research organizations to comply with regulations and standards, commonly referred to as good clinical practices, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the trial participants are adequately protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. Third parties may not complete activities on schedule or conduct our clinical trials in accordance with regulatory requirements or the respective trial plans and protocols. In addition, third parties may not be able to repeat their past successes in clinical trials. The third parties' failure to carry out their obligations could delay or prevent the development, approval and commercialization of our product candidates or result in enforcement action against us.

Use of third parties to manufacture our product candidates may increase the risk that we will not have sufficient quantities of our product candidates, products, or necessary quantities at an acceptable cost.

We do not own or operate manufacturing facilities for the production of clinical or commercial quantities of our product candidates, and we lack the resources and the capabilities to do so. As a result, we currently rely on third parties for supply of the active pharmaceutical ingredients ("API") for our product candidates. Our strategy is to outsource all manufacturing of our product candidates and products to third parties.

We currently engage a third-party manufacturer to provide clinical material of the API, lyophilization, release testing and fill and finish services for the final drug product formulation of nomacopan that is being used in our clinical trials. Although we believe that there are several potential alternative manufacturers who could manufacture nomacopan, we may incur added costs and delays in identifying and qualifying any such replacement. In addition, we have not yet concluded a commercial supply contract with any commercial manufacturer. There is no assurance that we will be able to timely secure needed supply arrangements on satisfactory terms, or at all. Our failure to secure these arrangements as needed could have a material adverse effect on our ability to complete the development of our product candidates or to commercialize them. We may be unable to conclude agreements for commercial supply with third-party manufacturers, or may be unable to do so on acceptable terms. There may be difficulties in scaling up to commercial quantities and formulation of nomacopan and the costs of manufacturing could be prohibitive.

Even if we are able to establish and maintain arrangements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- reliance on third-parties for manufacturing process development, regulatory compliance and quality assurance, which may result in delays or inadequate supply of product;
- limitations on supply availability resulting from capacity and scheduling constraints of third-parties;
- limitation on supply availability due to difficulties in sourcing raw materials;
- the possible breach of manufacturing agreements by third-parties because of factors beyond our control;

- the possible termination or non-renewal of the manufacturing agreements by the third-party, at a time that is costly or inconvenient to us; and
- delays associated with the lack of availability of staff at third-party manufacturers.

If we do not maintain our key manufacturing relationships, we may fail to find replacement manufacturers or develop our own manufacturing capabilities, which could delay or impair our ability to obtain marketing authorization for our products. If we do find replacement manufacturers, we may not be able to enter into agreements with them on terms and conditions favorable to us and there could be a substantial delay before new facilities could be qualified and registered with the FDA and other foreign regulatory authorities.

The FDA, MHRA EMA and other foreign regulatory authorities require manufacturers to register manufacturing facilities. The FDA and corresponding foreign regulators also inspect these facilities to confirm compliance with current good manufacturing practices ("cGMPs"). Contract manufacturers may face manufacturing or quality control problems causing drug substance production and shipment delays or a situation where the contractor may not be able to maintain compliance with the applicable cGMP requirements. Any failure to comply with FDA, MHRA, EMA and comparable foreign regulatory requirements could adversely affect our clinical research activities and our ability to develop our product candidates and market our products.

Moreover, the manufacturing of therapeutic biologics products is highly complex. Problems may arise during manufacturing for a variety of reasons, including but not limited to:

- equipment malfunction;
- failure to follow specific protocols and procedures;
- changes in product specification;
- low quality or insufficient supply of raw materials;
- delays in the construction of new facilities or the expansion of our existing manufacturing facilities as a result of changes in manufacturing production sites and limits to manufacturing capacity due to regulatory requirements;
- staffing shortages;
- advances in manufacturing techniques;
- physical limitations that could inhibit continuous supply; and
- man-made or natural disasters and other environmental factors.

Products with quality issues may have to be discarded, resulting in product shortages or additional expenses. This could lead to, among other things, increased costs, lost revenue, damage to customer relationships, time and expense spent investigating the cause and, depending on the cause, similar losses with respect to other batches or products. If problems are not discovered before the product is released to the market, recall and product liability costs may also be incurred.

Manufacturing methods and formulation are sometimes altered through the development of drug candidates from clinical trials to approval, and further to commercialization, in an effort to optimize manufacturing processes and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause the drug candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. This could delay the commercialization of any approved drugs and require bridging studies or the repetition of one or more clinical trials, which may result in increases in clinical trial costs, delays in drug approvals and may jeopardize our ability to commence product sales and generate revenue.

We may also experience shortages of qualified personnel, raw materials or key contractors, and experience unexpected damage to our facilities or the equipment in them. In these cases, we may be required to delay or suspend our manufacturing activities. We may be unable to secure temporary, alternative manufacturers for our drugs with the terms, quality and costs acceptable to us, or at all. Such an event could delay our clinical trials and/or the availability of our products for commercial sale. Moreover, we may spend significant time and costs to remedy these deficiencies before we can continue production at our manufacturing facilities.

In addition, the quality of our products, including drug candidates manufactured by us for research and development purposes and drugs manufactured by us for commercial use, depends significantly on the effectiveness of our quality control and quality assurance, which in turn depends on factors such as the production processes used in our manufacturing facilities, the quality and reliability of equipment used, the quality of our staff and related training programs and our ability to ensure that our employees adhere to our quality control and quality assurance protocol. However, there can be no assurances that our quality control and quality assurance procedures will be effective in consistently preventing and resolving deviations from our quality standards. Any significant failure or deterioration of our quality control and quality assurance protocol could render our products unsuitable for use, jeopardize any cGMP certifications we may have and/or harm our market reputation and relationship with business partners. Any such developments may have a material adverse effect on our business, financial condition and results of operations.

If our third-party manufacturer of nomacopan is unable to increase the scale of its production of nomacopan, and/or increase the product yield of its manufacturing, then our costs to manufacture the product may increase and/or commercialization may be slowed.

In order to produce sufficient quantities of nomacopan to meet the demand for future clinical trials and subsequent commercialization, our third party manufacturer of nomacopan will be required to increase its production while maintaining the quality of the product. The transition to larger scale production could prove difficult. In addition, if our third party manufacturer is not able to optimize its manufacturing process to increase the product yield for nomacopan, or if it is unable to produce increased amounts of nomacopan while maintaining the quality of the product, then we may not be able to meet the demands of clinical trials or market demands, which could decrease our ability to generate profits and have a material adverse impact on our business and results of operation.

Risks Related to our Ordinary Shares and ADSs

Ownership of our ADSs and/or ordinary shares involves a high degree of risk.

Investing in and owning our ADSs and ordinary shares involve a high degree of risk. Shareholders should read carefully the risk factors provided within this section, as well as our public documents filed with the SEC, including the financial statements therein.

Our ADSs may be involuntarily delisted from trading on the Nasdaq Capital Market if we fail to comply with the continued listing requirements. A delisting of our ADSs could reduce the liquidity of our ADSs and may inhibit or preclude our ability to raise additional capital.

Nasdaq requires us to meet certain financial, public float, bid price and liquidity standards on an ongoing basis in order to continue the listing of our ADSs. Generally, we must maintain a minimum closing bid price of $1.00 and a minimum amount of shareholders equity (generally $2.5 million).

On October 24, 2022, we were notified by Nasdaq that we were not in compliance with the minimum bid price requirements set forth in Nasdaq Listing Rule 5550(a)(2) for continued listing on the Nasdaq Capital Market because the bid price for our ADSs had closed below $1.00 per share (the "Minimum Bid Requirement") for the previous thirty consecutive business days, and in accordance with the applicable Nasdaq rules, we were provided with a grace period, through April 24, 2023, to regain compliance with this rule. On April 25, 2023, Nasdaq granted us an additional 180 calendar day period, or until October 23, 2023, in which to regain compliance with the minimum $1.00 bid price requirement. Following the successful completion of the ADS Ratio Change (as defined

below), we received a written notice from the Nasdaq staff that we have regained compliance with the Minimum Bid Requirement as a result of the our ADSs having a closing bid price of $1.00 per share or greater for 10 consecutive business days.

Separately, Nasdaq Listing Rule 5550(b)(1) requires us to maintain shareholders' equity of at least $2.5 million (the "Minimum Equity Requirement"). As of December 31, 2023, we had a shareholders' deficit of $0.2 million and therefore are not in compliance with the Minimum' Equity Requirement. Accordingly, we expect that once we file this Annual Report on Form 10-K for the year ended December 31, 2023, we will receive a related notice of non-compliance from Nasdaq.

If we fail to regain compliance with the Minimum Equity Requirement, or otherwise fail to meet any of the continuing listing requirements, our ADSs may be subject to delisting and we may become subject to delisting proceedings. If our ADSs are delisted and we are not able to list our ADSs on another national securities exchange, we expect our securities would be quoted on an over-the-counter market. If this were to occur, our shareholders could face significant material adverse consequences, including limited availability of market quotations for our ADSs and reduced liquidity for the trading of our securities. In addition, we could experience a decreased ability to issue additional securities and obtain additional capital in the future. There can be no assurance that an active trading market for our ADSs will develop or be sustained. We plan to raise additional capital in order to increase our shareholders' equity in order to meet the Nasdaq continued listing standards. Any additional equity financings may be financially dilutive to, and will be dilutive from an ownership perspective to our shareholders, and such dilution may be significant based upon the size of such financing. Additionally, we cannot assure that such funding will be available on a timely basis, in needed quantities, or on terms favorable to us, if at all.

Our business, operating results and growth rates may be adversely affected by current or future unfavorable economic and market conditions and adverse developments with respect to financial institutions and associated liquidity risk.

Our business depends on the health of the global economies. If the conditions in the global economies remain uncertain or continue to be volatile, or if they deteriorate, including as a result of the impact of military conflict, such as the war between Russia and Ukraine, terrorism or other geopolitical events, our business, operating results and financial condition may be materially adversely affected. Economic weakness, inflation and increases in interest rates, limited availability of credit, liquidity shortages and constrained capital spending have at times in the past resulted, and may in the future result, in challenging and delayed sales cycles, slower adoption of new technologies and increased price competition, and could negatively affect our ability to forecast future periods, which could result in an inability to satisfy demand for our products and a loss of market share.

In addition, inflation raises our costs for commodities, labor, materials and services and other costs required to grow and operate our business, and failure to secure these on reasonable terms may adversely impact our financial condition. Additionally, inflation, along with the uncertainties surrounding a resurgence of COVID-19, geopolitical developments and global supply chain disruptions, have caused, and may in the future cause, global economic uncertainty and uncertainty about the interest rate environment, which may make it more difficult, costly or dilutive for us to secure additional financing. A failure to adequately respond to these risks could have a material adverse impact on our financial condition, results of operations or cash flows.

More recently, the closures of SVB and Signature Bank and their placement into receivership with the FDIC created bank-specific and broader financial institution liquidity risk and concerns. Although the Department of the Treasury, the Federal Reserve and the FDIC jointly released a statement that depositors at SVB and Signature Bank would have access to their funds, even those in excess of the standard FDIC insurance limits, under a systemic risk exception, future adverse developments with respect to specific financial institutions or the broader financial services industry may lead to market-wide liquidity shortages, impair the ability of companies to access near-term working capital needs, and create additional market and economic uncertainty. There can be no assurance that future credit and financial market instability and a deterioration in confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, liquidity shortages, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, or if adverse developments are experienced by financial institutions, it may cause short-term liquidity risk and also make any necessary debt or equity financing more difficult, more costly, more onerous with

respect to financial and operating covenants and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to alter our operating plans. In addition, there is a risk that one or more of our service providers, financial institutions, manufacturers, suppliers and other partners may be adversely affected by the foregoing risks, which could directly affect our ability to attain our operating goals on schedule and on budget.

If we are deemed or become a passive foreign investment company ("PFIC") for U.S. federal income tax purposes in 2024 or in any prior or subsequent years, there may be negative tax consequences for U.S. taxpayers that are holders of our ADSs.

We will be treated as a PFIC for U.S. federal income tax purposes in any taxable year in which either (i) at least 75% of our gross income is "passive income" or (ii) on average at least 50% of our assets by value produce passive income or are held for the production of passive income. Passive income for this purpose generally includes, among other things, certain dividends, interest, royalties, rents and gains from commodities and securities transactions and from the sale or exchange of property that gives rise to passive income. Passive income also includes amounts derived by reason of the temporary investment of funds, including those raised in a public offering. In determining whether a non-U.S. corporation is a PFIC, a proportionate share of the income and assets of each corporation in which it owns, directly or indirectly, at least a 25% interest (by value) is taken into account.

We may have been a PFIC for 2023, but we have not performed a detailed analysis to determine PFIC status for 2023. Because the PFIC determination is highly fact sensitive, there can be no assurance that we were not a PFIC for 2023 and there can be no assurance that we will not be a PFIC for 2024 or for any other taxable year. If we were to be characterized as a PFIC for U.S. federal income tax purposes in any taxable year during which a U.S. shareholder owns our ADSs, and such U.S. shareholder does not make an election to treat us as a "qualified electing fund" ("QEF") or make a "mark-to-market" election, then "excess distributions" to such U.S. shareholder, and any gain realized on the sale or other disposition of our ADSs will be subject to special rules. Under these rules: (i) the excess distribution or gain would be allocated ratably over the U.S. shareholder's holding period for ADSs; (ii) the amount allocated to the current taxable year and any period prior to the first day of the first taxable year in which we were a PFIC would be taxed as ordinary income; and (iii) the amount allocated to each of the other taxable years would be subject to tax at the highest rate of tax in effect for the applicable class of taxpayer for that year, and an interest charge for the deemed deferral benefit would be imposed with respect to the resulting tax attributable to each such other taxable year. In addition, if the U.S. Internal Revenue Service ("IRS"), determines that we are a PFIC for a year with respect to which we have determined that we were not a PFIC, it may be too late for a U.S. shareholder to make a timely QEF or mark-to-market election. U.S. shareholders who hold our ADSs during a period when we are a PFIC will be generally subject to the foregoing rules, even if we cease to be a PFIC in subsequent years, subject to certain exceptions, including for U.S. shareholders who made a timely QEF or mark-to-market election. A U.S. shareholder can make a QEF election by completing the relevant portions of and filing IRS Form 8621 in accordance with the instructions thereto. A QEF election generally may not be revoked without the consent of the IRS. If an investor provides reasonable notice to us that it has determined to make a QEF election, we intend to provide annual financial information to such investor as may be reasonably required for purposes of filing United States federal income tax returns in connection with such QEF election.

U.S. investors are urged to consult their own tax advisors regarding the possible application of the PFIC rules.

The market price of our ADSs may be volatile and may fluctuate in a way that is disproportionate to our operating performance.

Our stock price may experience substantial volatility as a result of a number of factors. The market prices for securities of biotechnology companies in general have been highly volatile and may continue to be so in the future. The following factors, in addition to other risk factors described in this section, may have a significant impact on the market price of our ADSs:

- sales or potential sales of substantial amounts of our ordinary shares or ADSs;

- delay or failure in initiating, enrolling, or completing clinical trials or unsatisfactory results of these trials or events reported in any of our current or future clinical trials;
- announcements about us or about our competitors, including clinical trial results, marketing authorizations or new product introductions;
- a serious adverse event in a clinical trial and/or a long-term safety issue;
- developments concerning our licensors or product manufacturers;
- litigation and other developments relating to our patents or other proprietary rights or those of our competitors;
- conditions in the pharmaceutical or biotechnology industries;
- variations in our anticipated or actual operating results;
- governmental regulation and legislation, actual or anticipated;
- change in securities analysts' estimates of our performance, or our failure to meet analysts' expectations;
- whether, to what extent and under what conditions the FDA, MHRA or EMA will permit us to continue developing our product candidates, if at all, and if development is continued, any reports of safety issues or other adverse events observed in any potential future studies of these product candidates;
- adverse publicity;
- our ability to enter into new collaborative arrangements with respect to our product candidates;
- the terms and timing of any future collaborative, licensing or other arrangements that we may establish;
- our ability to raise additional capital to carry through with our clinical development plans and current and future operations and the terms of any related financing arrangements;
- the timing of achievement of, or failure to achieve, our and any potential future collaborators' clinical, regulatory and other milestones, such as the commencement of clinical development, the completion of a clinical trial or the receipt of marketing authorization;
- announcement of FDA, MHRA or EMA approval or non-approval of our product candidates or delays in or adverse events during the FDA, MHRA or EMA review process;
- actions taken by regulatory agencies with respect to our product candidates or products, our clinical trials or our future sales and marketing activities, including regulatory actions requiring or leading to restrictions, limitations and/or warnings in the label of an approved product candidate;
- uncontemplated problems in the supply of the raw materials used to produce our product candidates;
- the commercial success of any product approved by the FDA, MHRA, EMA or any other foreign counterpart;

- introductions or announcements of technological innovations or new products by us, our potential future collaborators, or our competitors, and the timing of these introductions or announcements;
- market conditions for equity investments in general, or the biotechnology or pharmaceutical industries in particular;
- we may have limited or very low trading volume that may increase the volatility of the market price of our ADSs;
- regulatory developments in the United States and foreign countries;
- changes in the structure or reimbursement policies of health care payment systems;
- any intellectual property infringement lawsuit involving us;
- actual or anticipated fluctuations in our results of operations;
- changes in financial estimates or recommendations by securities analysts;
- hedging activity that may develop regarding our ADSs;
- regional or worldwide recession;
- sales of our ordinary shares or ADSs by our executive officers, directors and significant shareholders;
- managerial costs and expenses;
- changes in accounting principles or practices;
- the loss of any of our key scientific or management personnel; and
- natural disasters and political and economic instability, including wars, terrorism, political unrest, results of certain elections and votes, emergence of a pandemic, or other widespread health emergencies (or concerns over the possibility of such an emergency, including for example, a resurgence of COVID-19), boycotts, adoption or expansion of government trade restrictions, and other business restrictions.

The stock markets in general, and the markets for biotechnology stocks in particular, have experienced significant volatility that has often been unrelated to the operating performance of particular companies. The financial markets continue to face significant uncertainty, resulting in a decline in investor confidence and concerns about the proper functioning of the securities markets, which decline in general investor confidence has resulted in depressed stock prices for many companies notwithstanding the lack of a fundamental change in their underlying business models or prospects. These broad market fluctuations may adversely affect the trading price of our ADSs.

In the past, class action litigation has often been instituted against companies whose securities have experienced periods of volatility in market price. Any such litigation brought against us, could result in substantial costs, which could hurt our financial condition and results of operations and divert management's attention and resources, which could result in delays of our clinical trials or commercialization efforts.

Insiders own a significant amount of our outstanding shares which could delay or prevent a change in corporate control or result in the entrenchment of management and/or the board of directors.

As of March 29, 2024, our directors and executive officers, together with their affiliates and related persons, beneficially own, in the aggregate, approximately 39% of our outstanding ordinary shares. Our Chairman,

Dr. Ray Prudo, and director, Dr. Samir Patel, each beneficially own approximately 22% and 16% of our outstanding ordinary shares, respectively. Accordingly, these shareholders, if acting together, or Dr. Prudo or Dr. Patel, each individually, may have the ability to impact the outcome of matters submitted to our shareholders for approval, including the election and removal of directors and any merger, consolidation, or sale of all or substantially all of our assets. In addition, these persons may have the ability to influence the management and affairs of our Company. Accordingly, this concentration of ownership may harm the market price of our ADSs by:

- delaying, deferring, or preventing a change in control;
- entrenching our management and/or the board of directors;
- impeding a merger, consolidation, takeover, or other business combination involving us; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

Future sales and issuances of our ordinary shares or ADSs or rights to purchase ordinary shares or ADSs pursuant to our equity incentive plans could result in additional dilution of the percentage ownership of our shareholders and could cause our share price to fall.

We expect that significant additional capital will be needed in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our shareholders may experience substantial dilution. We may sell ordinary shares (which may be represented by ADSs), convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell ordinary shares, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing shareholders, and new investors could gain rights superior to our existing shareholders. Additionally, any ordinary shares or ADSs issued pursuant to our equity incentive plan may result in material dilution to our existing shareholders.

The withdrawal of the United Kingdom from the European Union (Brexit) could adversely affect our business, financial condition, results of operations and prospects.

The UK formally left the EU on January 31, 2020 (commonly referred to as Brexit), and the EU and the UK have concluded a trade and cooperation agreement ("TCA"), which was provisionally applicable since January 1, 2021 and has been formally applicable since May 1, 2021. The TCA includes specific provisions concerning pharmaceuticals, which include the mutual recognition of GMP inspections of manufacturing facilities for medicinal products and GMP documents issued, but does not provide for wholesale mutual recognition of UK and EU pharmaceutical regulations. At present, Great Britain has implemented EU legislation on the marketing, promotion and sale of medicinal products through the Human Medicines Regulations 2012 (as amended) (under the Northern Ireland Protocol, the EU regulatory framework currently continues to apply in Northern Ireland). The regulatory regime in Great Britain therefore currently aligns in the most part with EU medicines regulations, however it is possible that these regimes will diverge more significantly in the future now that Great Britain's regulatory system is independent from the EU and the TCA does not provide for mutual recognition of UK and EU pharmaceutical legislation.

For instance, the EU Clinical Trials Regulation which became effective on January 31, 2022 and provides for a streamlined clinical trial application and assessment procedure covering multiple EU Member States has not been implemented into UK law, and a separate application must therefore be submitted for clinical trial authorization in the UK. In addition, Great Britain is no longer covered by centralized marketing authorizations (under the Northern Ireland Protocol, centralized marketing authorizations will continue to be recognized in Northern Ireland) until January 1, 2025; following which a single UK-wide marketing authorization will be required to market a medicinal product throughout the UK in accordance with the Windsor Framework outlined in the section above titled UK Regulation. Notwithstanding that there is no wholesale recognition of EU pharmaceutical legislation under the TCA, the MHRA put in place a new framework on January 1, 2024, whereby the MHRA may take into account decisions on the approval of marketing authorizations from the EMA (and certain other regulators)

when considering an application for a Great Britain marketing authorization. Any new regulations in the future could add time and expense to the conduct of our business in both the UK and EU, as well as the process by which our product candidates receive regulatory approval in the UK, the EU and elsewhere.

Provisions in our Articles of Association and under English law could make an acquisition of our Company more difficult and may prevent attempts by our shareholders to replace or remove our organization management.

Provisions in our Articles of Association may delay or prevent an acquisition or a change in management. These provisions include a staggered board and prohibition on actions by written consent of our shareholders. Although we believe these provisions collectively will provide for an opportunity to receive higher bids by requiring potential acquirors to negotiate with our board of directors, they would apply even if the offer might be considered beneficial by some shareholders. In addition, these provisions may frustrate or prevent any attempts by our shareholders to replace or remove then current management by making it more difficult for shareholders to replace members of the board of directors, which is responsible for appointing the members of management.

We do not anticipate paying cash dividends, and accordingly, shareholders must rely on appreciation in our ADSs for any return on their investment.

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Therefore, the success of an investment in our ADSs will depend upon any future appreciation in their value. There is no guarantee that our ADSs will appreciate in value or even maintain the price at which our shareholders have purchased their shares.

As of January 1, 2024, we were no longer a foreign private issuer and we are required to comply with the provisions of the Exchange Act, and the rules of Nasdaq, applicable to U.S. domestic issuers, which will continue to require us to incur significant expenses and expend time and resources.

As of January 1, 2024, we were no longer a foreign private issuer, and we are required to comply with all of the provisions applicable to a U.S. domestic issuer under the Exchange Act, including filing an annual report on Form 10-K, quarterly periodic reports and current reports for certain events, complying with the sections of the Exchange Act regulating the solicitation of proxies, requiring insiders to file public reports of their share ownership and trading activities and insiders being liable for profit from trades made in a short period of time. We are also no longer exempt from the requirements of Regulation FD promulgated under the Exchange Act related to selective disclosures. We are also no longer permitted to follow our home country's rules in lieu of the corporate governance obligations imposed by Nasdaq, and are required to comply with the governance practices required by U.S. domestic issuers listed on Nasdaq. We are also required to comply with all other rules of Nasdaq applicable to U.S. domestic issuers, including that our Articles of Association specify a quorum of no less than one-third of our outstanding ordinary shares for meetings of our common shareholders, the solicitation of proxies and the approval by our shareholders in connection with certain events such as the acquisition of stock or assets of another company, the establishment of or amendments to equity-based compensation plans for employees, a change of control and certain private placements. The regulatory and compliance costs associated with the reporting and governance requirements applicable to U.S. domestic issuers may be significantly higher than the costs we previously incurred as a foreign private issuer.

The regulatory and compliance costs associated with the reporting and governance requirements applicable to U.S. domestic issuers may be significantly higher than the costs we previously incurred as a foreign private issuer. We expect to continue to incur significant legal, accounting, insurance and other expenses and to expend greater time and resources to comply with these requirements. In addition, we may need to develop our reporting and compliance infrastructure and may face challenges in complying with the new requirements applicable to us.

We incur significant costs and demands upon management as a result of complying with the laws and regulations affecting public companies, which could harm our operating results.

As a public company, we incur significant legal, accounting and other expenses, including costs associated with public company reporting requirements. We also incur costs associated with current corporate governance

requirements, including requirements under Section 404 and other provisions of the Sarbanes-Oxley Act of 2002, as well as rules implemented by the SEC and the Nasdaq Stock Market. The regulatory and compliance costs associated with the reporting and governance requirements applicable to U.S. domestic issuers may be significantly higher than the costs we previously incurred as a foreign private issuer. The expenses incurred by public companies for reporting and corporate governance purposes have increased dramatically in recent years.

U.S. investors may not be able to enforce their civil liabilities against our Company or certain of our directors, controlling persons and officers.

It may be difficult for U.S. investors to bring and/or effectively enforce suits against our Company outside of the United States. We are a public limited company incorporated in England and Wales under the Companies Act 2006, as amended (the "Companies Act"). A majority of our directors are not residents of the United States, and all or substantial portions of their assets are located outside of the United States. As a result, it may be difficult for U.S. holders of our ordinary shares or ADSs to effect service of process on these persons within the United States or to make effective recovery in the United States by enforcing any judgments rendered against them. In addition, if a judgment is obtained in the U.S. courts based on civil liability provisions of the U.S. federal securities laws against us or our directors or officers, it may, depending on the jurisdiction, be difficult to enforce the judgment in the non-U.S. courts against us and any of our non-U.S. resident executive officers or directors. Accordingly, U.S. shareholders may be forced to bring legal proceedings against us and our respective directors and officers under English law and in the English courts in order to enforce any claims that they may have against us or our directors and officers. The enforceability of a U.S. judgment in the United Kingdom will depend on the particular facts of the case as well as the laws and treaties in effect at the time. The United States and the United Kingdom do not currently have a treaty providing for reciprocal recognition and enforcement of judgments (other than arbitration awards) in civil and commercial matters. Nevertheless, it may be difficult for U.S. shareholders to bring an original action in the English courts to enforce liabilities based on the U.S. federal securities laws against us and any of our non-U.S. resident executive officers or directors.

The rights of our shareholders may differ from the rights typically offered to shareholders of a U.S. corporation.

We are incorporated under English law. The rights of holders of ordinary shares and, therefore, certain of the rights of holders of ADSs, are governed by English law, including the provisions of the Companies Act, and by our Articles of Association. These rights differ in certain respects from the rights of shareholders in typical U.S. corporations.

Provisions in the UK City Code on Takeovers and Mergers may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our shareholders.

The UK City Code on Takeovers and Mergers ("Takeover Code"), applies, among other things, to an offer for a public company whose registered office is in the United Kingdom and whose securities are not admitted to trading on a regulated market in the United Kingdom if the company is considered by the Panel on Takeovers and Mergers ("Takeover Panel"), to have its place of central management and control in the United Kingdom. This is known as the "residency test." The test for central management and control under the Takeover Code is different from that used by the UK tax authorities. Under the Takeover Code, the Takeover Panel will determine whether we have our place of central management and control in the United Kingdom by looking at various factors, including the structure of our board of directors, the functions of the directors and where they are resident. As at the date of this report, our place of central management and control is not, and is not expected to be, in the UK (or the Channel Islands or the Isle of Man) for the purposes of the jurisdictional criteria of the Takeover Code. Accordingly, we are not currently subject to the Takeover Code and, as a result, our shareholders are not currently entitled to benefit from certain takeover offer protections provided under the Takeover Code, including the rules regarding mandatory takeover bids (a summary of which is set out below). In the event that this changes, or if the interpretation and application of the Takeover Code by the Takeover Panel, changes (including changes to the way in which the Takeover Panel assesses the application of the Takeover Code to English companies whose shares are listed outside of the UK), the Takeover Code may apply to us in the future.

If at the time of a takeover offer the Takeover Panel determines that we have our place of central management and control in the United Kingdom, we will be subject to a number of rules and restrictions, including

but not limited to the following: (1) our ability to enter into deal protection arrangements with a bidder will be extremely limited; (2) we may not, without the approval of our shareholders, be able to perform certain actions that could have the effect of frustrating an offer, such as issuing shares or carrying out acquisitions or disposals; and (3) we will be obliged to provide equality of information to all bona fide competing bidders.

Further, the Takeover Code contains certain rules in respect of mandatory offers. Under Rule 9 of the Takeover Code, if a person: (a) acquires an interest in our shares which, when taken together with shares in which he or persons acting in concert with him are interested, carry 30% or more of our voting rights; or (b) who, together with persons acting in concert with him, is interested in shares that in the aggregate carry not less than 30% of our voting rights and does not hold shares carrying more than 50% of our voting rights, acquires additional interests in shares that increase the percentage of shares carrying voting rights in which that person is interested, the acquirer and, depending on the circumstances, its concert parties, will be required (except with the consent of the Takeover Panel) to make a cash offer for our outstanding shares at a price not less than the highest price paid for any interest in our shares by the acquirer or its concert parties during the previous 12 months.

Holders of ADSs must act through the depositary to exercise their rights as shareholders of our Company.

Holders of our ADSs do not have the same rights of our shareholders and may only exercise the voting rights with respect to the underlying ordinary shares in accordance with the provisions of the deposit agreement for the ADSs. Under our Articles of Association, the minimum notice period required to convene a general meeting is 14 clear days' notice (or, for an annual general meeting, 21 clear days' notice (unless, in the case of an annual general meeting, all members entitled to attend and vote at the meeting, or, in the case of any other general meeting, a majority in number of the members entitled to attend and vote who hold not less than 95% of the voting shares (excluding treasury shares), agree to shorter notice)). When a general meeting is convened, holders of our ADSs may not receive sufficient notice of a shareholders' meeting to permit them to withdraw their ordinary shares to allow them to cast their vote with respect to any specific matter. In addition, the depositary and its agents may not be able to send voting instructions to holders of our ADSs or carry out their voting instructions in a timely manner. We will make all reasonable efforts to cause the depositary to extend voting rights to holders of our ADSs in a timely manner, but we cannot assure them that they will receive the voting materials in time to ensure that they can instruct the depositary to vote their ADSs. Furthermore, the depositary and its agents will not be responsible for any failure to carry out any instructions to vote, for the manner in which any vote is cast or for the effect of any such vote. As a result, holders of our ADSs may not be able to exercise their right to vote and they may lack recourse if their ADSs are not voted as they requested. In addition, in the capacity as an ADS holder, they will not be able to call a shareholders' meeting.

Holders of our ADSs may be subject to limitations on transfers of 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.

The rights of holders of our ADSs to participate in any future rights offerings may be limited, which may cause dilution to their holdings and they may not receive cash dividends if it is impractical to make them available to them.

We may from time to time distribute rights to our shareholders, including rights to acquire our securities. However, we cannot make rights available to holders of our ADSs in the United States unless we register the rights and the securities to which the rights relate under the Securities Act or an exemption from the registration requirements is available. Also, under the deposit agreement, the depositary will not make rights available to holders of our ADSs unless either both the rights and any related securities are registered under the Securities Act, or the distribution of them to ADS holders is exempted from registration under the Securities Act. We are under no obligation to file a registration statement with respect to any such rights or securities or to endeavor to cause such a registration statement to be declared effective. Moreover, we may not be able to establish an exemption from

registration under the Securities Act. Accordingly, holders of our ADSs may be unable to participate in our rights offerings and may experience dilution in their holdings.

In addition, the depositary has agreed to pay to holders 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. Holders of our ADSs will receive these distributions in proportion to the number of ordinary shares their ADSs represent. However, the depositary may, at its discretion, decide that it is inequitable or impractical to make a distribution available to any holders of ADSs. For example, the depositary may determine that it is not practicable to distribute certain property through the mail, or that the value of certain distributions may be less than the cost of mailing them. In these cases, the depositary may decide not to distribute such property and holders of our ADSs will not receive any such distribution.

Risks Related to the Proposed Merger with Peak Bio

There is no guarantee that the Merger will increase shareholder value or that Peak Bio will be successfully integrated into our operations or achieve its desired benefits.

As previously disclosed in our Form 8-K filed with the SEC on March 11, 2024, we entered into the Merger Agreement in connection with the Merger, with Peak Bio surviving the Merger as a wholly-owned subsidiary of us. We cannot guarantee our integration efforts as a result of the Merger and the related transactions will not impair shareholder value or otherwise adversely affect our business. The Merger poses significant integration challenges between our businesses and management teams that could result in management and business disruptions, any of which could harm our results of operation, business prospects, and impair the value of such Merger to our shareholders.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Cybersecurity Risk Management and Strategy

In recognition of the evolving cybersecurity threat landscape, we acknowledge the increasing sophistication and frequency of cybersecurity incidents. While we cannot completely protect against the possibility of a cybersecurity incident occurring, we take measures designed to mitigate risks from cybersecurity threats, including those implemented by our third-party managed services provider.

As part of our cybersecurity procedures, we leverage a number of security controls, including network and device monitoring and system backup procedures. We work to mitigate risks from cybersecurity threats stemming from third-party vendors by providing them with access only to systems that they need to provide services to us.

We have not identified any cybersecurity incidents or threats that have materially affected us or are reasonably likely to materially affect us, including our business strategy, results of operations, or financial condition. However, like

other companies in our industry, we and our third-party vendors have from time to time experienced threats that could affect our information or systems. For more information, please see “Item 1A, Risk Factors.”

Cybersecurity Governance

Senior management, including the Chief Executive Officer and Chief Financial Officer, are responsible for implementation of the Company’s risk management controls, including controls in connection with risks from cybersecurity threats.

The Audit Committee of our Board of Directors is primarily responsible for overseeing the Company's compliance and risk management obligations, including the management of risks from cybersecurity threats. Pursuant to its charter, the Audit Committee is responsible for monitoring the effectiveness of the Company’s information system and cybersecurity controls.

On a quarterly basis, the Audit Committee discusses with senior management, and internal audit, if applicable, the Company’s processes for assessing, identifying, and managing material risks from cybersecurity threats and the state of the Company’s cybersecurity processes. The Audit Committee also receives updates on, and monitors, the Company’s prevention, detection, mitigation and remediation of cybersecurity incidents.

Item 2. Properties.

We currently lease office space for both our U.K. and U.S. headquarters on a short-term basis. The lease for our U.K. headquarters, located in London, expires in August 2024, unless terminated earlier with not less than three months notice. We lease our U.S. headquarters office space, located in Boston, MA, on a month-to-month basis. We are not party to any material lease agreements.

Item 3. Legal Proceedings.

From time to time, we may become involved in litigation relating to claims arising out of operations in the normal course of business, which we consider routine and incidental to our business. We currently are not a party to any legal proceedings the adverse outcome of which, in management’s opinion, would have a material adverse effect on our business, results of operation or financial condition.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our ordinary shares, $0.0001 par value per share, in the form of ADSs, currently trade on the Nasdaq Capital Market under the symbol "AKTX".

ADS Ratio Changes

Currently, each ADS represents 2,000 ordinary shares, par value $0.0001 (the "Ordinary Shares"). The following summarizes historical changes to the ratio of ADSs to Ordinary Shares:

- Effective January 3, 2014, we changed the ratio of our ADSs to Ordinary Shares from one ADS representing two Ordinary Shares to a new ratio of one ADS representing ten Ordinary Shares.
- Effective September 17, 2015, we changed the ratio of our ADSs to Ordinary Shares from one ADS representing ten Ordinary Shares to a new ratio of one ADS representing one hundred Ordinary Shares.
- Effective August 17, 2023, we changed the ratio of our ADSs to Ordinary Shares from one ADS representing 100 ordinary shares to a new ratio of one ADS representing 2,000 ordinary shares (the "ADS Ratio Change").

Holders of Record

As of March 15, 2024, we had approximately 350 shareholders of record registered on our books, excluding shares held through banks and brokers. Of the approximate 350 shareholders, 50 hold our ordinary shares through ADSs.

Dividends

We have never declared or paid cash dividends on our common stock, and we do not expect to pay any cash dividends on our common stock in the foreseeable future. The declaration and payment of dividends in the future, of which there can be no assurance, will be determined by our board of directors in light of conditions then existing, including earnings, financial condition, capital requirements, and other factors.

Recent Sales of Unregistered Securities

The privately placed unregistered securities described below were offered and sold pursuant to an exemption from the registration requirements under Section 4(a)(2) of the Securities Act and Rule 506 of Regulation D promulgated thereunder since, among other things, the transactions did not involve a public offering and the securities were acquired for investment purposes only and not with a view to or for sale in connection with any distribution thereof.

December 2023 Private Placement

In December 2023, we entered into purchase agreements to sell in a private placement to existing investors, Dr. Prudo, our Chairman, and Dr. Samir Patel, our director, (the "December 2023 Private Placement") an aggregate of 947,868 ADSs at $2.11 per ADS, resulting in net proceeds of approximately $1.8 million after deducting placement agent fees and other expenses.

September 2023 Private Placement

In September 2023, we entered into purchase agreements to sell in a private placement to certain existing investors, including Dr. Ray Prudo, our Chairman, and Ms. Rachelle Jacques, our President and CEO (the "September 2023 Private Placement") an aggregate of 551,816 ADSs at $3.30 per ADS, and pre-funded warrants (the "Pre-Funded Warrants") to purchase up to 48,387 ADSs at a purchase price per Pre-Funded Warrant of $3.10, for aggregate gross proceeds of approximately $2.0 million. The Pre-Funded Warrants are exercisable at an exercise price of $0.20 per ADS and will not expire until exercised in full. In connection with this offering, we agreed to issue to Paulson Investment Company, LLC ("Paulson"), as placement agent for the September 2023 Private Placement, warrants to purchase 42,550 ADSs at an exercise price of $4.13 per ADS (representing 125% of the price per ADS in the September 2023 Private Placement) and a term expiring on September 22, 2028. Closing of the September 2023 Private Placement occurred on October 6, 2023. Net proceeds, after deducting placement agent fees and other expenses, were approximately $1.7 million.

The privately placed securities above were offered and sold pursuant to an exemption from the registration requirements under Section 4(a)(2) of the Securities Act and Rule 506 of Regulation D promulgated thereunder since, among other things, the transactions did not involve a public offering and the securities were acquired for investment purposes only and not with a view to or for sale in connection with any distribution thereof.

Issuer Purchases of Equity Securities

We did not repurchase any of our equity securities during the fiscal year ended December 31, 2023.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read together with our consolidated audited financial statements and accompanying notes appearing elsewhere in this Form 10-K. In addition to historical information, this discussion and analysis includes forward-looking statements that are subject to risks and uncertainties, including those discussed in the section titled "Risk Factors," set forth in Part I, Item 1A of this Form 10-K, that could cause actual results to differ materially from historical results or anticipated results.

Overview

We are a clinical-stage biotechnology company focused on developing advanced therapies for autoimmune and inflammatory diseases involving the complement component 5 ("C5") and leukotriene B4 ("LTB4") pathways. Each of these pathways has scientifically well-supported causative roles in the diseases we are targeting. We believe that blocking early mediators of inflammation will prevent initiation and continual amplification of the processes that cause certain diseases. Our activities since inception have consisted of performing research and development activities and raising capital.

Our lead product candidate, nomacopan, is a recombinant small protein (16,769 Da) derived from a protein originally discovered in the saliva of the *Ornithodoros moubata* tick, which modulates the host immune system to allow the parasite to feed without alerting the host to its presence or provoking an immune response. Nomacopan is a second-generation complement inhibitor which has been shown to act on complement C5, preventing release of C5a and formation of C5b–9 (also known as the membrane attack complex ("MAC")), and also independently and specifically inhibit LTB4 activity, both elements that are often co-located as part of the immune/inflammatory response. We believe the importance of nomacopan's therapeutic potential is twofold. First, its dual inhibitory action may be able to prevent inflammatory and prothrombotic activities of two key pathways, and second, nomacopan's bio-physical properties may allow it to be used in a variety of formulations and routes of administration, including subcutaneous, intravenous, topical to eye, inhaled and intravitreous.

We are currently conducting a clinical trial of subcutaneous nomacopan for the treatment of hematopoietic stem cell transplant-related thrombotic microangiopathy ("HSCT-TMA") in pediatric patients. We are planning for potential registrational Phase 3 trials of nomacopan in adult and pediatric HSCT-TMA. We are also investigating long-acting PASylated-nomacopan ("PAS-nomacopan") for treatment of geographic atrophy ("GA") secondary to dry age-related macular degeneration ("dry AMD") in preclinical studies.

Recent Developments

Merger

As previously disclosed in our Form 8-K filed with the SEC on March 11, 2024, we entered into the Merger Agreement with Peak Bio and Merger Sub, pursuant to which, upon the terms and subject to the conditions thereof, Merger Sub will be merged with and into Peak Bio (the "Merger"), with Peak Bio surviving the Merger as a wholly-owned subsidiary of Akari. See Part I, Item 1, Business for further details.

Results of Operations

Comparison of the Years Ended December 31, 2023 and 2022

Overview

During the year ended December 31, 2023, our loss from operations totaled $16.8 million, a 27% decrease, compared to a loss from operations of $23.1 million for the year ended December 31, 2022. General and administrative expenses comprise the majority of our total operating expenses, as shown in the table below:

	Year Ended December 31,		Change	
($ in thousands)	**2023**	**2022**	**$**	**%**
Operating expenses:				
Research and development	$ 5,450	$ 9,561	$ (4,111)	-43%
General and administrative	11,356	13,527	(2,171)	-16%
Total operating expenses	$ 16,806	23,088	$ (6,282)	-27%
Loss from operations	$ (16,806)	$ (23,088)	$ 6,282	-27%

Research and development expenses

Our research and development expenses are charged to operations as incurred and we incur both direct and indirect expenses for each of our programs. We track direct research and development expenses by preclinical and clinical programs, which may include third-party costs such as CROs, contract laboratories, consulting, and clinical trial costs. We do not allocate indirect research and development expenses, which may include product development and manufacturing, clinical, medical, regulatory, laboratory (equipment and supplies), personnel, facility and other overhead costs, to specific programs.

During the year ended December 31, 2023, total research and development expenses decreased by approximately $4.1 million, or 43%, as compared to the year ended December 31, 2022. The following sets forth research and development expenses for the years ended December 31, 2023 and 2022 by category:

	Year Ended December 31,		Change	
($ in thousands)	**2023**	**2022**	**$**	**%**
Clinical Trials:				
HSCT-TMA clinical development (AK901)	$ 1,802	$ 1,115	$ 687	62%
BP clinical development (AK802)	(1,073)	3,605	(4,678)	-130%
Chemistry, manufacturing and control	2,684	3,912	(1,228)	-31%
Other external development expenses	1,498	1,161	337	29%
Personnel costs	3,110	2,086	1,024	49%
Tax credits	(2,571)	(2,318)	(253)	11%
Total research and development expenses	$ 5,450	$ 9,561	$ (4,111)	-43%

HSCT-TMA clinical development (AK901)

These expenses include external expenses that we have incurred in connection with the development of nomacopan for the treatment of pediatric HSCT-TMA and primarily consist of payments to CROs and other vendors. The 62% increase in expenses incurred during the 2023 period, as compared to 2022, is primarily due to the prioritization of our HSCT program in 2023, as announced in the second half of 2022, and related timing of clinical activities.

BP clinical development (AK802)

These expenses include external expenses that we have incurred in connection with the development of nomacopan for the treatment of bullous pemphigoid (“BP”) and primarily consist of payments to CROs and other vendors. In 2022 we discontinued our BP clinical program and in connection with the final reconciliation of clinical trial

close-out costs, we recorded a $1.1 million credit in 2023 and do not expect to incur material additional costs related to this program.

Chemistry, manufacturing and control

These expenses include external expenses incurred related to the development and manufacturing of nomacopan for use in clinical trials and development of PAS-nomacopan. Such expenses primarily consist of payments to CMOs and other vendors for manufacturing of drug substances (including raw materials), drug product, supplies, and validation, quality assurance and manufacturing development activities. The 31% decrease in expenses incurred during the 2023 period, as compared to 2022, is primarily due to decreases in costs incurred for manufacturing of nomacopan due to timing of manufacturing, partially offset by increased spending on the development of PAS-nomacopan.

Other external development expenses

These expenses include external expenses, such as payments to contract vendors, that may be related to preclinical development activities, other discontinued programs and unallocated expenses. The 29% increase in expenses incurred during the 2023 period, as compared to 2022, is primarily related to the investigation of PAS-nomacopan for the treatment of GA secondary to dry AMD in preclinical studies to support an IND filing.

Personnel costs

These expenses include compensation and related costs associated with employees, independent consultants and staffing firms. The 49% increase during the 2023 period, as compared to 2022, is primarily due to changes in our organizational structure, including a shift to U.S.-based employees and consultants.

Tax credits

We record receipts of U.K. tax credits in the year received as a reduction in research and development expenses. Changes in tax credits received are the result of eligible research and development expenses incurred in the previous tax year, which can fluctuate depending on timing of and location in which expenses are incurred.

The extent of our future research and development expenditures will be determined based on future funding and following the outcome of an assessment of our combined pipeline following closing of the Merger, including program prioritization.

General and administrative expenses

During the year ended December 31, 2023, total general and administrative costs decreased by approximately $2.2 million, or 16%, as compared to the year ended December 31, 2022, primarily due to decreases in (i) financing-related costs of approximately $1.7 million as a result of costs incurred during the 2023 period being classified in shareholders' equity, (ii) directors' and officers' insurance premiums of approximately $0.6 million, and (iii) personnel costs (including directors and consultants) of approximately $1.5 million. These decreases were partially offset by increases in other expenses, including legal and professional fees of approximately $1.4 million, of which $0.8 million are costs incurred related to the proposed Merger.

Interest income

During each of the years ended December 31, 2023 and 2022, interest income was less than $0.1 million and not material. The nominal increase in interest income during 2023, as compared to 2022, was primarily due to higher interest rates. Amounts may fluctuate from period to period due to changes in average cash balances and prevailing interest rates.

Excess in fair value of warrant liability over cash proceeds

During the year ended December 31, 2022, we recorded a loss of $2.0 million for the excess in fair value of our liability-classified September 2022 Warrants issued over cash proceeds received in connection with our September 2022 Registered Offering. See Note 5 of the notes to the consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K for further details. No such loss was recorded during the year ended December 31, 2023.

Change in fair value of warrant liability

During the years ended December 31, 2023 and 2022, we recorded a change in the fair value of warrant liability, representing a non-cash warrant revaluation gain of approximately $6.6 million and $6.9 million, respectively, related to our liability-classified September 2022 Warrants, as more fully described in Note 5 of the notes to the consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K. Due to the nature of and inputs in the model used to assess the fair value of our outstanding September 2022 Warrants, it is not abnormal to experience significant fluctuations during each remeasurement period. These fluctuations may be due to a variety of factors, including changes in our stock price and changes in estimated stock price volatility over the remaining life of the warrants. Changes in the fair value of the warrant liability and resulting warrant revaluation gains for each of the years ended December 31, 2023 and December 31, 2022 was driven primarily by the decrease in our stock price during each of the reporting periods.

Foreign currency exchange gain, net

During the years ended December 31, 2023 and 2022, we recorded a net foreign currency exchange gain of $0.1 million and $0.5 million, respectively. Exchange gains and losses can fluctuate significantly from period to period due to changes in exchange rates as well as the volume and timing of expenditures and related payments denominated in foreign currencies.

Other expense, net

During the years ended December 31, 2023 and 2022, we recorded a net other expense of less than $0.1 million and approximately $0.1 million respectively. Such expenses are not material to our results of operations.

Net Loss Applicable to Common Shareholders

As a result of the factors discussed above, our net loss applicable to common shareholders for the years ended December 31, 2023 and 2022 was $10.0 million and $17.7 million, respectively.

Financial Condition, Liquidity and Capital Resources

Sources of Liquidity

Since inception, we have incurred substantial losses, and we have primarily funded our operations with proceeds from the sale of equity securities, including ordinary shares, warrants and pre-funded warrants. At December 31, 2023, we had $3.8 million in cash and an accumulated deficit of $227.5 million. To date, we have not generated any revenue.

We have devoted substantially all of our efforts to research and development, including clinical trials, and we have not commercialized any products. Our research and development activities, together with our general and administrative expenses, are expected to continue to result in substantial operating losses for the foreseeable future. These losses, among other things, have had and will continue to have an adverse effect on our shareholders' equity, total assets and working capital. Due to the numerous risks and uncertainties associated with developing drug candidates and, if approved, commercial products, we are unable to predict the extent of any future losses, whether or when any of our drug candidates will become commercially available or when we will become profitable, if at all. Our future capital requirements will depend on many factors, including:

- the progress and costs of our preclinical studies, clinical trials and other research and development activities;
- the scope, prioritization and number of our clinical trials and other research and development programs;
- the amount of revenues and contributions we receive under future licensing, development and commercialization arrangements with respect to our product candidates;
- the costs of the development and expansion of our operational infrastructure;
- the costs and timing of obtaining regulatory approval for our product candidates;
- the costs of filing, prosecuting, enforcing and defending patent claims and other intellectual property rights;
- the costs and timing of securing manufacturing arrangements for clinical or commercial production;
- the costs of contracting with third parties to provide sales and marketing capabilities for us;
- the magnitude of our general and administrative expenses; and
- any cost that we may incur under future in- and out-licensing arrangements relating to our product candidates.

We currently do not have any commitments for future external funding. We will need to raise additional funds, and we may decide to raise additional funds even before we need such funds if the conditions for raising capital are favorable. Until we can generate significant recurring revenues, we expect to satisfy our future cash needs through debt or equity financings, credit facilities or by out-licensing applications of our product candidates. The sale of equity or convertible debt securities may result in dilution to our existing shareholders. The incurrence of indebtedness would result in increased fixed obligations and could also subject us to covenants that restrict our operations. We cannot be certain that additional funding, whether through grants, financings, credit facilities or out-licensing arrangements, will be available to us on acceptable terms, if at all. If sufficient funds are not available, we may be required to delay, reduce the scope of or eliminate research or development plans for, or commercialization efforts with respect to, one or more applications of our product candidates, or obtain funds through arrangements with collaborators or others that may require us to relinquish rights to certain potential products that we might otherwise seek to develop or commercialize independently.

December 2023 Private Placement

In December 2023, we entered into purchase agreements to sell in a private placement to existing investors, Dr. Ray Prudo, our Chairman, and Dr. Samir Patel, our director, (the "December 2023 Private Placement") an aggregate of 947,868 ADSs at $2.11 per ADS, for aggregate gross proceeds of approximately $2.0 million. Net proceeds from the December 2023 Private Placement was approximately $1.8 million after deducting placement agent fees and other expenses.

September 2023 Private Placement

In September 2023, we entered into purchase agreements to sell in a private placement to existing investors, including Dr. Ray Prudo, our Chairman, and Ms. Rachelle Jacques, our President and CEO (the "September 2023 Private Placement") an aggregate of 551,816 ADSs at $3.30 per ADS, and pre-funded warrants (the "Pre-Funded Warrants") to purchase up to 48,387 ADSs at a purchase price per Pre-Funded Warrant of $3.10, for aggregate gross proceeds of approximately $2.0 million. The Pre-Funded Warrants are exercisable at an exercise price of $0.20 per ADS and will not expire until exercised in full. The September 2023 Private Placement closed in October 2023 resulting in net proceeds of approximately $1.7 million after deducting placement agent fees and other expenses.

At close of the September 2023 Private Placement, the Company issued to Paulson Investment Company, LLC ("Paulson"), as placement agent for the September 2023 Private Placement, warrants to purchase 42,550 ADSs at an exercise price of $4.13 per ADS (representing 125% of the price per ADS in the September 2023 Private Placement) and a term expiring on October 6, 2028 (the "October 2023 Placement Agent Warrants"). The estimated fair value of the October 2023 Placement Agent Warrants on the issuance date was approximately $0.1 million.

March 2023 Registered Direct Offering

In March 2023, we sold to certain accredited and institutional investors, led by our existing investors, including Dr. Ray Prudo, our Chairman, an aggregate of 1,333,333 ADSs in a registered direct offering (the "March 2023 Registered Offering"), at $3.00 per ADS for aggregate gross proceeds of approximately $4.0 million. Net proceeds after deducting placement agent fees and other expenses were approximately $3.5 million.

September 2022 Registered Offering

In September 2022, we sold to certain accredited and institutional investors, including our former Executive Chairman and current Chairman of the Board of Directors, Dr. Ray Prudo, an aggregate of 755,000 ADSs in a registered direct offering (the "September 2022 Registered Offering"), at $17.00 per ADS for aggregate gross proceeds of approximately $12.8 million. In addition, we issued to the investors in a private placement (the "September 2022 Private Placement") that closed simultaneously with the September 2022 Registered Offering (i) Series A warrants exercisable to purchase up to 755,000 ADSs at an exercise price of $17.00 per ADS and (ii) Series B warrants exercisable to purchase up to 755,000 ADSs at an exercise price of $17.00 per ADS (the Series A and B warrants collectively, the "September 2022 Warrants"). The September 2022 Warrants became exercisable immediately following the date of issuance and expire two years following issuance, in the case of the Series A warrants, and seven years following issuance, in the case of the Series B warrants. Net proceeds after deducting placement agent fees and other expenses were approximately $11.8 million.

March 2022 Registered Offering

In March 2022, we sold to certain accredited and institutional investors, led by our existing investors, including Dr. Ray Prudo, our Chairman, an aggregate of 372,042 ADSs in a registered direct offering (the "March 2022 Registered Offering"), at $24.00 per ADS for aggregate gross proceeds of approximately $8.9 million. In connection with this offering, we issued to the investors and Paulson, as placement agent for the March 2022 Registered Offering, registered warrants to purchase 186,020 ADSs at $28.00 per ADS and 14,882 ADSs at $30.00 per ADS, respectively. Net proceeds after deducting placement agent fees and other expenses were approximately $8.1 million.

2021 Registered Offering

In December 2021, we sold to certain accredited and institutional investors, led by our existing investors, including Dr. Ray Prudo, our Chairman, an aggregate of 215,550 ADSs in a registered direct offering (the "2021 Registered Offering") at $28.00 per ADS for aggregate gross proceeds of approximately $6.0 million, which closed on January 5, 2022. As of December 31, 2021, we had received approximately $1.1 million of gross proceeds which were classified as current liabilities on our balance sheet until closing in January 2022, which at that time the remaining $4.9 million in gross proceeds were received. In connection with the offering, we issued to the investors and Paulson, as placement agent for the 2021 Registered Offering, registered warrants to purchase 107,775 ADSs at $33.00 per ADS and 8,622 ADSs at $35.00 per ADS, respectively. Net proceeds after deducting placement agent fees and other expenses were approximately $5.4 million, of which $4.3 million was received in 2022.

Funding Requirements

As of the date of this report, we expect our existing cash, which includes gross proceeds of approximately $2.0 million received in connection with the March 2024 Private Placement (as defined below), will be sufficient to fund our operations through April 2024. While we have additional funding activities in progress to fund our operations through the anticipated closing of the Merger by the end of the second quarter of 2024, we will need to raise additional capital to continue to fund our operations and service our obligations in the future. If we are unable to raise additional capital when needed, we will not be able to continue as a going concern. We do not currently have any products approved for sale and do not generate any revenue from product sales. We are currently seeking and expect to continue to seek additional funding through financings of equity and/or debt securities. We may also engage in strategic research and development collaborations, clinical funding arrangements, the sale or license of technology assets, and/or other strategic alternatives.

Financing may not be available to us when we need it, or on favorable or acceptable terms, or at all. We could be required to seek funds through means that may require us to relinquish rights to some of our technologies, drug candidates or drugs that we would otherwise pursue on our own. In addition, if we raise additional funds by issuing equity securities, our then existing shareholders may experience dilution. The terms of any financing may adversely affect the holdings or the rights of existing shareholders. An equity financing that involves existing shareholders may cause a concentration of ownership. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, and are likely to include rights that are senior to the holders of our ordinary shares. Any additional debt or equity financing may contain terms which are not favorable to us or to our shareholders, such as liquidation and other preferences, or liens or other restrictions on our assets. As discussed in Note 9 to the consolidated financial statements included elsewhere in this Form 10-K, additional equity financings may also result in cumulative changes in ownership over a three-year period in excess of 50% which would limit the amount of net operating loss and tax credit carryforwards that we may utilize in any one year.

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 strategic alliances for research and development programs at an earlier stage than otherwise would be desirable or that we otherwise would have sought to develop independently, or on terms that are less favorable than might otherwise be available in the future;
- dispose of technology assets, including current product candidates, or relinquish or license on unfavorable terms, our rights to technologies or any of our product candidates that we otherwise would seek to develop or commercialize ourselves;
- pursue the sale of our company to a third party at a price that may result in a loss on investment for our shareholders; or
- file for bankruptcy or cease operations altogether.

Any of these events could have a material adverse effect on our business, operating results, and prospects.

We believe the key factors which will affect our ability to obtain funding are:

- the receptivity of the capital markets to financings by biotechnology companies generally and companies with drug candidates and technologies similar to ours specifically;
- the receptivity of the capital markets to any in-licensing, product acquisition or other transaction we may enter into or attempt to enter into;
- our ability to successfully integrate operations with Peak Bio following the Merger and realize anticipated benefits of the Merger;
- the results of our clinical development activities in our drug candidates we develop on the timelines anticipated;
- competitive and potentially competitive products and technologies and investors' receptivity to our drug candidates we develop and the technology underlying them in light of competitive products and technologies;
- the cost, timing, and outcome of regulatory reviews; and
- our transition out of foreign private issuer status and compliance with Exchange Act requirements.

In addition, increases in expenses or delays in clinical development may adversely impact our cash position and require additional funds or cost reductions.

Based on our recurring losses from operations incurred since inception, our expectation of continuing operating losses for the foreseeable future, negative operating cash flows for the foreseeable future, and the need to raise additional capital to finance its future operations, we have concluded that there is substantial doubt regarding our ability to continue as a going concern within one year after the date that our consolidated financial statements, included elsewhere in this Annual Report on Form 10-K (such consolidated financial statements, the "consolidated financial statements") are issued. Because of these uncertainties, the accompanying consolidated financial statements have been prepared assuming that we will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. As such, the accompanying consolidated financial statements do not reflect any adjustments relating to the recoverability and classification of recorded assets and liabilities that might be necessary if we are unable to continue as a going concern.

Cash Flows

The following table summarizes our sources and uses of cash for each of the periods presented (in thousands):

	Year Ended December 31,	
(In thousands)	**2023**	**2022**
Net cash (used in) provided by:		
Net cash used in operating activities	$ (16,432)	$ (21,504)
Net cash provided by financing activities	7,020	25,288
Effect of exchange rates on cash	7	105
Net (decrease) increase in cash	$ (9,405)	$ 3,889

Operating Activities. The net cash used in operating activities for the periods presented consists primarily of our net loss adjusted for non-cash charges and changes in components of working capital. The decrease in cash used in operating activities during the year ended December 31, 2023, as compared to the 2022 period, was primarily due to a $6.3 million decrease in operating expenses, as more fully described above under the heading "Results of Operations," and the net impact of changes in components of working capital.

Investment Activities. There were no investing activities during the years ended December 31, 2023 and 2022.

Financing Activities. Net cash provided by financing activities primarily consisted of the following:

- For the year ended December 31, 2023, an aggregate of $7.0 million in net proceeds received from various offerings of equity securities, including (i) $3.5 million in net proceeds from the March 2023 Registered Direct Offering, (ii) $1.7 million in net proceeds from the September 2023 Private Placement, and (iii) $1.8 million in net proceeds from the December 2023 Private Placement;

- For the year ended December 31, 2022, an aggregate of $25.3 million in net proceeds received from various offerings of equity securities, including (i) $4.3 million in net proceeds from our 2021 Registered Offering received in January 2022, (ii) $8.1 million in net proceeds received from the March 2022 Registered Direct Offering, and (iii) $12.8 million in gross proceeds (issuance costs associated with our September 2022 Registered Offering were expensed as incurred).

Material Cash Requirements

Insurance Financing Obligations

In January 2024, we entered into a short-term financing arrangement with a third-party vendor to finance insurance premiums. The aggregate amount financed under this agreement was $1.1 million which is scheduled to be paid in monthly installments through November 2024.

Other

As of the filing date of this Form 10-K, we have certain non-cancellable manufacturing-related obligations, the majority of which relate to the manufacture of PAS-nomacopan. These obligations are expected to result in payments of approximately $3.5 million in the third quarter of 2024.

We enter into a variety of agreements and financial commitments in the normal course of business. The terms generally provide us the option to cancel, reschedule and adjust our requirements based on our business needs, prior to the delivery of goods or performance of services. However, it is not possible to predict the amount of future payments under these agreements due to the conditional nature of our obligations and the unique facts and circumstances involved in each particular agreement.

Critical Accounting Estimates

This management's discussion and analysis of financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. GAAP. In doing so, we must make estimates and assumptions that affect our reported amounts of assets, liabilities and expenses, as well as related disclosure of contingent assets and liabilities. On an ongoing basis, management evaluates its estimates and judgments, including, but not limited to, those related to (i) stock-based compensation, (ii) fair value of warrants classified as liabilities, (iii) research and development prepayments, accruals and related expenses, and (iv) the valuation allowance for deferred income taxes. Management bases its estimates and judgments on historical experience and on various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We regard an accounting estimate or assumption underlying our financial statements as a "critical accounting estimate" if:

- the nature of the estimate or assumption is material due to the level of subjectivity and judgment necessary to account for highly uncertain matters or the susceptibility of such matters to change; and

- the impact of the estimates and assumptions on financial condition or operating performance is material.

While our significant accounting policies are described in more detail in Note 2 to our consolidated financial statements appearing elsewhere in this Form 10-K, we believe the following accounting policies to be the most critical to the judgments and estimates used in the preparation of our financial statements.

Stock-based compensation

We measure all stock-based awards granted to employees, directors and non-employees based on the estimated fair value on the date of grant and recognizes compensation expense of those awards over the requisite service period, which is generally the vesting period of the respective awards. Forfeitures are accounted for as they occur. We classify stock-based compensation expense in our consolidated statements of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

The fair value of each restricted ordinary share award is estimated on the date of grant based on the fair value of our ordinary shares on that same date. The fair value of each option grant is estimated on the date of grant using the Black-Scholes option pricing model, which requires inputs based on certain assumptions, including the expected stock price volatility, the expected term of the award, the risk-free interest rate, and expected dividends. We estimate our expected stock price volatility based on the historical volatility of our ADSs, considering the expected term of the options. The expected term of our options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that we have never paid cash dividends on ordinary shares and do not expect to pay any cash dividends in the foreseeable future.

Fair value of warrants classified as liabilities

We utilize a Black-Scholes model to value our outstanding September 2022 Warrants at each reporting period, with changes in fair value recognized in the consolidated statements of operations and comprehensive loss. The estimated fair value of the warrant liability is determined using Level 3 inputs. Inherent in an options pricing model are assumptions related to expected share-price volatility, expected life, risk-free interest rate and dividend yield. We estimate the expected volatility of our stock price based on historical volatility of our ADSs, considering the expected remaining life of the September 2022 Warrants. The risk-free interest rate is based on the U.S. Treasury zero-coupon yield curve on the valuation date for a maturity similar to the expected remaining life of the September 2022 Warrants. The expected life of the September 2022 Warrants is assumed to be equivalent to their remaining

contractual term. The dividend rate is based on the historical rate, which we anticipate to remain at zero. Due to the nature of and inputs in the model used to assess the fair value of the warrants, it is not abnormal to experience significant fluctuations during each remeasurement period.

Research and development prepayments, accruals and related expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued and prepaid expenses for research and development activities performed by third parties, including CROs and clinical investigators. These estimates are made as of the reporting date of the work completed over the life of the individual study in accordance with agreements established with CROs and clinical trial sites. Some CROs invoice on a monthly basis, while others invoice upon achievement of milestones and the expense is recorded as services are rendered. We determine the estimates of research and development activities incurred at the end of each reporting period through discussion with internal personnel and outside service providers as to the progress or stage of completion of trials or services, as of the end of each reporting period, pursuant to contracts with clinical trial centers and CROs and the agreed upon fee to be paid for such services. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary.

Valuation allowance for deferred income taxes

We record a valuation allowance to reduce our deferred tax assets to the amount that is more likely than not to be realized. Significant judgment is required in determining the valuation allowance. We consider projected future taxable income and ongoing tax planning strategies in assessing the need for the valuation allowance. If it is determined that we are able to realize deferred tax assets in excess of the net carrying value or to the extent we are unable to realize a deferred tax asset, we would adjust the valuation allowance in the period in which such a determination is made, with a corresponding increase or decrease to earnings.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to a variety of risks, including changes in foreign currency exchange risk and interest rates.

Currency Exchange Rate Sensitivity

The results of our operations are subject to currency transactional risk. Operating results and financial position are reported in local currencies and then translated into United States dollars at the applicable exchange rate for preparation of our consolidated financial statements. The fluctuation of the U.S. dollar in relation to the British Pound, Euro and Swiss Franc will therefore have an impact upon profitability of our operations and may also affect the value of our assets and the amount of shareholders' equity.

Our functional currency is the United States dollar and our activities are predominantly executed using both the U.S. dollar, Euro and British Pound. We have done a limited number of financings, and we are not subject to significant operational exposures due to fluctuations in these currencies. We have not entered into any agreements, or purchased any instruments, to hedge any possible currency risks at this time.

Interest Rate Sensitivity

We currently have no short-term or long-term debt requiring interest payments, except for our short-term insurance premium financing arrangement we entered into in January 2024, as more fully described above. This does not require us to consider entering into any agreements or purchasing any instruments to hedge against possible interest rate risks at this time. Our interest-earning investments are short-term. Thus, any reductions in future income or carrying values due to future interest rate declines are believed to be immaterial.

Based on a hypothetical ten percent adverse movement in interest rates, the potential losses in future earnings, fair value of risk sensitive financial instruments, and cash flows are immaterial to our earnings, although the actual effects may differ materially from the hypothetical analysis.

Item 8. Financial Statements and Supplementary Data.

All financial statements required to be filed hereunder are filed under Item 15(a) of this Form 10-K and are incorporated herein by reference.

We are a smaller reporting company, as defined by Rule 12b-2 of the Exchange Act, and therefore we are permitted to provide a scaled Item 8 disclosure.

There have been no retrospective changes to our consolidated statements of operations for any of the quarters within the two years ended December 31, 2023.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of December 31, 2023. In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applied its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our principal executive officer and principal financial officer concluded that, as of December 31, 2023, our disclosure controls and procedures were effective.

a) Management's Annual Report on Internal Control over Financial Reporting

Our management, with the participation of our principal executive officer and principal financial officer, is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) and 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, the Company's principal executive and principal financial officers and effected by the Company's Board of Directors, management, and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the Company;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and
- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the Company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management assessed the effectiveness of our internal control over financial reporting as of December 31, 2023. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in *Internal Control — Integrated Framework* (2013). Based on its assessment, management concluded that, as of December 31, 2023, the Company's internal control over financial reporting was effective based on those criteria.

b) Attestation Report of the Registered Public Accounting Firm

Not Applicable.

c) Changes in Internal Control over Financial Reporting.

No change in our internal control over financial reporting occurred during the fourth quarter of the fiscal year ended December 31, 2023 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

(a) The following information is included in this Annual Report on Form 10-K pursuant to Item 1.01 “Entry into a Material Definitive Agreement” and Item 3.02 “Unregistered Sales of Equity Securities” of Form 8-K in lieu of filing a Form 8-K:

As previously disclosed in a Current Report on Form 8-K dated March 11, 2024, we entered a definitive agreement with certain existing investors, pursuant to which we agreed to sell in a private placement approximately $1.6 million of ADSs at a to be determined purchase price per ADS equal to the lower of: (i) $1.57 (the product of 0.7 and the official closing price of the ADSs on Nasdaq on March 4, 2024 and (ii) the product of 0.7 and the volume weighted average price of the ADSs on Nasdaq for the 15 calendar day period following the public announcement of entry into a definitive agreement with respect to the Merger with Peak Bio, subject to a floor price of $1.12. Subsequently, on March 26, 2024, we entered into an amended and restated definitive agreement (the “Purchase Agreement”) with certain existing investors, pursuant to which we agreed to sell in a private placement approximately $2 million of ADSs at the same pre-determined purchase price. On March 28, 2024, we closed the private placement pursuant to which we sold an aggregate of 1,320,614 ADSs at $1.48 per ADS, for aggregate gross proceeds of approximately $2.0 million (the "March 2024 Private Placement").

The Purchase Agreement also contains representations, warranties, indemnification and other provisions customary for transactions of this nature.

We paid Paulson Investment Company, LLC (“Paulson”) a cash fee equal to 10% of the aggregate purchase price for the ADSs sold in the private placement and issued to Paulson at the closing of the private placement warrants exercisable into 132,061 ADSs, which warrants have a term of 5 years expiring March 27, 2029, have cashless exercise provisions and an exercise price of $1.85 per ADS.

Pursuant to the Purchase Agreement, we agreed to prepare and file a registration statement on Form S-3 with the Securities and Exchange Commission no later March 31, 2024 to register the resale of the ADSs purchased pursuant to the Purchase Agreement.

The securities issued to the purchasers under the Purchase Agreement were offered in reliance on an exemption from registration provided by Section 4(a)(2) of the Securities Act and Rule 506 of Regulation D promulgated thereunder. We relied on this exemption from registration based in part on representations made by the purchasers, including that each purchaser is an “accredited investor”, as defined in Rule 501(a) promulgated under the Securities Act.

The offer and sale of the securities pursuant to the Purchase Agreement have not been registered under the Securities Act or any state securities laws. The securities may not be offered or sold in the United States absent registration or an applicable exemption from registration requirements. Neither this Annual Report on Form 10-K, nor the exhibits attached hereto, is an offer to sell or the solicitation of an offer to buy the securities described herein or therein.

(b) None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Information about our Directors

Our Articles of Association provide that our business is to be managed by the board of directors (subject to any directions made by the members of the Company by special resolution). Our board of directors is divided into three classes for purposes of election (Class A Directors, who serve a one year term before being subject to re-election at the Company's annual general meeting; Class B Directors, who serve a two year term before being subject to re-election at the annual general meeting; and Class C Directors who serve a three year term before being subject to re-election at the annual general meeting, provided also that in any two year period, a majority of the board must stand for re-election).

Set forth below is information about each member of our board of directors, including (a) the year in which each director first became a director, (b) their age as of March 29, 2024, (c) their positions and offices with our Company, (d) their principal occupations and business experience during at least the past five years and (e) the names of other public companies for which they currently serve, or have served within the past five years, as a director. We have also included information about each director's specific experience, qualifications, attributes, or skills that led our board of directors to conclude that such individual should serve as one of our directors. We also believe that all of our directors have a reputation for integrity, honesty and adherence to high ethical standards. They each have demonstrated business acumen and an ability to exercise sound judgment, as well as a commitment of service to our Company and our board of directors.

The following table provides information about those persons who currently serve as directors of the Company.

			Committee Memberships (1)			
Name	**Age**	**Relationship**	**Audit**	**Comp**	**N&CG**	**Class - Election Year**
Ray Prudo, M.D.	79	Chair of the Board				Class C Director - 2024
Michael Grissinger	68	Director	X	X	C	Class A Director - 2024
Wa'el Hashad	61	Director	X		X	Class A Director - 2024
Rachelle Jacques	52	President, CEO and Director				Class B Director - 2024
Samir R. Patel, M.D.	55	Director		X		Class A Director - 2024
Donald Williams	65	Director	C	C	X	Class A Director - 2024

(1) "C" indicates Chair of applicable committee.

Raymond Prudo-Chlebosz, M.D., served as our Executive Chairman from September 2015 through December 2022. Effective January 1, 2023. Dr. Prudo began serving as the Chairman of our board of directors. Dr. Prudo has been an active investor and developer of healthcare companies for 25 years. Dr. Prudo was the Founder, Chairman, and Chief Executive Officer of Volution and its predecessor company, Varleigh Immuno Pharmaceuticals, since its inception in 2008. Dr. Prudo is also the co-founder of The Doctors' Laboratory ("TDL"), past CEO and its Chairman since 2002. Since 2015 he has also been a director of Health Services Laboratories ("HSL"). Both TDL and HSL are subsidiaries of Sonic Healthcare Limited (ASX: SHL.AX). Dr. Prudo is also currently a director of CIS Healthcare Limited, a privately-held UK healthcare company. Dr. Prudo holds an MBBS from the University of London, and an FRCP(C) from the Royal College of Physicians and Surgeons of Canada.

Michael Grissinger has served as a member of our board of directors since January 2018. Mr. Grissinger spent 22 years at Johnson & Johnson, retiring in 2018. During his Johnson and Johnson tenure, Mr. Grissinger served in a variety of senior-level management roles including Vice President and Head, Worldwide Pharmaceutical Licensing as well as Vice President and Head of Worldwide Pharmaceutical Corporate Development and M&A. Prior to Johnson & Johnson, Mr. Grissinger spent 12 years at Ciba-Geigy in finance, marketing, and business development roles. In addition to Akari, Mr. Grissinger also serves as a member of the board of directors of Aprea Therapeutics, Inc. (NASDAQ: APRE), and three privately-held biotechnology companies, Atriva Therapeutics Plc, Kira Biotech

Pty Ltd., and Envisagenics, Inc. Mr. Grissinger holds a B.Sc. in Chemistry from Juniata College and an MBA from Temple University, Fox School of Business.

Wa'el Hashad was appointed to our board of directors in June 2023. Mr. Hashad currently serves as CEO of Longeveron, Inc. (Nasdaq: LGVN), a U.S. clinical-stage biotechnology company developing regenerative medicines for rare pediatric diseases, aging-related conditions, and unmet medical needs, a position he has held since February 2023. Previously, he was President and Chief Executive Officer at Avanir Pharmaceuticals from 2017 until 2023. Avanir was acquired by Otsuka Pharmaceutical, and Mr. Hashad led the company's full integration into Otsuka's United States operations. From January 2016 until June 2017, Mr. Hashad was Executive Vice President and Chief Commercial Officer at Seres Therapeutics, where he established the company's launch and marketing strategy for microbiome-based therapies.

Mr. Hashad has held multiple leadership roles at Amgen, executing on cardiovascular, neuroscience, metabolic disorder, and nephrology product launches and was the general manager for Africa, the Middle East, and Asia. He was a Vice President at Boehringer Ingelheim leading the U.S. launch of the company's cardiovascular and metabolic products. Earlier, Mr. Hashad spent 20 years at Eli Lilly and Company, driving the company's marketing and commercial strategy across multiple regions and therapeutic areas. He concluded his time at Eli Lilly as the Vice President of the United States Cardiovascular Business Unit.

Mr. Hashad holds an M.B.A. in Finance and International Business from the University of Akron and a B.Sc. in Pharmacy and Pharmaceutical Sciences from the University of Cairo. Prior to 2017 he held the position of the Chairman of the Strategic Advisory Board at Morningside Biopharma, a private incubator of several pharmaceutical/bio-tech companies, for three years, and is currently a member of the Board of California Life Sciences.

Rachelle Jacques has served as our President and Chief Executive Officer and a member of our board of directors since March 2022. Before joining the Company, Ms. Jacques served, from February 2019 to March 2022, as Chief Executive Officer of Enzyvant Therapeutics Inc., a commercial-stage biotechnology company developing transformative regenerative therapies for rare diseases. Prior to Enzyvant, she served as the Senior Vice President and Global Complement Franchise Head at Alexion Pharmaceuticals, Inc., where she was responsible for global franchise strategy development and execution of the C5 complement inhibitors, eculizumab and ravulizumab, across the therapeutic areas of hematology, nephrology and neurology. She was Vice President of U.S. Hematology Marketing at Baxalta Inc. and then Shire plc, following Shire's acquisition of Baxalta in 2016. At Baxalta, she served as Vice President of Business Operations after its spinoff from Baxter International Inc. Ms. Jacques held multiple leadership positions at Baxter, including Vice President of Finance, U.S. BioScience Business.

Earlier in her career, Ms. Jacques served in various roles at Dow Corning Corporation, including operational management positions in the U.S., Europe, and China. She serves on the boards of directors of uniQure N.V. (NASDAQ: QURE) and Corbus Pharmaceuticals (NASDAQ: CRBP) and is a founding member of the Alliance for Regenerative Medicine (ARM) Action for Equality Task Force. Ms. Jacques received her B.A. in business administration from Alma College and is currently a member of the school's Board of Trustees.

Samir R. Patel, M.D,. has served as a member of our board of directors since November 2023. Dr. Patel is founder and, since April 2017, principal of PranaBio Investments, LLC, a firm providing consulting, strategic advisory, and investment services for small cap biotechnology companies. He is also a consultant to GE Global Research, Inc., GE's innovation engine that is creating novel products and solutions across several sectors including biomanufacturing and biotechnology, a position which he has held since May 2019.

Dr. Patel has more than 20 years of experience in life sciences including co-founding Digital Therapeutics, LLC, a startup advancing a therapy for scleroderma and other rheumatic diseases, where he has served as CEO since August 2011 and co-founding SPEC Pharma, LLC, a company that develops and manufactures injectables used in rheumatology applications. Previously, he held multiple roles in Medical Affairs with Centocor, Inc. (now Johnson & Johnson Innovative Medicine, part of Johnson & Johnson). From April 2020 to November 2021, Dr. Patel served on the board of directors of Cytodyn, Inc. (OTCQB: CYDY). He holds multiple patents, has been an author on several publications and has been an investigator in numerous clinical research studies.

Dr. Patel received his medical degree from the Medical College of Ohio (University of Toledo) in Toledo, Ohio, and completed his internal medicine internship and residency, as well as a rheumatology fellowship, at University of New Mexico School of Medicine Affiliated Hospitals.

Donald Williams has served as a member of our board of directors since June 2016 and is an "audit committee financial expert." Mr. Williams is a 35-year veteran of the public accounting industry who retired in 2014. Mr. Williams spent 18 years of his career as a partner at Ernst & Young, followed by seven years as a partner at Grant Thornton. During his time at Grant Thornton from 2007 to 2014, he served as the national leader of Grant Thornton's life sciences practice and the managing partner of the San Diego Office. He was the lead partner for both Ernst & Young and Grant Thornton on multiple initial public offerings, secondary offerings, and private and public debt financings, as well as numerous mergers and acquisitions. Mr. Williams currently serves as a director of Forte Biosciences, Inc. (NASDAQ: FBRX), Palisade Bio, Inc. (NASDAQ: PALI), and MONIA, a privately held company. Previously, Mr. Williams served as a director of Impedimed Limited (ASX: IPD) from 2017 to September 2023, Alphatec Spine (NASDAQ: ATEC) from 2015 to August 2021, and Adhera Therapeutics (OTC: ATRX) from 2014 to December 2019. Mr. Williams is a graduate of Southern Illinois University with a B.S. degree.

Information about our Executive Officers

Our currently-serving executive officers, their respective ages, positions, background and qualifications are described below. Our executive officers serve until they resign, or the board terminates their position.

Name	Age	Position
Rachelle Jacques*	52	President and CEO
Wendy DiCicco	56	Interim Chief Financial Officer

* Ms. Jacques is a member of our board of directors. See "Information about our Directors" above for more information about Ms. Jacques.

Wendy DiCicco has served as our Interim Chief Financial Officer since July 2023. Ms. DiCicco has more than 25 years of experience in the life sciences industry, currently serving as a board member or as an independent financial and board advisor to companies, often in the role of interim Chief Financial Officer (CFO).

Ms. DiCicco served as CFO for Renovacor, Inc., a pre-clinical biopharmaceutical company developing a gene therapy for cardiovascular disease from September 2019 to December 2022. Initially as interim CFO, then transitioning to permanent, she led the company through its business combination with Chardan Healthcare Acquisition 2 Corp. in 2021 and sale to Rocket Pharmaceuticals in December 2022. She also served as interim CFO for FerGene, Inc., a Phase 3 urologic oncology gene therapy company, from January 2020 through May 2022. Previously, from August 2017 to October 2018, she was CFO and Chief Operating Officer ("COO") of Centinel Spine and the President and COO of Camber Spine, from November 2014 to July 2017, both developers of best-in-class spinal implants. She has held CFO roles for several pre-IPO, private equity backed medical device and biotechnology companies, in varying stages of commercialization. Her first CFO role was with Kensey Nash Corporation, a publicly traded developer and manufacturer of biologics and medical devices in the cardiovascular and orthopedics industries, where she advanced the company from a pre-revenue IPO stage to approximately $100 million in global revenue across multiple product platforms. Her career started in public accounting at Deloitte & Touche.

Ms. DiCicco currently serves on the Board of Directors of EyePoint Pharmaceuticals, Inc., a publicly traded company, where she also serves as the Audit Committee Chair. In addition, she serves on the board of Imvax, Inc. Ms. DiCicco has also served on the boards of SWK Holdings Corp., II-VI, Inc (now Coherent Corp.), Sincerus Pharmaceuticals, Carmell Therapeutics, SynCardia Systems and CannaPharma Rx. She is currently on the Board of Directors of the Philadelphia Chapter of the National Association of Corporate Directors.

Ms. DiCicco received a B.S. in accounting from Philadelphia College of Textiles and Science and is a licensed Certified Public Accountant. She also is an appointed Board Leadership Fellow and Corporate Governance Fellow of the National Association of Corporate Directors.

Corporate Governance

Audit Committee

Our board has established a formal standing audit committee. The current members of our audit committee are Mr. Williams (Chair), Mr. Grissinger, and Mr. Hashad. Our board has determined that Mr. Williams is an "audit committee financial expert" within the meaning of SEC rules and regulations. Each member of the audit committee is independent as defined under applicable rules of the Nasdaq, including the independence requirements contemplated by Rule 10A-3 under the Exchange Act.

The Board has adopted a written Audit Committee Charter. The composition and responsibilities of the Audit Committee and the attributes of its members, as reflected in its Charter, are intended to be in accordance with certain listing requirements of Nasdaq and the rules of the SEC for corporate audit committees. The Audit Committee Charter may be found in the "Investor Relations — Corporate Governance" section of our website, which is located at www.akaritx.com.

Compensation Committee

Our compensation committee currently consists of three members, appointed by the board of directors: Mr. Williams (Chair), Mr. Grissinger, and Dr. Patel, all of whom are independent within the meaning of SEC corporate governance rules of independence for purposes of the compensation committee.

The Board has adopted a written Compensation Committee Charter. The composition and responsibilities of the compensation committee and the attributes of its members, as reflected in its Charter, are intended to be in accordance with certain listing requirements of Nasdaq and the rules of the SEC for corporate compensation committees. The Compensation Committee Charter may be found in the "Investor Relations — Corporate Governance" section of our website, which is located at www.akaritx.com.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee currently consists of three members, appointed by our board of directors: Mr. Williams, Mr. Grissinger (Chair), and Mr. Hashad, all of whom are independent within the meaning of SEC corporate governance rules of independence for purposes of the nominating and corporate governance committee. None of our non-employee directors have any service contracts with us or any of our subsidiaries that provide for benefits upon termination of employment.

The Board has adopted a written Nominating and Corporate Governance Committee Charter. The composition and responsibilities of the nominating and corporate governance committee and the attributes of its members, as reflected in its Charter, are intended to be in accordance with certain listing requirements of Nasdaq and the rules of the SEC for corporate nominating and corporate governance committees. The Nominating and Corporate Governance Committee Charter may be found in the "Investor Relations — Corporate Governance" section of our website, which is located at www.akaritx.com.

Code of Business Conduct and Ethics

We have adopted a written code of business conduct and ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. We have posted a current copy of the Code of Business Conduct and Ethics in the "Investor Relations — Corporate Governance" section of our website, which is located at www.akaritx.com. We intend to satisfy the disclosure requirements under Item 5.05 of Form 8-K regarding an amendment to, or waiver from, a provision of our code of business conduct and ethics by posting such information on our website at www.akaritx.com.

Item 11. Executive Compensation.

In accordance with Item 402(l) of Regulation S-K, the Company has elected to avail itself of the scaled disclosure requirements available to smaller reporting companies.

This section discusses the material components of the Company's executive compensation program for our named executive officers ("NEOs") for the fiscal year ended December 31, 2023:

- Rachelle Jacques, President and Chief Executive Officer
- Wendy DiCicco, Interim Chief Financial Officer
- Torsten Hombeck, Former Chief Financial Officer

Summary Compensation Table

The following table sets forth information concerning the compensation of our NEOs during the fiscal years ended December 31, 2023 and 2022:

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)(3)	Option Awards ($)(4)	All Other Compensation ($)(5)	Total ($)
Rachelle Jacques	2023	615,750	–	729,393	198,498	16,500	1,560,141
President and Chief Executive Officer	2022	458,333	875,000	253,410	1,965,991	49,865	3,602,599
Wendy DiCicco[(1)]	2023	226,184	45,000	–	6,480	–	277,664
Interim Chief Financial Officer							
Torsten Hombeck[(2)]	2023	138,945	–	–	–	28,561	167,506
Former Chief Financial Officer	2022	300,150	72,036	–	32,448	44,111	448,745

(1) Ms. DiCicco was appointed as the Company's Interim Chief Financial Officer on July 17, 2023.

(2) Dr. Hombeck served as the Company's Chief Financial Officer until June 15, 2023.

(3) Represents the aggregate grant date fair value of time-based restricted stock units ("RSUs") issued under our 2014 Equity Incentive Plan (the "2014 Plan") and 2023 Equity Incentive Plan (the "2023 Plan"), as computed in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 718, disregarding estimated forfeitures related to service-based vesting. See Note 6 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K regarding assumptions we made in determining the fair value of RSUs.

(4) Represents the aggregate grant date fair value of options to purchase ordinary shares issued under our 2014 Plan and 2023 Plan, as computed in accordance with FASB ASC Topic 718, disregarding estimated forfeitures related to service-based vesting. See Note 6 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K regarding assumptions we made in determining the fair value of option awards.

(5) For 2023, all other compensation includes the following amounts:

Name	Company 401(k) Plan Match	Other[(a)]	Total
Ms. Jacques	16,500	–	16,500
Ms. DiCicco	–	–	–
Dr. Hombeck	11,461	17,100	28,561

(a) Amounts reported as "Other" in the table above represent earned and unused vacation paid to Dr. Hombeck upon termination of his employment with us.

Narrative Disclosure to Summary Compensation Table

Employment Agreements with Our NEOs

We have entered into employment agreements with each of our NEOs (or non-employee consulting services agreements in the case of Ms. DiCicco). All employee NEOs are at-will employees.

Rachelle Jacques Employment Agreement

We are a party to an executive employment agreement, effective February 28, 2022, with Ms. Jacques, our President and Chief Executive Officer (the "Jacques Agreement"). Pursuant to the Jacques Agreement, Ms. Jacques's initial annual base salary was $600,000, which is subject to review and increase on an annual basis and she is eligible to receive an annual cash bonus with a target of 50% of base salary based on the achievement of performance goals established by the chairman of the board of directors and the full board of directors, in consultation with Ms. Jacques. Under the terms of the Jacques Agreement, Ms. Jacques received a cash signing bonus of $650,000 in connection with her hire. Ms. Jacques was required to repay us 50% of the signing bonus if, prior to the first anniversary of her start date, her employment was terminated by us for "cause" (as defined in the Jacques Agreement") or by her without "good reason" (as defined in the Jacques Agreement) and she is required to repays us one-third of the signing bonus if her employment is terminated by us for cause or by her without good reason after the first anniversary but prior to the second anniversary of her start date. In addition, the Jacques Agreement provides for the following RSU awards: (i) RSUs having a face value of $262,000 within 75 days of her start date, which vest 50% on the first anniversary of the start date and monthly thereafter for the following year, (ii) RSUs having a value of $446,000 on the first anniversary of her start date, which vest 50% on the second anniversary of the start date and monthly thereafter for the following year, and (iii) RSUs having a value of $446,000 on the second anniversary of her start date, which vest 50% on the third anniversary of the start date and monthly thereafter for the following year. Such RSU grants are subject to full acceleration in the event of a "change in control" (as defined in the Jacques Agreement), involuntary termination of employment without cause, resignation for good reason, or termination of employment due to death or "disability" (as defined in the Jacques Agreement). In the event that any change in control, involuntary termination of employment without cause, resignation for good reason, or termination of employment due to death or disability occurs prior to any such grant, the Company is obligated to pay Ms. Jacques a lump sum in cash equal to the face value of the ungranted RSU award. The Jacques Agreement further provides that the Company will grant Ms. Jacques an option to purchase 237,396,700 ordinary shares, subject to ratable vesting on a semiannual basis over four years from her start date. Commencing with annual long-term incentive awards to senior executives in 2023, in addition to the RSU and option awards described above, the Jacques Agreement provides that Ms. Jacques will be eligible to receive awards under the Company's equity incentive plan not less frequently than annually with a target grant value of not less than 100% of Ms. Jacques's annual base salary for fiscal year 2023 and thereafter otherwise commensurate with awards to executives at similarly situated companies as recommended by a reputable compensation consultant engaged by the board of directors.

Upon termination of Ms. Jacques's employment due to Ms. Jacques's death or disability, Ms. Jacques or her estate or beneficiaries shall be entitled to receive (i) a pro-rated portion of the annual bonus, if any, that she would have otherwise earned for the year in which the employment terminates had no termination occurred (the "Pro-Rata Bonus").

Upon termination of Ms. Jacques's employment by us without cause, or by Ms. Jacques for good reason, subject to her compliance with the confidentiality provisions of the Jacques Agreement and her execution and the effectiveness of a release of claims in favor of the Company and its affiliates in a form provided by the Company (the "Release"), she is entitled to receive (i) a lump sum payment equal to the sum of the annual base salary and target annual performance bonus in effect for the year in which the date of termination occurs (the "Cash Severance"), (ii) any earned but unpaid annual bonus for the previous year, (iii) the Pro-Rata Bonus, and (iv) provided she timely and properly elects COBRA coverage, reimbursement for the monthly COBRA premium paid by Ms. Jacques for her and her eligible dependents until the earliest of (x) 12 months following the date of termination, (y) the date on which she is no longer eligible to receive such coverage, and (z) the date on which Ms. Jacques becomes eligible to receive similar coverage from another employer or other source (the "COBRA Reimbursement"). In addition, if Ms. Jacques agrees in writing that the non-competition restrictions in the Jacques Agreement shall continue to apply following the termination of her employment, (i) all outstanding equity-based compensation awards that do not vest

based on the attainment of performance goals shall fully vest, and (ii) all outstanding equity-based compensation awards that vest based on the attainment of performance goals shall remain outstanding and eligible to vest based on attainment of the applicable performance goals.

In the event of a termination of Ms. Jacques's employment by us without cause (other than on account of death or disability), or by Ms. Jacques for good reason, in each case within 18 months following a change in control, and subject to her compliance with the cooperation, confidentiality, restrictive covenants, and proprietary rights provisions of the Jacques Agreement and her execution and the effectiveness of a Release, in lieu of the severance payments and benefits described in the preceding paragraph, she is entitled to receive (i) the Cash Severance, (ii) a lump sum payment equal to her target bonus for the year in which the date of termination occurs (or the year in which the change in control occurs, if higher) and (iii) the COBRA Reimbursement. In addition, if Ms. Jacques agrees in writing that the non-competition restrictions in the Jacques Agreement will continue to apply following the termination of her employment, (i) all outstanding unvested stock options held by her will become fully vested and will remain exercisable for the remainder of their original term and (ii) all outstanding equity-based awards other than stock options that do not vest based on the attainment of performance goals will fully vest. If the payments or benefits payable to Ms. Jacques in connection with a change in control would be subject to the excise tax on golden parachutes imposed under Section 4999 of the Internal Revenue Code of 1986, as amended (the "Code"), those payments or benefits will be reduced if such reduction would result in a higher net after-tax benefit to Ms. Jacques.

The employment agreement also contains restrictive covenants for the Company's benefit and Ms. Jacques is required to maintain the confidentiality of our confidential information.

Wendy DiCicco Consulting Services Agreements

We are a party to a consulting services agreement, dated January 15, 2024, with an entity controlled by Ms. DiCicco (the "DiCicco Agreement"). The DiCicco Agreement provides for a $40,000 per month fee for services up to 80 hours per month, paid in two equal installments on the 15th and 30th date of each month in which services are rendered and reimbursement of certain expenses. Any time exceeding 80 hours per month requires advance approval by the CEO. The DiCicco Agreement expires on May 31, 2024, provided, however, either party may terminate the DiCicco Agreement at any time without cause on 30 days' prior written notice or with cause on five days' prior written notice.

Prior to entering into the DiCicco Agreement, the Company was party to a consulting services agreement, dated July 17, 2023, and amended on September 1, 2023 (as amended, the "Original DiCicco Agreement"), with an entity controlled by Ms. DiCicco. The Original DiCicco Agreement had a six month term and provided for a $32,000 per month fee, which was increased to $40,000 effective September 1, 2023, a performance bonus in an amount of up to $70,000 upon achievement of certain milestones, and reimbursement of certain expenses. The Original DiCicco Agreement also provided that Ms. DiCicco would be granted an initial option to purchase 5,000,000 ordinary shares. If we terminate Ms. DiCicco's engagement for any reason other than for cause prior to the date that such option is fully vested, the option will continue to vest through July 17, 2024 or be accelerated, at our option.

The DiCicco Agreement also contains restrictive covenants for our benefit and Ms. DiCicco is required to maintain the confidentiality of our confidential information.

Hombeck Employment Agreement

Prior to his departure in June 2023, we were party to an executive employment agreement, effective as of June 30, 2020, with Dr. Hombeck (the "Hombeck Agreement"). The Hombeck Agreement had an initial term of one year from June 30, 2020 with automatic renewals for successive one-year periods, provided that either party could have given written notice of non-renewal of the current term at least three months prior to the expiration of the then-current term.

Dr. Hombeck's annual base salary for 2023 was $303,152 and he was eligible for an annual cash bonus with a target of 30% of base salary. The Hombeck Agreement also provided that Dr. Hombeck would be granted an initial option to purchase 7,000,000 shares and an additional option to purchase 3,000,000 shares on January 1, 2021.

Pursuant to the Hombeck Agreement, upon termination of Dr. Hombeck's employment without "cause" (as defined in the Hombeck Agreement), or by Dr. Hombeck for "good reason" (as defined in the Hombeck Agreement) or upon non-renewal by the Company of the term of the Hombeck Agreement, in addition to any accrued but unpaid base salary, expense reimbursements and vested and accrued benefits and subject to Dr. Hombeck's execution and the effectiveness of a release of claims in a form acceptable to the Company, he would have been entitled to receive (i) an amount equal to the sum of (x) his annual base salary at the rate in effect as of the termination date, plus (y) other than in the case of a termination due to non-renewal of the term, an amount equal to the greater of his actual or target annual performance bonus for the year in which the employment terminated and (ii) an amount equal to the Company's share of the premium paid by Dr. Hombeck while he was an active employee for medical insurance coverage under the Company's health care plan (the "Healthcare Subsidy") for 12 months following termination.

If Dr. Hombeck's employment had been terminated by us without cause, or by him for good reason, in each case with one year following a "change in control" (as defined in the Hombeck Agreement), and subject to Dr. Hombeck's execution and the effectiveness of a release of claims in a form acceptable to the Company, in lieu of the severance payments and benefits described in the preceding paragraph, he would have been entitled to receive (i) an amount equal to one and a half times the sum of (x) his annual base salary at the rate in effect as of the termination date, plus (y) his target annual performance bonus for the year in which the employment terminated and (ii) the Healthcare Subsidy for 18 months following termination. If the payments or benefits payable to Dr. Hombeck in connection with a change in control would have been subject to the excise tax on golden parachutes imposed under Section 4999 of the Code, those payments or benefits would have been reduced if such reduction would result in a higher net after-tax benefit to Dr. Hombeck.

Dr. Hombeck is also subject to restrictive covenants for our benefit, including a requirement to maintain the confidentiality of our confidential information.

Determining Compensation

Our board of directors and compensation committee review compensation annually for our executives. In setting executive base salaries and bonuses and granting equity incentive awards, we consider compensation for comparable positions in the market, the historical compensation of our executives, individual performance as compared to our expectations and objectives, our desire to motivate our employees to achieve short- and long-term results that are in the best interests of our shareholders, and a long-term commitment to our Company.

Our compensation committee is primarily responsible for determining the compensation for our executive officers. Our compensation committee typically reviews and discusses management's proposed compensation with our Chief Executive Officer for all executives other than the Chief Executive Officer. Based on those discussions and its discretion, taking into account the factors noted above, the compensation committee then sets the compensation for each executive officer other than the Chief Executive Officer and recommends the compensation for the Chief Executive Officer to our board of directors for approval. Our board of directors discusses the compensation committee's recommendation and ultimately approves the compensation of our Chief Executive Officer without members of management present.

In 2023, our compensation committee utilized the services of Amplify Strategy & Consulting LLC ("Amplify"), an independent compensation consultant. During 2023, Amplify did not provide material services to us other than the services to our compensation committee. Based on its evaluation, our compensation committee has determined that Amplify's work has not raised any conflict of interests.

Elements of Compensation

The compensation of our NEOs generally consists of three primary components, consisting of base salary, annual cash incentive awards, and long-term incentive-based compensation in the form of stock-based awards.

Base Salary

In 2023, Ms. Jacques received an annual salary of $615,750 and, prior to his departure in June 2023, Dr. Hombeck received an annual salary of $303,152. Ms. DiCicco is a non-employee consultant and received a monthly fee of $32,000 from July 17, 2023 through August 31, 2023 and a monthly fee of $40,000 from September 1, 2023 through December 31, 2023.

Annual Cash Incentives

Annual cash incentive awards provide an opportunity for additional compensation to employee NEOs if pre-established annual performance goals are attained. The annual cash incentive award targets are based on a target percentage of each employee NEO's salary. The compensation committee generally links cash awards to the achievement of the annual corporate goals; however, the compensation committee may take into consideration unexpected corporate performance outside of the corporate goals and individual performance. The amount of the bonus paid, if any, may vary among the employee NEOs depending on individual performance, individual contribution to the achievement of our annual corporate goals.

Annual cash incentive awards for 2023 for employees, including our NEOs, were based on corporate goals related to financing, pipeline advancement, reputation, and strengthening our capabilities. For 2023, the annual cash incentive award for Ms. Jacques was targeted at 50% of base salary and the annual cash incentive award for Dr. Hombeck was targeted at 30% of his base salary. However, Dr. Hombeck was not eligible to receive an incentive bonus because his employment terminated in July 2023. After reviewing Company performance against the corporate goals, the compensation committee determined not to award cash bonuses to the employee NEOs for the year ended December 31, 2023.

Pursuant to the Original DiCicco Agreement, Ms. DiCicco was eligible for performance bonuses in the aggregate amount of $70,000 upon achievement of certain milestones, including (i) $25,000 upon achievement of a specified guaranteed cash flow target by August 23, 2023 ("Milestone 1"), (ii) $25,000 upon resolving NASDAQ non-compliance on minimum bid price and shareholders' equity by October 23, 2023 ("Milestone 2"), and (iii) $20,0000 upon achievement of internal finance capability improvements by December 31, 2023 ("Milestone 3"). Ms. DiCicco received total bonuses of $45,000 for 2023 in light of achievement of Milestone 2 and Milestone 3.

Equity-Based Awards

Equity grants are intended as both a reward for contributing to our long-term success and an incentive for future performance. Additionally, the vesting feature of our equity awards is intended to further our goal of executive retention by providing an incentive to our NEOs to remain in our service during the vesting period. The compensation committee typically makes initial stock option awards to our employee NEOs upon commencement of employment and annual equity awards in the form of either stock options, RSUs, or a combination of stock options and RSUs, thereafter.

In 2023, we awarded equity compensation under the 2014 Plan and/or the 2023 Plan to Ms. Jacques and Ms. DiCicco in the form of time-vesting stock options and/or time-based RSUs. We determine equity award amounts based on contractual obligations, competitive market factors in our industry, and the judgment of the compensation committee of the board of directors, taking into account information and recommendations provided by our independent compensation consultant. With respect to our NEO's other than our Chief Executive Officer, the compensation committee also considers recommendations provided by our Chief Executive Officer. For the 2023 awards of stock options and RSUs to our NEOs, the primary consideration was the award amounts included in the applicable NEO's employment and/or consulting services agreements.

Other Compensation and Benefits

We have established various employee benefit plans, including medical and 401(k) plans, in which employee NEOs are eligible to participate on the same basis as other employees. It is generally our policy not to extend perquisites to our executives that are not available to our employees generally.

401(k) Plan and Defined Contribution Pension Scheme

We have adopted an employee benefit plan under Section 401(k) of the Code for our U.S.-based employees. The 401(k) plan allows employees to make salary deferral contributions up to the statutorily prescribed annual limit under the Code. We provide matching contributions to the 401(k) plan in an amount equal to 100% of each participant's contribution up to a maximum of 5% of the participant's annual eligible cash compensation, subject to certain other limits.

Additionally, we have adopted a defined contribution pension scheme which allows for U.K.-based employees to make salary deferral contributions and we contribute 10% of employee compensation to the pension plan, subject to U.K. law.

Clawback Policy

In November 2023, our compensation committee adopted a formal clawback policy, which applies in the event we are required to prepare an accounting restatement due to any material noncompliance with any financial reporting requirement under the U.S. federal securities laws. This policy requires us to (subject to certain limited exceptions set forth in the clawback policy and permitted under the final clawback rules) recover from any of our current or former executive officers who receive incentive-based compensation (including stock options and RSUs) after the effective date of the clawback policy and during the three-year period preceding the date on which we are required to prepare an accounting restatement, the excess of what would have been paid to such executive officer under the accounting restatement.

Outstanding Equity Awards at Fiscal End

The following table sets forth information regarding the outstanding equity held by our NEOs as of December 31, 2023.

	Option Awards					Stock Awards		
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable		Option Exercise Price ($)	Option Expiration Date	Number of Shares, Units or Other Rights that have Not Vested (#)		Market or Payout Value of Shares, Units or Other Rights Not Vested ($)(1)
Rachelle Jacques	77,862,900	129,771,500	(2)	0.0124	6/1/2032			
	11,160,863	18,601,438	(3)	0.0124	7/29/2032			
	19,086,338	133,604,363	(4)	0.0016	6/1/2033			
						5,368,900	(5)	8,375
						189,787,200	(6)	296,068
						190,798,825	(7)	297,646
Wendy DiCicco	—	5,000,000	(8)	0.0013	7/17/2033			
Torsten Hombeck (9)								

(1) Market Value is calculated based on a price per ADS of $3.12 (equivalent to $0.00156 per ordinary share), which was the closing price of our ADSs on December 29, 2023, the last trading day of 2023.

(2) Represents the unvested portion of a stock option award that vests in five equal installments of 25,954,300 ordinary shares on each of March 28, 2024, September 28, 2024, March 28, 2025, September 28, 2025, and March 28, 2026, subject to Ms. Jacques's continued employment with us through the applicable vesting date.

(3) Represents the unvested portion of a stock option award that vests in five equal installments of 3,720,288 ordinary shares on each of March 28, 2024, September 28, 2024, March 28, 2025, September 28, 2025, and March 28, 2026, subject to Ms. Jacques's continued employment with us through the applicable vesting date.

(4) Represents the unvested portion of a stock option award that vests in seven equal installments of 19,086,338 ordinary shares on each of June 1, 2024, December 1, 2024, June 1, 2025, December 1, 2025, June 1, 2026, December 1, 2026, and June 1, 2027, subject to Ms. Jacques's continued employment with us through the applicable vesting date.

(5) Represents the unvested portion of time-based RSUs granted on June 1, 2022 that vest in equal monthly installments over the six-month period beginning on January 1, 2024 and ending on June 1, 2024, subject to Ms. Jacques's continued employment with us through the applicable vesting date.

(6) Represents the unvested portion of time-based RSUs granted on March 28, 2023 that vest 50% on March 28, 2024, with the remainder vesting in 12 equal monthly installments thereafter, subject to Ms. Jacques's continued employment with us through the applicable vesting date.

(7) Represents the unvested portion of time-based RSUs granted on June 30, 2023 that vest in seven equal installments of 27,256,975 ordinary shares on each of June 30, 2024, December 31, 2024, June 30, 2025, December 31, 2025, June 30, 2026, December 31, 2026, and June 30, 2027, subject to Ms. Jacques's continued employment with us through the applicable vesting date.

(8) Represents the unvested portion of a stock option award that vests 100% on July 17, 2024, subject to Ms. DiCicco's continued service to us through the vesting date.

(9) All options (vested and unvested) previously held by Dr. Hombeck were either forfeited as of, or expired subsequent to, the date of Dr. Hombeck's termination of employment with us on June 30, 2023.

Director Compensation

Directors who are also employees are not compensated separately for serving on our board of directors or any of its committees. Each of our non-employee directors receives cash compensation for his or her services. In addition, to better align the interests of our board of directors with our shareholders, the compensation committee considers and recommends to the board of directors long-term equity compensation in the form of stock options to our non-employee directors. The compensation committee periodically conducts reviews of peer company director compensation practices, including before considering changes to our director compensation program.

Under our director compensation program, each director receives an annual cash retainer for service on the board and for service on each committee of which the director is a member. The chairperson of each committee receives a higher retainer for such service. These fees are typically paid quarterly in arrears, with the exception of the chairman of the board of directors who is paid monthly. The fees paid to non-employee directors for service on the board and for service on each committee of the board on which the director was a member during 2023 were as follows:

	Member Annual Fee	Chairperson Annual Fee
Board of Directors	$ 41,305	$ 100,000
Audit Committee	$ 7,875	$ 18,375
Compensation Committee	$ 5,570	$ 11,139
Nominating and Corporate Governance Committee	$ 5,570	$ 11,139

A non-employee director may elect to receive annual cash payments in the form of fully-vested ordinary shares. During 2023, no director elected to receive his or her annual cash retainer in shares.

Directors typically receive an initial grant of an option to purchase 5,000,000 ordinary shares (or 10,000,000 ordinary shares for the non-executive chairman) or equivalent value of ADSs, upon being appointed to the board and on the date of each annual general meeting. The board reserves the discretion to review and amend this amount.

These awards typically vest in full on the date of the next annual general meeting following the date of grant, subject to the non-employee director's continued service on the board of directors through such date, have a term of 10 years from date of grant, and accelerate upon a change of control.

The following table below sets forth information for the fiscal year ended December 31, 2023 regarding the compensation of our non-employee directors.

	Fees Earned or Paid in Cash ($)(1)	Option Awards ($)(2)	Total ($)
Ray Prudo, M.D. [3]	100,000	13,000	113,000
Michael Grissinger	60,350	6,500	66,850
Wa'el Hashad [4]	28,684	6,500	35,184
Samir R. Patel, M.D.[5]	3,704	6,103	9,807
Donald Williams	65,280	6,500	71,780
David Byrne [6]	49,170	-	49,170
James Hill [6]	29,343	-	29,343
Stuart Ungar [6]	23,645	-	23,645

(1) Represents cash fees earned for service as a non-employee director for 2023.

(2) Represents the aggregate grant date fair value of option awards made to each listed director in 2023, as computed in accordance with FASB ASC Topic 718, disregarding estimated forfeitures related to service-based vesting. See Note 6 to the financial statements included elsewhere in this Annual Report on Form 10-K regarding assumptions we made in determining the fair value of option awards. As of December 31, 2023, our non-employee directors held options to purchase our ordinary shares as follows: Dr. Prudo: 10,000,000 shares; Mr. Grissinger: 16,500,000 shares; Mr. Hashad: 5,000,000 shares; Dr. Patel: 5,000,000

shares; and Mr. Williams: 19,850,000 shares. Messrs. Byrne, Hill, and Ungar did not hold any outstanding options as of December 31, 2023.

(3) Dr. Prudo served as our Executive Chairman from September 2015 through December 2022. Effective January 1, 2023. Dr. Prudo began serving as the Chairman of our board of directors with a renumeration package of $100,000 per annum, paid in equal monthly installments.

(4) Mr. Hashad was appointed to our board of directors effective June 30, 2023, at our 2023 annual general meeting. Mr. Hashad has served as a member of our audit committee and nominating and corporate governance committee since June 30, 2023.

(5) Dr. Patel was appointed to our board of directors effective November 29, 2023. Dr. Patel has served as a member of our compensation committee since January 30, 2024.

(6) This individual served as a director until our 2023 annual general meeting on June 30, 2023.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth, as of March 29, 2024 (except as otherwise indicated below), information we know about the beneficial ownership of our ordinary shares by:

- each person or entity, including any "group" as that term is used in Section 13(d)(3) of the Exchange Act, who is known by us to own beneficially more than 5% of the issued and outstanding shares of our common stock;
- each of our current directors and director nominees;
- each of our NEOs, as set forth in the Summary Compensation Table set forth Item 11 of this Annual Report on Form 10-K;
- all of our current directors and executive officers as a group.

We have determined beneficial ownership in accordance with the rules of the SEC, and the information in the table below is not necessarily indicative of beneficial ownership for any other purpose. The SEC has defined "beneficial" ownership of a security to mean the possession, directly or indirectly, of voting power and/or investment power. In computing the percentage ownership of each person, ordinary shares subject to options, warrants, or rights held by that person that are currently exercisable, or exercisable within 60 days of March 29, 2024, are deemed to be outstanding and beneficially owned by that person. These shares, however, are not deemed outstanding for the purpose of computing the percentage ownership of any other person.

To our knowledge and except as indicated in the notes to this table and pursuant to applicable community property laws, each stockholder named in the table has sole voting and investment power with respect to the shares set forth opposite such shareholders' name. The percentage of ownership is based on 15,847,391,523 ordinary shares issued and outstanding on March 29, 2024. All fractional share amounts have been rounded to the nearest whole number. To our knowledge, except as noted below, no person or entity is the beneficial owner of more than 5% of the voting power of the Company's ordinary shares.

Name and Address of Beneficial Owner[1]	Number of Ordinary Shares Beneficially Owned[2]		Percentage of Ordinary Shares Beneficially Owned
5% Shareholders:			
Ray Prudo and Affiliates	3,484,957,900	[4]	21.6%
PranaBio Investments LLC	2,607,011,500	[5]	16.0%
RPC Pharma Limited [3]	809,977,100	[6]	5.1%
Named Executive Officers and Directors:			
Rachelle Jacques	397,563,063	[7]	2.5%
Wendy F. DiCicco	—		*
Wa'el Hashad	—		*
Samir Patel	2,607,011,500	[8]	16.0%
Ray Prudo	3,484,957,900	[9]	21.6%
Michael Grissinger	31,500,000	[10]	*
Donald Williams	34,850,000	[11]	*
All current directors and executive officers as a group (7 individuals)	6,555,882,463	[12]	38.9%

* Denotes less than 1% beneficial owner.

(1) Except as otherwise noted, the address for each person listed above is c/o Akari Therapeutics, Plc, 22 Boston Wharf Road FL 7, Boston, MA 02210.

(2) Our shareholders, named executive officers and directors may hold ordinary shares, ADS or a combination of both. This column shows each holder's beneficial ownership assuming all shares were held as ordinary shares, which may not be the case. Our ADSs are listed on The Nasdaq Capital Market under the trading symbol "AKTX." Ordinary shares are convertible to ADSs at a 2,000 to one ratio.

(3) The principal business office of RPC Pharma Limited is c/o Landmark Fiduciare (Suisse) SA, 6 Place des Eaux-Vives, P.O. Box 3461, Geneva, V8 1211, Switzerland.

(4) Based on the Amendment No. 7 Schedule 13D filed with the SEC on January 4, 2024 by RPC Pharma Limited ("RPC"), together with Ray Prudo, M.D. and Praxis Trustees Limited as trustee of The Sonic Healthcare Holding Company ("Praxis," and together with Ray Prudo and RPC, "Ray Prudo and Affiliates") in which Dr. Prudo reported sole voting power with respect to 2,636,271,200 shares, shared voting power with respect to 3,484,957,900 shares, sole dispositive power with respect to 2,636,271,200 shares, and shared dispositive power with respect to 3,484,957,900 shares as of January 4, 2024. In his individual capacity, Dr. Prudo beneficially owns the 3,484,957,900 Ordinary Shares (inclusive of 304,690,600 and 9,210,500 Ordinary Shares issuable upon exercise of warrants held by Dr. Prudo and RPC Pharma, respectively). RPC beneficially owns the 809,977,100 Ordinary Shares (inclusive of 9,210,500 Ordinary Shares issuable upon exercise of warrants). Praxis beneficially owns 38,709,600 Ordinary Shares. Voting and investment decisions with respect to shares owned by RPC and Praxis are controlled by Dr. Prudo.

(5) Based on the Form 4 filed with the SEC on January 2, 2024 by Samir Patel, principal of PranaBio Investments, LLC, and information provided by Dr. Patel. Consists of (i) 2,085,237,500 ordinary shares, (ii) prefunded warrants exercisable to purchase 96,774,000 ordinary shares (represented by 48,387 ADSs) at an exercise price of $0.0001 per ordinary share (or $0.20 per ADS), and (iii) warrants exercisable to purchase 425,000,000 ordinary shares (represented by 212,500 ADSs) at exercise prices ranging from $0.0016 to $0.03 per ordinary share (or $17.00 to $60.00 per ADS).

(6) Based on the Amendment No. 7 Schedule 13D filed with the SEC on January 4, 2024 by RPC, together with Ray Prudo, M.D. and Praxis in which RPC reported sole voting power with respect to 0 shares, shared voting power with respect to 809,977,100 shares, sole dispositive power with respect to 0 shares, and shared dispositive power with respect to 809,977,100 shares as of January 4, 2024. Voting and investment decisions with respect to shares owned by RPC are controlled by Dr. Prudo.

(7) Consists of (i) 155,187,375 ordinary shares held by Ms. Jacques, (ii) 137,784,677 ordinary shares underlying outstanding stock options that are exercisable within 60 days of March 15, 2024, and (iii) 104,597,000 unvested time-based RSUs vesting within 60 days of March 15, 2024.

(8) Dr. Patel is principal of PranaBio Investments, LLC. Refer to Note 5.

(9) Refer to Note 3.

(10) Consists of (i) 20,000,000 ordinary shares held by Mr. Grissinger, and (ii) 11,500,000 ordinary shares underlying outstanding stock options that are exercisable within 60 days of March 15, 2024.

(11) Consists of (i) 20,000,000 ordinary shares held by Mr. Williams, and (ii) 14,850,000 ordinary shares underlying outstanding stock options that are exercisable within 60 days of March 15, 2024.

(12) Includes (i) 164,134,688 ordinary shares underlying outstanding stock options that are exercisable within 60 days of March 15, 2024, (ii) 104,591,000 ordinary shares underlying unvested time-based RSUs stock options that vest within 60 days of March 15, 2024, (iii) prefunded warrants exercisable to purchase 96,774,000 ordinary shares, and (iv) warrants exercisable to purchase 738,901,100, which are held by our directors and NEOs as a group.

Equity Compensation Plan Information

We have two compensation plans under which our equity securities are authorized for issuance. The 2014 Equity Incentive Plan and the 2023 Equity Incentive Plan. The following table sets forth certain information relating to these equity compensation plans as of December 31, 2023:

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights(2)	Number of Securities Remaining Available For Future Issuance Under Equity Compensation Plans
Equity compensation plans approved by shareholders[(1)]			
2014 Equity Incentive Plan	789,393,500	$ 0.01	—
2023 Equity Incentive Plan	247,798,825	0.00	765,819,200
Total	1,037,192,325	$ 0.01	765,819,200
Equity compensation plans not approved by shareholders	N/A	N/A	N/A

(1) Consists of our 2014 Plan and 2023 Plan. As of December 31, 2023, new awards are only available for issuance under our 2023 Plan.

(2) The calculation of the weighted-average exercise price does not consider the effect of 385,954,925 RSUs included in the number of securities reported in column (a).

Item 13. Certain Relationships and Related Transactions, and Director Independence.

Transactions with Related Persons

Since January 1, 2022, we have not entered into or engaged in any related party transactions, as defined by the SEC, with our directors, officers, and shareholders who beneficially owned more than 5% of our outstanding ordinary shares ("5% holders"), as well as affiliates or immediate family members of those directors, officers, and 5% holders, except with respect to the transactions described below.

The Doctors Laboratory

The Company leases office space for its U.K. headquarters in London from The Doctors Laboratory ("TDL") and has incurred expenses of approximately $0.1 million plus VAT during each of the years ended December 31, 2023 and 2022, respectively. David Byrne, a former non-employee director of the Company, is the Chief Executive Officer of TDL and Dr. Ray Prudo, the Company's Chairman, is the non-Executive Chairman of the Board of Directors of TDL.

The Company received certain laboratory testing services for its clinical trials provided by TDL, including certain administrative services, and incurred expenses of approximately $0.1 million during each of the years ended December 31, 2023 and 2022.

Other

Mr. Grissinger began providing business development consulting services in January 2018. The consulting agreement was terminated in November 2022. The Company incurred less than $0.1 million in expenses during the year ended December 31, 2022. No such expenses were incurred during the year ended December 31, 2023.

Policies and Procedures for Related Person Transactions

Our board is committed to upholding the highest legal and ethical conduct in fulfilling its responsibilities and recognizes that related party transactions can present a heightened risk of potential or actual conflicts of interest. Accordingly, as a general matter, it is our preference to avoid related party transactions.

In accordance with our audit committee charter, members of the audit committee, all of whom are independent directors, review and approve all related party transactions for which approval is required under applicable laws or regulations, including SEC and the Nasdaq Listing Rules. Current SEC rules define a related party transaction for smaller reporting companies to include any transaction, arrangement, or relationship in which we are a participant and the amount involved is the lesser of $120,000 or 1% of total assets, and in which any of the following persons has or will have a direct or indirect interest:

- our executive officers, directors, or director nominees;
- any person who is known to be the beneficial owner of more than 5% of our common stock
- any person who is an immediate family member, as defined under Item 404 of Regulation S-K, of any of our executive officers, directors, or director nominees or beneficial owners of more than 5% of our common stock; or
- any firm, corporation, or other entity in which any of the foregoing persons is employed or is a partner or principal or in a similar position or in which such person, together with any other of the foregoing persons, has a 5% or greater beneficial ownership interest.

Under our code of business conduct and ethics, our directors, officers, and employees are expected to avoid any relationship, influence or activity that would cause or even appear to cause a conflict of interest. Under our code of business conduct and ethics, a director is required to promptly disclose to our board any potential or actual conflict of interest involving him or her. In accordance with our code of business conduct and ethics, the board will determine an appropriate resolution on a case-by-case basis. All directors must recuse themselves from any

discussion or decision affecting their personal, business, or professional interests. In addition, the audit committee is responsible for reviewing with our primary counsel the results of their review of the monitoring of compliance with our code of business conduct and ethics.

Director Independence

Our securities are listed on the Nasdaq Capital Market, and we use the standards of "independence" prescribed by rules set forth by Nasdaq. Under Nasdaq rules, a majority of a listed company's board of directors must be comprised of independent directors. In addition, Nasdaq rules require that, subject to specified exceptions, each member of a listed company's audit committee and compensation committee be independent and satisfy additional independence criteria set forth in Rules 10A-3 and 10C-1, respectively, under the Exchange Act. Under the applicable Nasdaq rules, a director will only qualify as an "independent director" if, in the opinion of our board, that person does not have a relationship which would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. Our board determined that each of Dr. Prudo, Mr. Grissinger, Mr. Hashad, Dr. Patel, and Mr. Williams are independent as defined under applicable rules of the Nasdaq, and, in the case of all members of the audit and compensation committees, the independence requirements contemplated by Rule 10A-3 and Rule 10C-1 under the Exchange Act. Additionally, the board determined that Dr. James Hill, Dr. Stuart Ungar, and Mr. David Byrne, each of whom served on the board until our 2023 Annual Meeting in June 2023, were independent. As Ms. Jacques is our President and Chief Executive Officer, she is not independent.

Item 14. Principal Accounting Fees and Services.

Independent Registered Public Accounting Firm Fees

Our independent public accounting firm is BDO USA, P.C., New York, New York, PCAOB Auditor ID: 243.

The following table sets forth all fees paid or accrued by us for professional services rendered by BDO USA, P.C. (previously BDO USA, LLP) during the years ended December 31, 2023 and 2022:

Fee Category	2023	2022
Audit Fees	$ 344,384	$ 280,455
Tax Fees	40,000	—
Total Fees	$ 384,384	$ 280,455

Audit Fees

Audit fees represent the aggregate fees for professional services rendered by our independent registered public accounting firm for: (i) the audit of our annual consolidated financial statements, (ii) review of our interim financial statements filed on Form 6-K that are customary under the standards of the Public Company Accounting Oversight Board (United States), and (iii) issuance of consents in connection with the filing of registration statements and related post-effective amendments.

Tax Fees

Tax fees consist of all services, except those services specifically related to the audit of the financial statements, performed by the independent registered public accounting firm's tax personnel, including tax compliance and reporting. Tax fees during 2023 primarily related to the conduct of a IRS Section 382 study. No such fees were incurred during 2022.

Audit Committee Pre-Approval Policies and Procedures

Our audit committee has adopted policies and procedures relating to the approval of all audit and non-audit services that are to be performed by our independent registered public accounting firm. This policy generally provides that we will not engage our independent registered public accounting firm to render audit or non-audit services unless the service is specifically approved in advance by the audit committee, or the engagement is entered into pursuant to the pre-approval procedures described below.

From time to time, the audit committee may pre-approve specified types of services that are expected to be provided to us by our independent registered public accounting firm during the next 12 months. Any such pre-approval is detailed as to the particular service or type of services to be provided and is also generally subject to a maximum dollar amount. All of the services described above under the headings "Audit Fees" and "Tax Fees" were pre-approved by our audit committee.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) (1) Financial Statements.

(2) We are not filing any financial statement schedules as part of this Annual Report on Form 10-K because they are not applicable or the required information is included in the financial statements or notes thereto.

(3) The list of Exhibits filed as part of this Annual Report on Form 10-K is set forth on the Exhibit Index below.

(b) The list of Exhibits filed as part of this Annual Report on Form 10-K is set forth on the Exhibit Index below.

(c) None.

Item 16. Form 10-K Summary

Not applicable.

Exhibit Index

Exhibit Number	Description
2.1	Agreement and Plan of Merger, dated as of March 4, 2024, by and among Akari Therapeutics, Plc, Peak Bio, Inc. and Pegasus Merger Sub, Inc. (incorporated by reference to Exhibit 2.1 to Registrant's Current Report on Form 8-K, as filed with the SEC on March 5, 2024).
2.2	Share Exchange Agreement, dated as of July 10, 2015, by and between Celsus Therapeutics Plc and RPC Pharma Limited (incorporated by reference to Exhibit 2.1 to Registrant's Current Report on Form 8-K, as filed with the SEC on July 13, 2015).
3.1	Amended Articles of Association of Akari Therapeutics, Plc (incorporated by reference to the Exhibit 3.1 to Registrant's Current Report on Form 6-K, as filed with the SEC on July 7, 2023).
4.1	Form of Deposit Agreement among the Registrant, Deutsche Bank Trust Company Americas, as Depositary, and all Owners and Holders from time to time of American Depositary Shares issued thereunder (incorporated by reference to the exhibit 99-a previously filed with the Registrant's Registration Statement on Form F-6 (No. 333-185197) filed on November 30, 2012).
4.2	Amendment to Deposit Agreement among the Registrant, Deutsche Bank Trust Company Americas, as Depositary, and all Owners and Holders from time to time of American Depositary Shares issued thereunder (incorporated by reference to the registrant's Post-Effective Amendment No. 1 to Registration Statement on Form F-6 (No. 333-185197) filed on December 24, 2013).
4.3	Form of American Depositary Receipt; the Form is Exhibit A of Amendment No. 1 to the Deposit Agreement (incorporated by reference to the exhibit previously filed with the Registrant's Registration Statement on Form F-6 (No. 333-185197) filed on November 30, 2012).
4.4	Form of Amendment No. 2 to Deposit Agreement (incorporated by reference to the exhibit previously filed with the Registrant's Post-Effective Amendment on Registration Statement Form F-6 (File No. 333-185197) filed on September 9, 2015).
4.5	Form of Amendment No. 3 to Deposit Agreement (incorporated by reference to the exhibit previously filed with the Registrant's Post-Effective Amendment on Registration Statement Form F-6 (File No. 333-185197) filed on August 17, 2023).
4.6	Form of American Depositary Receipt; the Form is Exhibit A of Amendment No. 2 to the Deposit Agreement (incorporated by reference to the exhibit previously filed with the Registrant's Post-Effective Amendment on Registration Statement Form F-6 (File No. 333-185197) filed on September 9, 2015).
4.7*	Description of the Akari Therapeutics Plc Securities Registered Under Section 12 of the Securities Exchange Act of 1934.
10.1	Relationship Agreement, dated as of July 10, 2015, by and between Celsus Therapeutics Plc and RPC Pharma Limited. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, as filed with the SEC on July 13, 2015).
10.2	Form of Working Capital Agreement, by and between Volution Immuno Pharmaceuticals SA and the Shareholders named therein. (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K, as filed with the SEC on July 13, 2015).
10.3†	2014 Equity Incentive Plan (incorporated by reference to Exhibit 99.1 to the Registrant's Report on Form 6-K (No. 001-36288), as filed with the SEC on June 24, 2014).
10.4†	Amended and Restated 2014 Equity Incentive Plan (incorporated by reference to Annex E to the Registrants Definitive Proxy Statement on Schedule 14A, as filed with the SEC on August 3, 2015).
10.5†	2023 Equity Incentive Plan (incorporated by reference to Exhibit 4.8 to the Registrant's Form S-8, as filed with the SEC on October 12, 2023).
10.6†*	Form of ISO/NQ Stock Option Agreement Granted Under the 2023 Equity Incentive Plan
10.7†*	Form of Restricted Stock Unit Agreement Granted Under the 2023 Equity Incentive Plan
10.8	Amended and Restated Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, as filed with the SEC on June 30, 2016).
10.9	Form of Securities Purchase Agreement dated as of June 28, 2019 between Akari Therapeutics, Plc and the investors listed therein (incorporated by reference to Exhibit 10.1 to the Registrant's Report on Form 6-K, as filed with the SEC on July 2, 2019).

10.10	Form of Warrant issued by Akari Therapeutics, Plc in connection with the July 2019 Registered Direct Offering (incorporated by reference to Exhibit 10.2 to the Registrant's Report on Form 6-K, as filed with the SEC on July 2, 2019).
10.11	Form of Placement Agent Warrant issued by Akari Therapeutics, Plc in connection with the July 2019 Registered Direct Offering (incorporated by reference to Exhibit 4.6 to the Registrant's Registration Statement on Form F-1 (333-233048), as filed with the SEC on August 6, 2019).
10.12	Form of Warrant issued by Akari Therapeutics, Plc in connection with the February 2020 Private Placement (incorporated by reference to Exhibit 10.2 to the Registrant's Report on Form 6-K, as filed with the SEC on March 4, 2020).
10.13	Registration Rights Agreement dated June 30, 2020 between the Company and Aspire Capital Fund, LLC (incorporated by reference to Exhibit 4.1 to the Registrant's Report on Form 6-K, as filed with the SEC on July 1, 2020).
10.14	Form of Warrant issued by Akari Therapeutics, Plc in connection with the July 2021 Private Placement (incorporated by reference to Exhibit 10.2 to the Registrant's Report on Form 6-K, as filed with the SEC on July 20, 2021).
10.15	Form of Warrant issued by Akari Therapeutics, Plc in connection with the December 2021 Registered Direct Offering (incorporated by reference to Exhibit 10.2 to the Registrant's Report on Form 6-K, as filed with the SEC on January 4, 2022).
10.16	Form of Warrant issued by Akari Therapeutics, Plc in connection with the March 2022 Registered Direct Offering (incorporated by reference to Exhibit 10.2 to the Registrant's Report on Form 6-K, as filed with the SEC on March 10, 2022).
10.17	Form of Series A Warrant issued by Akari Therapeutics, Plc in connection with the September 2022 Registered Direct Offering and Concurrent Private Placement (incorporated by reference to Exhibit 10.2 to the Registrant's Report on Form 6-K, as filed with the SEC on September 14, 2022).
10.18	Form of Series B Warrant issued by Akari Therapeutics, Plc in connection with the September 2022 Registered Direct Offering and Concurrent Private Placement (incorporated by reference to Exhibit 10.3 to Registrant's Report on Form 6-K, as filed with the SEC on September 14, 2022).
10.19	Form of Pre-Funded Warrant issued under the Securities Purchase Agreement dated as of September 20, 2023 between Akari Therapeutics, Plc and the investors listed therein (incorporated by reference to Exhibit 10.2 to Registrant's Current Report on Form 8-K, as filed with the SEC on September 21, 2023.
10.20	Form of Placement Agent Warrant issued under the Securities Purchase Agreement dated as of September 20, 2023 between Akari Therapeutics, Plc and the investors listed therein (incorporated by reference to Exhibit 10.3 to Registrant's Current Report on Form 8-K, as filed with the SEC on September 21, 2023.
10.21	Executive Employment Agreement between the Company and Rachelle Jacques dated June 1, 2022 (incorporated by reference to Exhibit 10.11 to the Registrant's Registration Statement on Form F-1, as filed with the SEC on October 12, 2022).
10.22	Stock Option Agreement between the Company and Rachelle Jacques dated June 1, 2022 (incorporated by reference to Exhibit 10.12 to Registrant's Registration Statement on Form F-1, as filed with the SEC on October 12, 2022).
10.23	Restricted Stock Unit Agreement between the Company and Rachelle Jacques dated June 1, 2022 (incorporated by reference to Exhibit 10.13 to Registrant's Registration Statement on Form F-1, as filed with the SEC on October 12, 2022).
10.24†*	Stock Option Agreement between the Company and Rachelle Jacques dated March 28, 2023.
10.25†*	Restricted Stock Unit Agreement between the Company and Rachelle Jacques dated June 1, 2023.
10.26†*	Consulting Agreement between the Company and Wendy DiCicco dated July 17, 2023.
10.27†*	Amendment No. 1 to Consulting Agreement between the Company and Wendy DiCicco dated September 1, 2023.
10.28†*	Consulting Agreement between the Company and Wendy F. DiCicco dated January 15, 2024.
10.29†*	Stock Option Agreement between the Company and Wendy F. DiCicco dated July 17, 2023.
10.30	Form of Voting and Support Agreement, dated as of March 4, 2024, by and among Akari, and certain stockholders of Peak Bio (incorporated by reference to Exhibit 10.1 to Registrant's Current Report on Form 8-K, as filed with the SEC on March 5, 2024).

10.31	Form of Voting and Support Agreement, dated as of March 4, 2024, by and among Peak Bio and certain shareholders of Akari (incorporated by reference to Exhibit 10.2 to Registrant's Current Report on Form 8-K, as filed with the SEC on March 5, 2024).
21.1*	List of Subsidiaries.
23.1*	Consent of Independent Registered Public Accounting Firm.
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97*	Clawback Policy.
101.INS	Inline XBRL Instance Document–the instance document does not appear in the Interactive Data File as its XBRL tags are embedded within the Inline XBRL document.
101.SCH	line XBRL Taxonomy Extension Schema With Embedded Linkbase Documents.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

* Filed herewith.

† Indicates management contract or compensatory arrangement.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized**.**

Akari Therapeutics, Plc

By:

Date: March 29, 2024

/s/ Rachelle Jacques

Rachelle Jacques
President, Chief Executive Officer and Director

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ Rachelle Jacques **Rachelle Jacques**	President, Chief Executive Officer and Director *(principal executive officer)*	March 29, 2024
/s/ Wendy DiCicco **Wendy DiCicco**	Interim Chief Financial Officer *(principal financial officer and principal accounting officer)*	March 29, 2024
/s/ Dr. Ray Prudo **Dr. Ray Prudo**	Chairman	March 29, 2024
/s/ Donald Williams **Donald Williams**	Director	March 29, 2024
/s/ Michael Grissinger **Michael Grissinger**	Director	March 29, 2024
/s/ Wa'el Hashad **Wa'el Hashad**	Director	March 29, 2024
/s/ Samir Patel **Samir Patel**	Director	March 29, 2024

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

Shareholders and Board of Directors
Akari Therapeutics, Plc
Boston, Massachusetts

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Akari Therapeutics, Plc (the "Company") as of December 31, 2023 and 2022, the related consolidated statements of operations and comprehensive loss, changes in shareholders' (deficit) equity, and cash flows for each of the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2023 and 2022, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern Uncertainty

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has suffered recurring losses from operations and has a net capital deficiency that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by

communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Classification of Warrants

As described in Note 5 to the consolidated financial statements, in September 2023, the Company entered into purchase agreements to sell in a private placement to existing investors an aggregate of 551,816 American Depository Shares ("ADSs") at $3.30 per ADS, and pre-funded warrants (the "Pre-Funded Warrants") to purchase up to 48,387 ADSs at a purchase price per Pre-Funded Warrant of $3.10, for aggregate gross proceeds of approximately $2.0 million. The Company determined that the Pre-Funded Warrants met all of the criteria for equity classification and recorded them as a component of additional paid-in capital upon the closing of the transaction in October 2023.

We identified the evaluation of the financial statement classification for the Pre-Funded Warrants as a critical audit matter. Our principal considerations included the existence of accounting complexities related to certain provisions of the warrant agreement, including settlement provisions and derivative elements. Auditing these elements involved especially complex auditor judgment due to the terms of the applicable agreement, including the extent of specialized knowledge and skills needed.

The primary procedures we performed to address this critical audit matter included:

- Evaluating the appropriateness of management's conclusions through the review of: (i) the relevant terms of the warrant agreement, (ii) the completeness and accuracy of the Company's technical accounting analysis, and (iii) the appropriateness of application of the relevant accounting literature.

- Utilizing personnel with specialized knowledge and skills in technical accounting to assist in: (i) evaluating relevant terms of the warrant agreement in relation to the appropriate accounting literature, and (ii) assessing the appropriateness of conclusions reached by the Company.

/S/ BDO USA, P.C.

We have served as the Company's auditor since 2016.

New York, New York

March 29, 2024

AKARI THERAPEUTICS, PLC
Consolidated Balance Sheets
as of December 31, 2023 and 2022
(in U.S. dollars)

(In thousands, except share and per share amounts)	December 31, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash	$ 3,845	$ 13,250
Prepaid expenses	299	465
Other current assets	197	100
Total current assets	4,341	13,815
Patent acquisition costs, net	14	17
Total assets	$ 4,355	$ 13,832
LIABILITIES AND SHAREHOLDERS' (DEFICIT) EQUITY		
Current liabilities:		
Accounts payable	$ 1,671	$ 947
Accrued expenses	1,566	3,148
Warrant liability	1,253	7,852
Other current liability	94	94
Total liabilities	4,584	12,041
Commitments and contingencies (Note 8)		
Shareholders' (deficit) equity:		
Share capital of $0.0001 par value		
Authorized: 45,122,321,523 and 15,000,000,000 ordinary shares at December 31, 2023 and 2022, respectively; issued and outstanding: 13,234,315,298 and 7,444,917,123 at December 31, 2023 and 2022, respectively	1,324	745
Additional paid-in capital	174,754	167,076
Capital redemption reserve	52,194	52,194
Accumulated other comprehensive loss	(1,040)	(771)
Accumulated deficit	(227,461)	(217,453)
Total shareholders' (deficit) equity	(229)	1,791
Total liabilities and shareholders' (deficit) equity	$ 4,355	$ 13,832

The accompanying notes are an integral part of these consolidated financial statements.

AKARI THERAPEUTICS, PLC
Consolidated Statements of Operations and Comprehensive Loss
for the Years ended December 31, 2023 and 2022
(in U.S. dollars)

(In thousands, except share and per share amounts)	Year Ended December 31, 2023	2022
Operating expenses:		
Research and development	$ 5,450	$ 9,561
General and administrative	11,356	13,527
Loss from operations	(16,806)	(23,088)
Other income (expense):		
Interest income	82	46
Excess in fair value of warrant liability over cash proceeds	—	(1,963)
Change in fair value of warrant liability	6,599	6,946
Foreign currency exchange gains (losses), net	136	453
Other expense, net	(19)	(142)
Net loss	$ (10,008)	$ (17,748)
Net loss per share — basic and diluted	$ (0.00)	$ (0.00)
Weighted-average number of common shares used in computing net loss per share — basic and diluted	9,788,980,193	6,243,462,410
Comprehensive loss:		
Net loss	$ (10,008)	$ (17,748)
Other comprehensive loss, net of tax:		
Foreign currency translation adjustment	(269)	(230)
Total other comprehensive loss, net of tax	(269)	(230)
Total comprehensive loss	$ (10,277)	$ (17,978)

The accompanying notes are an integral part of these consolidated financial statements.

AKARI THERAPEUTICS, PLC
Consolidated Statements of Changes in Shareholders' Equity (Deficit)
for the Years ended December 31, 2023 and 2022
(in U.S. dollars)

(In thousands, except share amounts)	Share Capital $0.0001 par value		Additional Paid-in-Capital	Capital Redemption Reserve	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Shareholders' Equity (Deficit)
	Shares	Amount					
Balance, December 31, 2021	**4,759,731,923**	**$ 476**	**$ 153,131**	**$ 52,194**	**$ (541)**	**$ (199,705)**	**$ 5,555**
Issuance of share capital related to financing, net of issuance costs	2,685,185,200	269	13,210	—	—	—	13,479
Stock-based compensation	—	—	735	—	—	—	735
Foreign currency translation	—	—	—	—	(230)	—	(230)
Net loss	—	—	—	—	—	(17,748)	(17,748)
Balance, December 31, 2022	7,444,917,123	745	167,076	52,194	(771)	(217,453)	1,791
Issuance of share capital related to financing, net of issuance costs	5,666,034,700	567	6,394	—	—	—	6,961
Issuance of share capital for vendor services	80,000,000	8	134	—	—	—	142
Vesting of restricted shares	43,363,475	4	—	—	—	—	4
Stock-based compensation	—	—	1,150	—	—	—	1,150
Foreign currency translation	—	—	—	—	(269)	—	(269)
Net loss	—	—	—	—	—	(10,008)	(10,008)
Balance, December 31, 2023	13,234,315,298	$ 1,324	$ 174,754	$ 52,194	$ (1,040)	$ (227,461)	$ (229)

The accompanying notes are an integral part of these consolidated financial statements.

AKARI THERAPEUTICS, PLC
Consolidated Statements of Cash Flows
for the Years ended December 31, 2023 and 2022
(in U.S. dollars)

(In thousands)	Year Ended December 31, 2023	2022
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (10,008)	$ (17,748)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	4	4
Stock-based compensation	1,150	735
Issuance of share capital for vendor services	142	—
Excess fair value of warrant liability over cash proceeds	—	1,963
Change in fair value of warrant liability	(6,599)	(6,946)
Foreign currency exchange (gains) losses	(255)	(334)
Change in assets and liabilities:		
Prepaid expenses and other current assets	70	1,699
Accounts payable and accrued expenses	(936)	(877)
Net cash used in operating activities	(16,432)	(21,504)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of shares, net of issuance costs	7,016	25,194
Proceeds from employee vesting of restricted shares	4	—
Proceeds for future exercises of warrants to purchase shares	—	94
Net cash provided by financing activities	7,020	25,288
Effect of exchange rates on cash	7	105
Net (decrease) increase in cash and cash equivalents	(9,405)	3,889
Cash at beginning of period	13,250	9,361
Cash at end of period	$ 3,845	$ 13,250
SUPPLEMENTAL DISCLOSURES OF NONCASH ACTIVITIES:		
Financing costs in accrued expenses	$ 55	$ —
Ordinary share subscription deposit	$ —	$ 1,120
Initial valuation of warrant liability	$ —	$ 14,798

The accompanying notes are an integral part of these consolidated financial statements.

AKARI THERAPEUTICS, PLC
Notes to Consolidated Financial Statements

Note 1. Description of Business

Business Overview

Akari Therapeutics, Plc, (the "Company" or "Akari") is incorporated in the United Kingdom. The Company is a clinical-stage biotechnology company focused on developing advanced therapies for autoimmune and inflammatory diseases involving the complement component 5 (C5) and leukotriene B4 (LTB4) pathways. The Company's activities since inception have consisted of performing research and development activities and raising capital.

The Company is subject to a number of risks similar to those of clinical stage companies, including dependence on key individuals, uncertainty of product development and generation of revenues, dependence on outside sources of capital, risks associated with clinical trials of products, dependence on third-party collaborators for research and development operations, need for marketing authorization of products, risks associated with protection of intellectual property, and competition with larger, better-capitalized companies.

To fully execute its business plan, the Company will need, among other things, to complete its research and development efforts and clinical and regulatory activities. These activities may take several years and will require significant operating and capital expenditures in the foreseeable future. There can be no assurance that these activities will be successful. If the Company is not successful in these activities it could delay, limit, reduce or terminate preclinical studies, clinical trials or other research and development activities.

Agreement and Plan of Merger

As further described in Note 10, in March 2024, the Company entered into an Agreement and Plan of Merger with Peak Bio, Inc. Following the anticipated closing of the Merger (as defined below), we expect to have an expanded pipeline that contains multiple compelling assets spanning early and late development stages with the addition of Peak Bio Inc.'s Phase 2-ready PHP-303 program targeting alpha-1 antitrypsin deficiency.

Liquidity and Financial Condition

The Company follows the provisions of Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 205-40, *Presentation of Financial Statements—Going Concern*, which requires management to assess the Company's ability to continue as a going concern within one year after the date the consolidated financial statements are issued.

The Company has incurred substantial losses and negative cash flows since inception and had an accumulated deficit of $227.5 million as of December 31, 2023. The Company's cash balance of $3.8 million as of December 31, 2023 is not sufficient to fund its operations for the one-year period after the date these consolidated financial statements are issued. These factors raise substantial doubt about the Company's ability to continue as a going concern. The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The consolidated financial statements do not include any adjustments related to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

The Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales of its product candidates currently in development. The Company is subject to a number of risks and uncertainties similar to those of other companies of the same size within the biotechnology industry, such as uncertainty of clinical trial outcomes, uncertainty of additional funding, and history of operating losses. Substantial additional financing will be needed by the Company to fund its operations and to commercially develop its product candidates. Management is currently evaluating different strategies to obtain the required funding for future operations. These strategies may include, but are not limited to: product development financing, private placements and/or public

offerings of equity and/or debt securities, and strategic research and development collaborations and/or similar arrangements. There can be no assurance that these future funding efforts will be successful.

Nasdaq Continued Listing Rules

On October 24, 2022, the Company received a deficiency notification letter from the Listing Qualifications Staff (the "Staff") of the Nasdaq Stock Market ("Nasdaq") indicating that the Company was not in compliance with Nasdaq Listing Rule 5550(a)(2) because the bid price for the Company's Common Stock had closed below $1.00 per share (the "Minimum Bid Requirement") for the previous thirty consecutive business days. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), the Company had 180 calendar days from the date of such notice, or until April 24, 2023, to regain compliance with the Minimum Bid Requirement. To regain compliance, the bid price for the Company's American Depository Shares ("ADSs") must have closed at $1.00 per share or more for a minimum of ten consecutive business days. On April 25, 2023, the Staff granted the Company an additional 180 calendar day period, or until October 23, 2023, in which to regain compliance with the Minimum Bid Requirement. Following the successful completion of the ADS Ratio Change (defined below), the Company received a written notice from the Staff that it has regained compliance with the Minimum Bid Requirement as a result of the Company's ADSs having a closing bid price of $1.00 per share or greater for 10 consecutive business days.

Nasdaq Listing Rule 5550(b)(1) requires companies listed on The Nasdaq Capital Market to maintain shareholders' equity of at least $2.5 million (the "Shareholders' Equity Requirement"). As of December 31, 2023, the Company had a shareholders' deficit of $0.2 million and therefore is not in compliance with the Shareholders' Equity Requirement. If the Company continues to not be in compliance or it fails to meet any of the other Nasdaq continuing listing requirements, its ADSs may be subject to delisting and the Company may become subject to delisting proceedings. The Company is currently assessing its available options to regain compliance with the Shareholders' Equity Requirement.

ADS Ratio Change

Effective August 17, 2023, the Company changed the ratio of its ADSs to ordinary shares, par value $0.0001 per share, from one ADS representing 100 ordinary shares to a new ratio of one ADS representing 2,000 ordinary shares (the "ADS Ratio Change"). All ADS and per ADS amounts in the accompanying consolidated financial statements and notes thereto have been retroactively adjusted for all periods presented to reflect the ADS Ratio Change.

Note 2. Summary of Significant Accounting Policies

Basis of presentation – The accompanying consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP") and assumes that the Company will continue to operate as a going concern.

Principles of consolidation – The consolidated financial statements include the accounts of the Company, Celsus Therapeutics, Inc., a Delaware corporation, Volution Immuno Pharmaceuticals SA, a private Swiss company, and Akari Malta Limited, a private Maltese company, each wholly-owned subsidiaries. All intercompany transactions have been eliminated.

Foreign currency – The functional currency of the Company is U.S. dollars, as that is the currency of the primary economic environment in which the Company operates as well as the currency in which it has been financed.

The reporting currency of the Company is U.S. dollars. The Company translates its non-U.S. operations' assets and liabilities denominated in foreign currencies into U.S. dollars at current rates of exchange as of the balance sheet date and income and expense items at the average exchange rate for the reporting period. Translation adjustments resulting from exchange rate fluctuations are recorded as foreign currency translation adjustments, a component of accumulated other comprehensive loss. Gains or losses from foreign currency transactions are included in foreign currency exchange gains/(losses).

Use of estimates – The preparation of the Company's consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that may affect the reported amounts of assets, liabilities, expenses and related disclosures. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, the valuation of share-based awards, the valuation of warrant liabilities, research and development prepayments, accruals and related expenses, and the valuation allowance for deferred income taxes. The Company bases its estimates on historical experience, known trends and other market-specific or other relevant factors that it believes to be reasonable under the circumstances. Estimates are periodically reviewed considering changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results may differ from those estimates or assumptions.

Segments – Operating segments are defined as components of an enterprise in which separate discrete information is available for evaluation by the chief operating decision maker ("CODM"), or decision-making group, in deciding how to allocate resources and assessing performance. The Company's CODM is its Chief Executive Officer (CEO). Neither the CODM nor the Company's directors receive disaggregated financial information about the locations in which research and development is occurring. Therefore, the Company views its operations and manages its business as one operating segment, which is the business of developing advanced therapies for autoimmune and inflammatory diseases.

Concentration of credit risk – Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash. The Company generally maintains balances in various operating accounts at financial institutions in amounts that may exceed federally insured limits. The Company has not experienced any losses related to its cash and does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

Fair value measurements – Certain assets and liabilities are carried at fair value under U.S. GAAP. Fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or a liability. As a basis for considering such assumptions, ASC 820, *Fair Value Measurements and Disclosures* ("ASC 820") establishes a three-tier value hierarchy, which prioritizes the inputs used in the valuation methodologies in measuring fair value:

- *Level 1* – quoted prices in active markets for identical assets and liabilities.
- *Level 2* – inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices in active markets for similar assets or liabilities, quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- *Level 3* – unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Determining which category an asset or liability falls within the hierarchy requires significant judgment. The Company evaluates its hierarchy disclosures each reporting period. The fair value hierarchy also requires the Company to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value.

The carrying values of the Company's cash, prepaid expenses and other current assets, accounts payable and accrued expenses approximate their fair values due to the short-term nature of these assets and liabilities. The Company's liability-classified warrants are recorded at their estimated fair value. See Note 3.

Cash – The Company considers all highly-liquid investments with original maturities of 90 days or less at the time of acquisition to be cash equivalents. The Company had no cash equivalents as of December 31, 2023 or December 31, 2022.

Prepaid expenses – Payments made prior to the receipt of goods or services are capitalized until the goods or services are received.

Other current assets – Other current assets as of December 31, 2023 and December 21, 2022 were principally comprised of Value Added Tax ("VAT") receivables.

Patent acquisition costs – Patent acquisition costs and related capitalized legal fees are amortized on a straight-line basis over the shorter of the legal or economic life. The estimated useful life is 22 years. The Company expenses costs associated with maintaining and defending patents after their issuance in the period incurred. Amortization expense for each of the years ended December 31, 2023 and 2022 was less than $0.1 million.

Accrued expenses – As part of the process of preparing the consolidated financial statements, the Company estimates accrued expenses. This process involves identifying services that third parties have performed on the Company's behalf and estimating the level of service performed and the associated cost incurred on these services as of each balance sheet date in the Company's consolidated financial statements. Examples of estimated accrued expenses include contract service fees in conjunction with pre-clinical and clinical trials, professional service fees and contingent liabilities. In connection with these service fees, the Company's estimates are most affected by its understanding of the status and timing of services provided relative to the actual services incurred by the service providers. If the Company does not identify certain costs that have been incurred or it under or over-estimates the level of services or costs of such services, the Company's reported expenses for a reporting period could be understated or overstated. The date on which certain services commence, the level of services performed on or before a given date, and the cost of services are often subject to the Company's estimation and judgment. The Company makes these judgments based upon the facts and circumstances known to it in accordance with U.S. GAAP. See Note 4.

Warrant Liability – The Company accounts for ordinary share or ADS warrants as either equity instruments, liabilities or derivative liabilities in accordance with ASC Topic 480, *Distinguishing Liabilities from Equity* ("ASC 480") and/or ASC Topic 815, *Derivatives and Hedging* ("ASC 815"), depending on the specific terms of the warrant agreement. Liability-classified warrants are recorded at their estimated fair values at issuance are remeasured each reporting period until they are exercised, terminated, reclassified or otherwise settled. Changes in the estimated fair value of liability-classified warrants are recorded in "change in fair value of warrant liability" in the Company's consolidated statements of operations and comprehensive loss. Equity-classified warrants are recorded within "additional paid-in capital" in the Company's consolidated statements of shareholders' (deficit) equity at the time of issuance and not subject to remeasurement.

Research and development expenses – Costs associated with research and development are expensed as incurred unless there is an alternative future use in other research and development projects. Research and development expenses include, among other costs, salaries and personnel–related expenses, fees paid for contract research services, fees paid to clinical research organizations, costs incurred by outside laboratories, manufacturers and other accredited facilities in connection with clinical trials and preclinical studies.

Payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods or services are received. The Company records expenses related to clinical studies and manufacturing development activities based on its estimates of the services received and efforts expended pursuant to contracts with multiple contract research organizations and manufacturing vendors that conduct and manage these activities on its behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract, and may result in uneven cash flows. There may be instances in which payments made to the Company's vendors will exceed the level of services provided and result in a prepayment of the expense. Payments under some of these contracts depend on factors such as the successful enrollment of subjects and the completion of clinical study milestones. In amortizing or accruing service fees, the Company estimates the time period over which services will be performed, enrollment of subjects, number of sites activated and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the Company's estimate, the Company will adjust the accrued or prepaid expense balance accordingly.

The Company accounts for research and development tax credits at the time its realization becomes probable as a credit to research and development expenses in the consolidated statements of operations and comprehensive loss.

Stock-based compensation expense – The Company measures all stock-based awards granted to employees, directors and non-employees based on the estimated fair value on the date of grant and recognizes compensation expense of those awards over the requisite service period, which is generally the vesting period of the respective awards. Forfeitures are accounted for as they occur. The Company classifies stock-based compensation expense in its consolidated statements of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

The fair value of each restricted ordinary share award is determined on the date of grant based on the fair value of the Company's ordinary shares on that same date. The fair value of each share option grant is determined on the date of grant using the Black-Scholes option pricing model, which requires inputs based on certain assumptions, including the expected stock price volatility, the expected term of the award, the risk-free interest rate, and expected dividends (See Note 6). Beginning on January 1, 2023, the Company began using its historical stock price volatility to determine the volatility assumption to be used in its Black-Scholes option pricing model. Prior to January 1, 2023, the Company estimated its expected stock price volatility based on the historical volatility of publicly traded peer companies. The expected term of the Company's options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. The expected dividend yield is based on the fact that the Company has never paid cash dividends on ordinary shares and does not expect to pay any cash dividends in the foreseeable future.

Leases – The Company accounts for its leases in accordance with ASC 842, *Leases*. In accordance with ASC 842, the Company records a right-of-use ("ROU") asset and corresponding lease liability on the balance sheet for all leases with terms longer than 12 months. Leases with an initial term of twelve months or less are not recorded on the consolidated balance sheet and are recognized on a straight-line basis over the lease term. As of December 31, 2023 and 2022, the Company did not have any leases with a term longer than twelve months. Accordingly, no ROU assets and corresponding lease liabilities are included in the Company's consolidated balance sheets as of December 31, 2023 or 2022.

Income taxes – The Company accounts for income taxes in accordance with the accounting rules that require an asset and liability approach to accounting for income taxes based upon the future expected values of the related assets and liabilities. Deferred income tax assets and liabilities are determined based on the differences between the financial reporting and tax bases of assets and liabilities and for tax loss and credit carry forwards and are measured using the expected tax rates estimated to be in effect when such basis differences reverse. Valuation allowances are established, if necessary, to reduce the deferred tax asset to the amount that will, more likely than not, be realized. The Company has recorded a full valuation allowance on its deferred tax assets as of December 31, 2023 and 2022.

The Company follows the provisions of ASC 740 "*Accounting for Uncertainty in Income Taxes*", which prescribes recognition thresholds that must be met before a tax position is recognized in the financial statements and provides guidance on de-recognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. Under ASC 740 "*Accounting for Uncertainty in Income Taxes*," an entity may only recognize or continue to recognize tax positions that meet a "more-likely-than-not" threshold. Interest and penalties related to uncertain tax positions are recognized as general and administrative expense. At December 31, 2023 and 2022, the Company had no uncertain tax positions.

Comprehensive Income (Loss) - Comprehensive loss is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. The Company's other comprehensive loss is comprised of foreign currency translation adjustments.

Net loss per share – Basic net income (loss) per ordinary share is computed by dividing net income (loss) available to ordinary shareholders by the weighted average number of ordinary shares outstanding during the period, which includes ordinary shares underlying pre-funded warrants, as such warrant is exercisable, in whole or in part, for nominal cash consideration with no expiration date. Diluted net income (loss) per ordinary share is computed by dividing the diluted net income (loss) available to ordinary shareholders by the weighted average number of ordinary shares, including potential dilutive ordinary shares assuming the dilutive effect as determined using the treasury stock method.

For periods in which the Company has reported net losses, diluted net loss per ordinary share is the same as basic net loss per ordinary share, since dilutive ordinary shares are not assumed to have been issued if their effect is anti-dilutive. The Company reported a net loss for each of the years ended December 31, 2023 and 2022.

The following potential dilutive securities, presented based on amounts outstanding at the end of each reporting period, have been excluded from the calculation of diluted net loss per share because including them would have had an anti-dilutive impact:

	Year Ended December 31,	
	2023	2022
Stock options	651,237,400	513,673,885
Restricted stock units	385,954,925	21,475,400
Warrants	4,240,447,500	4,155,347,500
Total	5,277,639,825	4,690,496,785

New Accounting Pronouncements – From time to time, new accounting pronouncements are issued by the FASB and rules are issued by the SEC that the Company has or will adopt as of a specified date. Unless otherwise noted, management does not believe that any other recently issued accounting pronouncements issued by the FASB or guidance issued by the SEC had, or is expected to have, a material impact on the Company's present or future consolidated financial statements.

Recently Issued (Not Yet Adopted) Accounting Pronouncements

In November 2023, the FASB issued Accounting Standards Update ("ASU") 2023-07, *Segment Reporting: Improvements to Reportable Segment Disclosures*. This ASU modified the disclosure and presentation requirements primarily through enhanced disclosures of significant segment expenses and clarified that single reportable segment entities must apply Topic 280 in its entirety. This guidance is effective for the Company for the year beginning January 1, 2024, with early adoption permitted. The amendments should be applied retrospectively to all prior periods presented in the financial statement. The Company is currently assessing the impact of this guidance on its consolidated financial statements and related disclosures.

In December 2023, the FASB issued ASU 2023-09, *Improvements to Income Tax Disclosures*. This ASU improves the transparency of income tax disclosure by requiring consistent categories and greater disaggregation of information in the rate reconciliation, and income taxes paid disaggregated by jurisdiction. This guidance is effective for the Company for the year beginning January 1, 2025, with early adoption permitted. The amendments should be applied on a prospective basis, with retrospective application permitted. The Company is currently assessing the impact of this guidance on its consolidated financial statements and related disclosures.

Note 3. Fair Value Measurements

Assets and Liabilities Measured at Fair Value on a Recurring Basis

The following table presents information about the Company's financial liabilities measured at fair value on a recurring basis and indicates the level of the fair value hierarchy used to determine such values:

	December 31, 2023			
(In thousands)	Total	Level 1	Level 2	Level 3
Liabilities				
Warrant liability - Series A	$ 15	$ —	$ —	$ 15
Warrant liability - Series B	1,238	—	—	1,238
Total liabilities	$ 1,253	$ —	$ —	$ 1,253

(In thousands)	December 31, 2022			
	Total	Level 1	Level 2	Level 3
Liabilities				
Warrant liability - Series A	$ 1,812	$ —	$ —	$ 1,812
Warrant liability - Series B	6,040	—	—	6,040
Total liabilities	$ 7,852	$ —	$ —	$ 7,852

The Company's Level 3 liabilities consist of the September 2022 Warrants (defined below), which were determined to be liability-classified instruments. There were no transfers between Level 1, Level 2, and Level 3 during the years ended December 31, 2023 and 2022.

Changes in Level 3 Liabilities Measured at Fair Value on a Recurring Basis

The following table summarizes the activity in the warrant liability measured at fair value on a recurring basis using unobservable inputs (Level 3) during the years ended December 31, 2023 and 2022:

(In thousands)	Warrant Liability		
	Series A	Series B	Total
Balance, December 31, 2021	$ —	$ —	$ —
Issuance of warrants	5,285	9,513	14,798
Change in the fair value of liability	(3,473)	(3,473)	(6,946)
Balance, December 31, 2022	$ 1,812	$ 6,040	$ 7,852
Change in the fair value of liability	(1,797)	(4,802)	(6,599)
Balance, December 31, 2023	$ 15	$ 1,238	$ 1,253

Assumptions Used in Determining Fair Value of Liability-Classified Warrants

The fair value of the warrant liability is based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. The fair value of both the Series A Warrants and the Series B Warrants (each defined below) was determined using the Black-Scholes Option Pricing Model, which uses various assumptions, including (i) fair value of the Company's ADSs, (ii) exercise price of the warrant, (iii) expected term of the warrant, (iv) expected volatility and (v) expected risk-free interest rate.

Below are the assumptions used for the fair value calculations of the Series A Warrants and Series B Warrants (each defined below), as of December 31, 2023 and 2022, adjusted, where applicable, to reflect the ADS Ratio Change for all periods presented, as more fully described in Note 1:

	December 31, 2023		December 31, 2022	
	Series A	Series B	Series A	Series B
Stock (ADS) price	$ 3.12	$ 3.12	$ 9.40	$ 9.40
Exercise price	$ 17.00	$ 17.00	$ 17.00	$ 17.00
Expected term (in years)	0.7	5.7	1.7	6.7
Expected volatility	85.0%	95.0%	80.0%	120.0%
Risk-free interest rate	5.1%	3.9%	4.4%	4.0%
Expected dividend yield	—	—	—	—

Note 4. Accrued Expenses

Accrued expenses consisted of the following as of December 31, 2023 and 2022:

($ in thousands)	December 31, 2023	December 31, 2022
Employee compensation and benefits	$ 187	$ 1,426
External research and development expenses	635	1,446
Professional and consulting fees	669	148
Other	75	128
Total accrued expenses	$ 1,566	$ 3,148

Note 5. Shareholders' (Deficit) Equity

Ordinary Shares

On June 30, 2023, the Company's shareholders approved an increase to the number of authorized ordinary shares the Company can issue by 35,000,000,000 ordinary shares in addition to the number of shares outstanding on June 30, 2023. Accordingly, following June 30, 2023 and as of December 31, 2023, the Company was authorized to issue up to 45,122,321,523 ordinary shares. As of December 31, 2022, the Company was authorized to issue up to 15,000,000,000 ordinary shares.

December 2023 Private Placement

In December 2023, the Company entered into purchase agreements to sell in a private placement to existing investors, Dr. Prudo, the Company's Chairman, and Dr. Patel, director, (the "December 2023 Private Placement") an aggregate of 947,868 ADSs at $2.11 per ADS, for aggregate gross proceeds of approximately $2.0 million. Net proceeds from the December 2023 Private Placement was approximately $1.8 million after deducting placement agent fees and other expenses.

September 2023 Private Placement

In September 2023, the Company entered into purchase agreements to sell in a private placement to existing investors, including Dr. Ray Prudo, the Company's Chairman, and Ms. Rachelle Jacques, the Company's President and CEO (the "September 2023 Private Placement") an aggregate of 551,816 ADSs at $3.30 per ADS, and pre-funded warrants (the "Pre-Funded Warrants") to purchase up to 48,387 ADSs at a purchase price per Pre-Funded Warrant of $3.10, for aggregate gross proceeds of approximately $2.0 million. The Pre-Funded Warrants are exercisable at an exercise price of $0.20 per ADS and will not expire until exercised in full. The September 2023 Private Placement closed in October 2023 resulting in net proceeds of approximately $1.7 million after deducting placement agent fees and other expenses.

At close of the September 2023 Private Placement, the Company issued to Paulson Investment Company, LLC ("Paulson"), as placement agent for the September 2023 Private Placement, warrants to purchase 42,550 ADSs at an exercise price of $4.13 per ADS (representing 125% of the price per ADS in the September 2023 Private Placement) and a term expiring on October 6, 2028 (the "October 2023 Placement Agent Warrants"). The estimated fair value of the October 2023 Placement Agent Warrants on the issuance date was approximately $0.1 million.

The Company determined that the Pre-Funded Warrants and October 2023 Placement Agent Warrants met all of the criteria for equity classification. Accordingly, upon closing of the September 2023 Private Placement, each of the Pre-Funded Warrants and October 2023 Placement Agent Warrants were recorded as a component of additional paid-in capital.

March 2023 Registered Direct Offering

On March 31, 2023, the Company entered into securities purchase agreements with certain accredited and institutional investors, including Dr. Ray Prudo, the Company's Chairman, (the "March Registered Direct Offering") providing for the issuance of an aggregate of 1,333,333 ADSs in a registered direct offering at $3.00 per ADS, resulting in gross proceeds of approximately $4.0 million. Net proceeds from the March Registered Direct Offering was approximately $3.5 million after deducting placement agent fees and expenses.

September 2022 Registered Direct Offering

On September 14, 2022, the Company sold to certain accredited and institutional investors, led by existing investors of the Company, including Dr. Ray Prudo, the Company's Chairman, an aggregate of 755,000 ADSs in a registered direct offering ("September 2022 Registered Direct Offering") at $17.00 per ADS for aggregate gross proceeds of approximately $12.8 million. In connection with the sale of the ADSs in the September 2022 Registered Direct Offering, the Company issued to the investors registered Series A warrants ("Series A Warrants") to purchase an aggregate of 755,000 ADSs at $17.00 per ADS and registered Series B warrants ("Series B Warrants") to purchase an aggregate of 755,000 ADSs at $17.00 per ADS (collectively, the "September 2022 Warrants").

The Company determined that the September 2022 Warrants are not indexed to the Company's own stock in the manner contemplated by ASC 815-40-15, *Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock*. Accordingly, the Company classifies the September 2022 Warrants as derivative liabilities in its consolidated balance sheets. The grant date fair value of the September 2022 Warrants totaled $14.8 million, which exceeded the $12.8 million proceeds received from the sale of ADSs. The Company concluded that the September 2022 Registered Direct Offering was conducted on an arm's length basis recorded the excess in fair value of the September 2022 Warrants over the proceeds received of $2.0 million on the issuance date, which is classified as a non-operating expense in the Company's consolidated statement of operations and comprehensive loss.

The Company measures the fair value of the September 2022 warrants at the end of each reporting period and recognizes changes in the fair value of the September 2022 warrants as a non-operating expense in the Company's consolidated statement of operations and comprehensive loss. See Note 3 for discussion of fair value measurement of the warrant liabilities.

March 2022 Registered Direct Offering

On March 10, 2022, the Company sold to certain accredited and institutional investors, led by existing investors of the Company, including Dr. Ray Prudo, the Company's Chairman, an aggregate of 372,042 ADSs in a registered direct offering ("March 2022 Registered Direct Offering") at $24.00 per ADS for aggregate gross proceeds of approximately $8.9 million. In connection with the sale of the ADSs in the March 2022 Registered Direct Offering, the Company issued to the investors registered warrants to purchase an aggregate of 186,020 ADSs at $28.00 per ADS (the "March 2022 Investor Warrants"). The March 2022 Investor Warrants are immediately exercisable and will expire five years from issuance, subject to adjustment as set forth therein. In connection with the offering, the Company paid Paulson, as placement agent, approximately $0.8 million in placement agent fees and expenses and issued registered warrants to Paulson to purchase an aggregate of 14,882 ADS (the "March 2022 Placement Agent Warrants") on the same terms as the March 2022 Investor Warrants, except that the March 2022 Placement Agent Warrants are exercisable at $30.00 per ADS.

The Company determined that the March 2022 Investor Warrants and March 2022 Placement Agent Warrants met all of the criteria for equity classification. Accordingly, upon closing of the March 2022 Registered Direct Offering, each of the March 2022 Investor Warrants and March 2022 Placement Agent Warrants were recorded as a component of additional paid-in capital.

2021 Registered Offering

In December 2021, The Company sold to certain accredited and institutional investors, led by existing investors, including Dr. Ray Prudo, the Company's Chairman, an aggregate of 215,550 ADSs in a registered direct offering (the "2021 Registered Offering") at 28.00 per ADS for aggregate gross proceeds of approximately $6.0 million, which closed on January 5, 2022. As of December 31, 2021, the Company had received approximately $1.1 million of gross proceeds which were classified as current liabilities on its balance sheet until closing in January 2022, which at that time the remaining $4.9 million in gross proceeds were received. In connection with the offering, the Company issued to the investors and Paulson, as placement agent for the 2021 Registered Offering, registered warrants to purchase 107,775 ADSs at $33.00 per ADS and 8,622 ADSs at $35.00 per ADS, respectively. Net proceeds after deducting placement agent fees and other expenses were approximately $5.4 million, of which $4.3 million was received in 2022.

Warrants

In connection with various financing transactions, the Company has issued warrants to purchase the Company's ordinary shares represented by ADSs. The Company accounts for such warrants as equity instruments or liabilities, depending on the specific terms of the warrant agreement. See Note 2 for further details on accounting policies related to the Company's warrants.

The following table summarizes the Company's outstanding warrants as of December 31, 2023 and 2022:

	Number of Warrant ADSs			
	December 31, 2023	December 31, 2022	Weighted-Average Exercise Price	Expiration Date
Equity-classified Warrants				
2019 Investor Warrants	59,211	59,211	$ 60.00	7/1/2024
2019 Placement Warrants	8,881	8,881	$ 57.00	6/28/2024
2020 Investor Warrants	139,882	139,882	$ 44.00	Feb-Mar 2025
2020 Placement Warrants	22,481	22,481	$ 51.00	Feb-Mar 2025
July 2021 Placement Agent Warrants	19,919	19,919	$ 46.40	7/7/2026
December 2021 Investor Warrants	107,775	107,775	$ 33.00	1/4/2027
December 2021 Placement Agent Warrants	8,622	8,622	$ 35.00	12/29/2026
March 2022 Investor Warrants	186,020	186,020	$ 28.00	3/10/2027
March 2022 Placement Agent Warrants	14,882	14,882	$ 30.00	3/10/2027
October 2023 Investor Prefunded Warrants	48,387	—	$ 0.20	—
October 2023 Placement Agent Warrants	42,550	—	$ 4.13	10/6/2028
	658,610	567,673		
Liability-classified Warrants				
September 2022 Series A Investor Warrants	755,000	755,000	$ 17.00	9/14/2024
September 2022 Series B Investor Warrants	755,000	755,000	$ 17.00	9/14/2029
	1,510,000	1,510,000		
Total outstanding	2,168,610	2,077,673		

The following table summarizes the Company's warrants activity for the year ended December 31, 2023:

($ in thousands, except per share data)	Number of Warrants	Weighted-Average Exercise Price
Outstanding at December 31, 2022	2,077,673	$ 22.85
Issued	90,937	2.04
Exercised	—	—
Expired	—	—
Outstanding at December 31, 2023	2,168,610	$ 21.97

Note 6. Stock-Based Compensation

2023 Equity Incentive Plan

On June 30, 2023, the Company's shareholders approved the 2023 Equity Incentive Plan (the "2023 Plan"), which provides for the grant of stock options, both incentive stock options and nonqualified stock options, stock, with and without vesting restrictions, restricted stock units and stock appreciation rights, to be granted to employees, directors and consultants. The Company is permitted to grant up to 980,000,000 ordinary share incentive awards under the 2023 Plan.

All outstanding ordinary shares under the 2014 Equity Incentive Plan (the "2014 Plan") relating to stock options and restricted stock units may be issued under the 2023 Plan if such awards are forfeited, cancelled or expire unexercised. As of June 30, 2023, the Company had 855,637,300 ordinary shares underlying outstanding equity awards under the 2014 Plan, consisting of stock options and restricted stock units. Accordingly, the total number of ordinary shares that may ultimately be issued under rights granted under the 2023 Plan, including shares subject to outstanding grants under the 2014 Plan, shall not exceed 1,835,637,300 ordinary shares. In addition, if an award issued under the 2023 Plan is terminated or results in any shares not being issued, the unissued or reacquired shares shall again be available for issuance under the 2023 Plan. As of December 31, 2023, the Company had 247,798,825 ordinary shares underlying outstanding equity awards under the 2023 Plan and 765,819,200 ordinary shares were available for future issuance under the 2023 Plan.

The 2023 and 2014 Plans provide that they be administered by the compensation committee of the board of directors. The exercise price for stock option awards may not be less than 100% of the fair market value of the Company's ordinary shares on the date of grant and the term of awards may not be greater than ten years. The Company determines the fair value of its ordinary shares based on the quoted market price of its ADSs. Vesting periods are determined at the discretion of the compensation committee. Awards granted to employees typically vest over two to four years and directors over one year.

2014 Equity Incentive Plan

Under the 2014 Plan the Company was authorized to grant stock options, restricted stock units and other awards, to employees, members of the board of directors and consultants. Upon effectiveness of the 2023 Plan no further awards were available to be issued under the 2014 Plan. As of December 31, 2023, the Company had 789,393,500 ordinary shares underlying outstanding equity awards under the 2014 Plan, consisting of stock options and restricted stock units.

Stock Options

The following is a summary of the Company's stock option activity under the 2014 Plan and the 2023 Plan for the year ended December 31, 2023:

($ in thousands, except share and per share data)	Stock Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2022	513,673,885	$ 0.02	8.7	$ —
Granted	223,690,700	0.00		
Exercised	—	—		
Forfeited	(27,127,185)	0.03		
Expired	(59,000,000)	0.04		
Outstanding at December 31, 2023 (1)	651,237,400	$ 0.01	8.5	$ —
Exercisable at December 31, 2023	212,510,100	$ 0.02	7.6	$ —

(1) Includes both vested stock options as well as unvested stock options for which the requisite service period has not been rendered but that are expected to vest based on achievement of a service condition.

The aggregate intrinsic value of options is calculated as the difference between the exercise price of the options and the fair value of the Company's common stock for those options that had exercise prices lower than the fair value of the Company's common stock.

The weighted-average grant-date fair value per share of options granted during each of the years ended December 31, 2023 and 2022 was less than $0.01.

Option Valuation

The weighted-average assumptions that the Company used to determine the fair value of share options granted were as follows, presented on a weighted average basis:

	2023	2022
Expected volatility	98.7%	76.1%
Risk-free interest rate	3.8%	3.1%
Expected dividend yield	—	—
Expected term (in years)	6.0	6.1

Restricted Stock Units

The 2014 Plan provided, and the 2023 Plan provides, for the award of restricted stock units ("RSUs"). RSUs are granted to employees that are subject to time-based vesting conditions that lapse between one year and four years from date of grant, assuming continued employment. Compensation cost for time-based RSUs, which vest only on continued service, is recognized on a straight-line basis over the requisite service period based on the grant date fair of the RSU's, which is derived from the closing price of the Company's ADS's on the date of grant.

The following table summarizes the Company's restricted stock activity for the year ended December 31, 2023:

($ in thousands, except per share data)	Time-based Awards	
	Number of Shares	Weighted-Average Grant Date Fair Value
Nonvested shares at December 31, 2022	21,475,400	$ 0.01
Granted	407,843,000	0.00
Forfeited	—	—
Vested	(43,363,475)	0.01
Nonvested shares at December 31, 2023	385,954,925	$ 0.00

The fair value of time-based RSUs that vested during the year ended December 31, 2023 was approximately $0.2 million. No time-based RSUs vested during the year ended December 31, 2022.

As of December 31, 2023, 28,151,775 ordinary shares underlying vested time-based RSUs, which have been included in the consolidated statement of shareholders' equity, were pending issuance.

Stock-Based Compensation Expense

The Company classifies stock-based compensation expense in the statement of operations in the same manner in which the award recipients' payroll costs are classified or in which the award recipients' service payments are classified. Total stock-based compensation expense attributable to stock-based payments made to employees, consultants and directors included in operating expenses in the Company's consolidated statements of operations and comprehensive loss for the years ended December 31, 2023 and 2022, was as follows:

($ in thousands)	Year Ended December 31,	
	2023	2022
Research and development	$ 153	$ 120
General and administrative	997	615
Total stock-based compensation expense	$ 1,150	$ 735

As of December 31, 2023, total unrecognized compensation cost related to unvested stock options and time-based RSUs was $1.7 million and $0.6 million, respectively, each of which is expected to be recognized over a weighted average period of 2.4 years.

Note 7. Related Party Transactions

The Doctors Laboratory

The Company leases office space for its U.K. headquarters in London from The Doctors Laboratory ("TDL") and has incurred expenses of approximately $0.1 million plus VAT during each of the years ended December 31, 2023 and 2022, respectively. David Byrne, a former non-employee director of the Company, is the Chief Executive Officer of TDL and Dr. Ray Prudo, the Company's Chairman, is the non-Executive Chairman of the Board of Directors of TDL.

The Company received certain laboratory testing services for its clinical trials provided by TDL, including certain administrative services, and incurred expenses of approximately $0.1 million during each of the years ended December 31, 2023 and 2022.

The Company recorded payable balances owed to TDL of less than $0.1 million as of December 31, 2023 and 2022.

Other

A non-employee director of the Company began providing business development consulting services in January 2018. The consulting agreement was terminated in November 2022. The Company incurred less than $0.1 million in expenses during the year ended December 31, 2022. No such expenses were incurred during the year ended December 31, 2023.

Note 8. Commitments and Contingencies

Leases

The Company currently leases office space for its U.S headquarters on a month-to-month basis and is party to a short-term lease with TDL for its London offices, which expires in August 2024. The Company is not party to any material lease agreements.

For each of the years ended December 31, 2023 and 2022, the Company incurred rent expense of approximately $0.2 million.

Employee Benefit Plans

The Company adopted an employee benefit plan under Section 401(k) of the Internal Revenue Code for its U.S.-based employees. The plan allows employees to make contributions up to a specified percentage of their compensation. Under the plan, the Company matches 100% of employees' contributions up to 5% of annual eligible compensation contributed by each employee, subject to Internal Revenue Code limitations.

The Company also adopted a defined contribution pension scheme which allows for U.K. employees to make contributions and provides U.K. employees with a Company contribution of 10% of compensation, subject to U.K. law.

During each of the years ended December 31, 2023 and 2022, the Company charged approximately $0.2 million to operating expenses related to the Company's contributions to employee benefit plans.

Note 9. Income Taxes

The components of net loss before income tax are as follows:

	Year Ended December 31,	
	2023	2022
Domestic (UK)	$ (10,267)	$ (18,018)
Foreign	259	270
Net loss before income tax	$ (10,008)	$ (17,748)

The components of income tax expense are as follows:

	Year Ended December 31,	
	2023	2022
Current income taxes		
Domestic (UK)	$ —	$ —
U.S.	—	—
Foreign	—	—
Deferred income taxes		
Domestic (UK)	—	—
Foreign	—	—
Income tax expense	$ —	$ —

As of December 31, 2023 and 2022 the tax effects of temporary differences and carryforwards that give rise to significant portions of the Company's deferred tax assets were as follows:

(in thousands)	December 31, 2023	December 31, 2022
Deferred tax assets		
Stock-based compensation	$ 480	$ 955
PP&E and other accrued liabilities	899	642
Intangibles	780	1,659
Warrant revaluation	(2,895)	(947)
Tax loss carry forward	42,978	32,307
Total deferred tax assets	42,242	34,616
Valuation allowance	(42,242)	(34,616)
Net deferred tax assets	$ —	$ —

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Management currently believes that since the Company has a history of losses, it is more likely than not that the deferred tax assets relating to the loss carryforwards and other temporary differences will not be realized in the foreseeable future. Therefore, the Company provided a full valuation allowance to reduce the deferred tax assets as of December 31, 2023 and 2022.

The United Kingdom’s Finance Act 2021, which was enacted on June 10, 2021, maintained the corporate income tax rate at 19% up until the tax year commencing April 1, 2023, at which point the rate rose to 25%. As of December 31, 2023, the Company used a 25% and 21% tax rate in respect of the measurement of deferred taxes existing in the U.K. and the U.S., respectively, which reflects the currently enacted tax rates and the anticipated timing of the reversing of the deferred tax balances.

The following is a reconciliation of income tax expense computed at the UK statutory rate (2023: 23.5% (pro-rated), 2022: 19%) compared to the Company's income tax expense as reported in its consolidated statements of operations and comprehensive loss:

	Year Ended December 31,	
	2023	2022
Net loss before income tax	$ (10,008)	$ (17,748)
Statutory rate	23.50%	19.00%
Expected income tax recovery	(2,352)	(3,372)
Impact on income tax expense/recovery from		
Change in valuation allowance	7,617	4,327
Permanent differences	4	408
U.S. state taxes (net of FBOS)	1,394	(1,114)
Tax rate difference in foreign jurisdictions	(974)	(248)
Change of tax rate due to U.S. tax reform	—	4
Change in equity compensation	123	752
Change in operating losses	(94)	(133)
Change of tax rate from prior year	(6,635)	(624)
Deferred tax adjustments	760	—
Non-deductible transaction costs	157	—
Income tax expense	$ —	$ —

At December 31, 2023 and 2022, there were no known domestic or foreign uncertain tax positions and the Company has not identified any tax positions for which it is reasonably possible that a significant change will occur during the next 12 months. The Company's position is to record penalties and interest on any uncertain tax position, if any, to general and administrative expense in the consolidated statements of operations.

At December 31, 2023, the Company had cumulative UK, US federal, various US state, and Switzerland net operating loss carryforwards ("NOLs") of approximately $125.2 million, $33.5 million, $60.3 million, and less than $0.1 million, respectively, available to reduce UK, US federal, US state and Switzerland taxable income, respectively. The UK NOLs do not expire. Of the $33.5 million of US federal NOLs, $27.7 million have an unlimited carryforward and the remaining NOLs are subject to expiration through 2037. Of the $60.3 million of US state NOLs, $29.2 million have an unlimited carryforward and the remaining NOLs are subject to expiration through 2043.

In general, an ownership change, as defined by Section 382 of the Internal Revenue Code, results from transactions increasing the ownership of certain shareholders or public groups in the stock of a corporation by more than 50% over a three-year period. In the second quarter of 2023, the Company conducted a study to assess whether a change of control has occurred. The Company concluded that it had experienced a change of control, as defined by Section 382, and utilization of certain net operating loss carryforwards would be subject to an annual limitation under Section 382. The Company determined that the limitation was immaterial to its consolidated financial statements. As no study has been completed subsequent to the second quarter of 2023, additional ownership change limitations may result from ownership changes that have occurred, or may occur in the future.

Research and development credits

The Company carries out extensive research and development activities and may benefit from the UK research and development tax relief regime, whereby the Company can receive an enhanced UK tax deduction on its research and development activities. Qualifying expenditures comprise of chemistry and manufacturing consumables, employment costs for research staff, clinical trials management, and other subcontracted research expenditures. Where the Company is loss making for the period it can elect to surrender taxable losses for a refundable tax credit. The losses available to surrender are equal to the lower of the sum of the research and development qualifying expenditure and enhanced tax deduction and the Company's taxable losses for the period with the tax credit for December 31, 2023 available at a rate of 14.5%. The credit therefore gives a cash flow advantage to Company at a

lower rate than would be available if the enhanced losses were carried forward and relieved against future taxable profits.

The Company accounts for research and development tax credits at the time its realization becomes probable (Note 2). Due to the uncertainty of the approval of these tax credit claims and the potential that an election for a tax credit in the form of cash is not made, the Company did not record a receivable for the 2023 tax year at December 31, 2023.

Note 10. Subsequent Events

The Company considers events or transactions that occur after the balance sheet date but prior to the issuance of the financial statements to provide additional evidence relative to certain estimates or to identify matters that require additional disclosure. In some instances, such subsequent events may require retroactive adjustment to information reported at the balance sheet date.

March 2024 Private Placement

In March 2024, the Company entered into a definitive purchase agreement with certain existing investors, pursuant to which the Company sold and issued in a private placement an aggregate of 1,320,614 ADSs at $1.48 per ADS, for aggregate gross proceeds of approximately $2.0 million. Net proceeds from the March 2024 Private Placement was approximately $1.7 million after deducting placement agent fees and other expenses.

Agreement and Plan of Merger

On March 4, 2024, the Company entered into an Agreement and Plan of Merger (the “Merger Agreement”) with Peak Bio, Inc. (“Peak Bio”) and Pegasus Merger Sub, Inc., a Delaware corporation and a wholly-owned subsidiary of Akari (“Merger Sub"), pursuant to which, upon the terms and subject to the conditions thereof, Merger Sub will be merged with and into Peak Bio (the “Merger”), with Peak Bio surviving the Merger as a wholly-owned subsidiary of Akari.

Pursuant to the Merger Agreement, and upon the terms and subject to the conditions thereof, at the effective time of the Merger (the “Effective Time”), each issued and outstanding share of Peak Bio common stock, par value $0.0001 per share (the “Peak Common Stock”) (other than (x) shares of Peak Common Stock held by Peak Bio as treasury stock, or shares of Peak Common Stock owned by Akari, Merger Sub or any direct or indirect wholly-owned subsidiaries of Akari and (y) Dissenting Shares (as defined in the Merger Agreement), will be converted into the right to receive the Company's ADSs representing a number of Akari ordinary shares, par value $0.0001 per share (the “Akari Ordinary Shares”) equal to an exchange ratio calculated in accordance with the Merger Agreement (the “Exchange Ratio”), each such share duly and validly issued against the deposit of the requisite number of Akari Ordinary Shares in accordance with the Deposit Agreement (as defined in the Merger Agreement). The Exchange Ratio will be calculated such that the total number of shares of Akari ADSs to be issued as merger consideration for the Peak Common Stock will be expected to be, upon issuance, approximately 50% of the outstanding shares of Akari ADSs (provided, certain adjustments to this ratio will be made in respect of the net cash, as determined in accordance with the Merger Agreement, of each of Akari and Peak Bio at the close of business one business day prior to the anticipated consummation of the Merger). The Merger Agreement provides that, under certain circumstances, additional Akari ADSs may be issued to the holders of shares of Peak Common Stock following the consummation of the Merger equal to an exchange ratio calculated in accordance with the Merger Agreement (the “Additional Exchange Ratio”).

The board of directors of each of Akari and Peak has unanimously approved the Merger Agreement and the transactions contemplated thereby. Consummation of the Merger is subject to various conditions, including, among others, (i) approval of the Merger Agreement and Merger by Peak Bio stockholders, (ii) Akari’s shareholders authorizing Akari’s board of directors to allot all Akari ordinary shares to be issued in connection with the Merger (to be represented by Akari ADSs), (iii) the absence of any law or order prohibiting consummation of the Merger, (iv) Akari’s Registration Statement on Form S-4 (to be issued in connection with the Merger) having been declared effective, (v) the Akari ADSs issuable to Peak Bio stockholders having been authorized for listing on Nasdaq, (vi) accuracy of the other party’s representations and warranties (subject to certain materiality standards set forth in

the Merger Agreement), (vii) compliance by the other party in all material respects with such other party's obligations under the Merger Agreement; (viii) the absence of a material adverse effect on the other party, (ix) the other party's net cash being greater than negative $13,500,000 and (x) the PIPE Investment (as defined in the Merger Agreement) shall have been consummated simultaneously with, and conditioned only upon, the occurrence of the closing, and shall result in net proceeds to Akari of at least $10,000,000.

Either Akari or Peak Bio may terminate the Merger Agreement under certain circumstances, including if (i) the Merger is not completed by September 4, 2024, (ii) the other party's board of directors withdraws, modifies or qualifies its recommendation in favor of the transactions contemplated by the Merger Agreement or approves or recommends an alternative transaction or (iii) Akari's or Peak Bio's board of directors, as applicable, resolves to enter into a definitive agreement with respect to a superior proposal prior to obtaining approval of the Akari ADS issuance or Merger, as applicable, from Akari's shareholders or Peak Bio's stockholders, as applicable. The Merger Agreement also provides that under certain specified circumstances of termination described in the Merger Agreement, Akari or Peak Bio, as applicable, will be required to pay a termination fee equal to $300,000 and reimburse the other party for expenses related to the transaction up to $1.5 million.

Concurrently with the Merger Agreement, Akari and Peak Bio entered into voting and support agreements (the "Voting Agreements") with certain shareholders of Akari (the "Akari Shareholders"), and certain stockholders of Peak Bio (the "Peak Stockholders" and, together with the Akari Shareholders, the "Supporting Holders"). The Supporting Holders have agreed to, among other things, vote their shares in favor of the Merger Agreement and the Merger or the issuance of Akari Ordinary Shares in connection therewith, as applicable, in accordance with the recommendation of the respective boards of directors of Akari and Peak Bio.

As of March 1, 2024, the Akari Shareholders beneficially owned an aggregate of approximately 39.51% of the outstanding Akari Ordinary Shares. As of March 1, 2024, the Peak Stockholders beneficially owned an aggregate of approximately 39.3% of the outstanding shares of Peak Common Stock.

The Voting Agreements will terminate at the earliest to occur of (a) the Effective Time, (b) receipt of approval of the Supporting Holders, as applicable, and (c) such date and time as the Merger Agreement is validly terminated.