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, 2024

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 **(State or other jurisdiction of incorporation or organization)**	**98-1034922** **(I.R.S. Employer Identification No.)**
22 Boston Wharf Road, FL 7 Boston, Massachusetts **(Address of principal executive offices)**	**02210** **(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, 2024, was $14.0 million.

The number of shares of Registrant's Ordinary Shares outstanding as of March 31, 2025 was 57,752,981,523.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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GENERAL INFORMATION

Unless otherwise stated or the context requires otherwise, references in this Annual Report on Form 10-K ("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 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 Form 10-K.

Statements made in this 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 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 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 our actual results, performance, or achievements 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 American Depositary Shares ("ADSs") 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 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 Form 10-K as part of your evaluation of an investment in our ADSs.

- We have a history of operating losses and cannot give assurance of future revenues or operating profits.
- We will require substantial 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.
- We have identified material weaknesses in our internal control over financial reporting.
- We have not initiated clinical studies for any of the programs in our active pipeline or entered into any strategic partnerships regarding the continued development of our legacy pipeline assets. As a result, it may be years before we commercialize a product candidate, if ever.
- If preclinical studies or clinical trials of our product candidates are prolonged or delayed, we may be unable to obtain required regulatory approvals, and therefore be unable to commercialize our product candidates or any of our future product candidates on a timely basis or at all.
- We may encounter substantial delays in the commencement, enrollment or completion of clinical trials or we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities, which could prevent us from commercializing any product candidates we determine to develop on a timely basis, if at all.
- Serious adverse events, undesirable side effects or other unexpected properties of our product candidates may be identified during development or after approval, which could lead to the discontinuation of our development programs, refusal by regulatory authorities to approve our product candidates or, if discovered following marketing approval, revocation of marketing authorizations or limitations on the use of our product candidates, any of which would limit the commercial potential of such product candidates.
- Our proprietary ADC Platform is based on novel technologies that are unproven and may not result in approvable or marketable products, which exposes us to unforeseen risks and makes it difficult for us to predict the time and cost of product development and potential for regulatory approval, and we may not be successful in our efforts to expand our development portfolio of product candidates.
- Interim, initial, or preliminary results from our preclinical testing or clinical trials that we announce or publish from time to time may change 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.
- We or a future strategic partner may choose to, or may be required to, suspend, repeat, or terminate clinical trials of our assets if they are not conducted in accordance with regulatory requirements, the results are negative or inconclusive or the trials are not well designed.
- Our employees, independent contractors, principal investigators, contract research organizations, consultants, vendors and collaboration partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards.
- Our industry is highly competitive, and our product candidates may become obsolete.
- If we are unable to establish sales, marketing and distribution capabilities on our own or through collaborations with partners, we may not be successful in commercializing any approved drugs.

- Even if any of our current or future product candidates receive marketing approval, such product candidates may fail to achieve market acceptance by physicians, patients, third-party payors or others in the medical community necessary for commercial success, in which case we may not generate significant revenues or become profitable.

- Even if we are able to commercialize any product candidate, the third-party payor coverage and reimbursement status of newly-approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for our product candidates could limit our ability to market those products and decrease our ability to generate revenue.

- Our future growth may depend, in part, on our ability to commercialize products in foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

- EU drug marketing and reimbursement regulations may materially affect our ability to market and receive coverage for our products in the EU Member States.

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

- We rely on third parties to conduct, supervise and monitor our preclinical studies and clinical trials, and to manufacture our product candidates, and if those third parties perform in an unsatisfactory manner it may harm our business.

- We are currently operating in a period of economic uncertainty and capital markets disruption, which has been significantly impacted by geopolitical instability. Our business, financial condition and results of operations could be materially adversely affected by any negative impact on the global economy and capital markets resulting from the geopolitical tensions or high inflation.

- Our business is subject to risks associated with conducting business internationally.

- 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.

- 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.

- We have in the past and may in the future fail to meet the requirements for continued listing on Nasdaq, causing our ADSs to be delisted.

- 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 an oncology company developing next-generation antibody-drug conjugates ("ADCs") designed around novel, proprietary cancer-killing toxins ("payloads"). We believe these novel payloads may have the potential to transform the efficacy and safety outcomes of ADCs as cancer therapies beyond options that are currently available or in development.

Cancers are the second leading cause of mortality in the United States and the leading cause of death for those under 65 years of age. The American Cancer Society estimates that approximately 618,000 people will die of cancer in the United States in 2025.

ADCs are a class of cancer therapies that combine the precision targeting of antibodies with payload toxins that attack cancer cells. To date, innovation in the field of ADC therapies has focused primarily on the development of novel antibodies linked to existing classes of payload toxins. For example, there is a range of approved ADCs with antibodies that target the Her2, Trop2, CD19, CD22, CD30, Nectin-4, Tissue Factor, and FR alpha antibodies. But there is a surprising lack of diversity in the payload toxins to which those antibodies are linked, as all of these marketed products, and more than 90% of ADCs in late-stage clinical development of which we are aware, utilize payloads from just two standard classes: (1) microtubule inhibitors or (2) DNA-damaging agents such as topoisomerase I inhibitors.

Despite the initial success of ADCs as oncology therapies, each of these payload classes has limitations in terms of providing significant and enduring efficacy and manageable toxicity and tolerability for cancer patients:

- Microtubule Inhibitors: resistance by cancer cells after initial response, off-target toxicity to healthy tissues and cells, and limited efficacy against static cancer cells that are not in division mode.

- Topoisomerase I Inhibitors: resistance by cancer cells after initial response, off-target toxicities, that include lung scarring, gastrointestinal and hematological toxicities (including low white blood cells and platelets), and limited ability to combine with other cancer therapies due to cumulative toxicities.

Our approach centers on creating novel payloads that work through different biological mechanisms than these standard payload classes. We believe that doing so may allow us to discover and develop ADCs that solve for the known limitations of therapies that utilize existing payload classes. However, our strategy is new and unproven, and we cannot guarantee that we will be successful in our efforts.

Our differentiated ADC discovery and development platform (our "ADC Platform") enables us to generate a range of ADC product candidates that pair our novel payloads with biologically validated antibody targets prevalent in cancer tumors. We believe that our focus on the development of ADCs that utilize our novel payloads may allow us to develop ADCs with benefits that include:

- more effective cancer-killing properties, or cytotoxicity;

- generation of greater numbers of neoepitopes than currently available ADCs, leading to activation of both B-cells and T-cells in the tumor microenvironment to generate an immune response that has the potential to continue to kill cancer cells in the tumor microenvironment and throughout the body;

- ability to be used in combination with key immunotherapy agents such as anti-PD1 and anti-PD-L1 therapies ("checkpoint inhibitors") to potentially deliver synergistic efficacy results (more than additive);

- sustained duration of response of tumor regression or elimination;

- reduced tumor resistance; and

- improved safety and tolerability relative to ADCs that are currently available.

Our lead payload, PH1, derives its cytotoxic properties from its ability to disrupt the function of spliceosomes, which play a critical role in protein synthesis, and we believe it is unique among ADC payloads that are currently in development or used in approved ADC therapies in that regard. We have observed in preclinical studies that PH1 may also have the ability to trigger an immune response that leads to additional cancer cell killing via the activation B-cells and T-cells through neoepitope formation. We believe this dual action of tumor killing by PH1 is differentiated from current standard ADC payloads used today and suggests that PH1 possesses a "bifunctional" mechanism of action ("MoA").

Our lead product candidate is AKTX-101, a preclinical stage Trop2-targeting ADC that combines PH1 with the Trop2 antibody, which is expressed in the highest number of solid tumor cancer types, including lung, breast, colon and prostate. We aim to establish AKTX-101 as a best-in-class Trop2-targeting ADC for the treatment of a variety of solid tumors.

Beyond AKTX-101, our ADC Platform enables us to develop additional ADCs that combine the PH1 payload and other novel payloads that we are developing or may in the future develop with a number of antibodies known to be key cancer targets. Our pipeline currently consists of AKTX-101 and AKTX-102, a discovery-stage ADC that pairs PH1 with an undisclosed target antibody.

We are also pursuing research on two additional novel payloads that possess distinct MoAs from those demonstrated by traditional payloads:

- PH5: inhibits DNA mismatch repair ("MMR") and DNA Damage Response ("DDR") to generate neoepitopes.
- PH6: inhibits DNA transcription in cancer cells and co-opted immune cells.

We acquired the proprietary rights to PH1, PH5 and PH6 in our business combination (the "Merger") with Peak Bio, Inc. ("Peak Bio"), which was completed in November 2024. Prior to that time, we were primarily focused on advancing our former product candidates nomacopan and PAS-nomacopan (longer-acting nomacopan that is PASylated). Since the closing of the Merger, we have focused substantially all of our efforts on the development of ADCs and our ADC Platform. We have suspended further internal development of our legacy programs, nomacopan and PAS-nomacopan, and intend to seek strategic partners to advance their development externally. For our PHP-303 program, a program that Peak Bio had advanced prior to the closing of the Merger, we intend to seek strategic partners for it as well to further its development externally. See "—Our Legacy Programs" for more information.

Our Strategy

We aim to create more effective and safer ADC cancer therapies by leveraging our novel payload expertise to potentially improve cancer outcomes for patients. We intend to leverage the core capabilities of our experienced team in cancer biology and chemistry, as well as experienced senior leadership in the oncology space to advance our novel ADC Platform and candidates. In March 2025, we announced that our director Abizer Gaslightwala would be joining our management team as President and CEO effective April 21, 2025. Mr. Gaslightwala brings a proven track record of successfully developing and commercializing oncology therapies as well as expertise in antibody-based therapies.

Our approach is focused on five key areas:

- *Advance AKTX-101 to IND and potential initiation of first-in-human ("FIH") trial.* AKTX-101 has demonstrated its potential efficacy and safety in several preclinical models to date. We intend to focus on defining the tumor strategy that drives maximum future commercial opportunity, developing additional preclinical data to support this strategy, developing a manufacturing supply, and completing formal toxicology studies to potentially support a future IND or other regulatory submission for a FIH trial.
- *Progress AKTX-102, our discovery-stage ADC that utilizes PH1 against a novel cancer target.* Our AKTX-102 product candidate is a novel bispecific ADC that utilizes PH1 as its payload and targets two key antigens present on many solid tumor cancers. From our initial early data, we believe AKTX-102 has the potential to overcome shortcomings of ADCs focused on similar targets that use standard payloads. We plan to advance AKTX-102 through additional efficacy and safety preclinical experiments to further understand its potential benefits.
- *Develop additional ADC programs that utilize our PH5 and PH6 payloads.* In addition to our efforts to identify additional product candidates utilizing PH1, we intend to continue our efforts to discover product candidates that utilize PH5 and PH6, each of which may have the potential to kill cancer cells in novel ways that may be more beneficial than ADCs containing standard payloads.

- *Leverage our ADC product candidates and payload library to partner with biopharmaceutical companies that desire to develop ADCs with novel payloads.* Our focus on the development of novel proprietary payloads and antibody-payload linkers affords us with a broad and flexible partnering strategy that allows us to out-license rights to specific molecules, such as AKTX-101, or to our novel proprietary payloads, such as PH1, and to develop novel ADC product candidates for our potential future partners based on the partner's specifications.

- *Out-license our legacy non-oncology assets.* Nomacopan and PHP-303 are clinical stage assets with key clinical data in inflammation and rare diseases. PAS- nomacopan is a preclinical, longer-acting version of nomacopan with a focus on geographic atrophy for retinal/ophthalmological diseases. We hope to out-license these assets as a means for raising capital that can be applied to the advancement of our ADC product candidates and the development of our ADC Platform.

Our Novel Payloads

PH1: Our Lead Payload

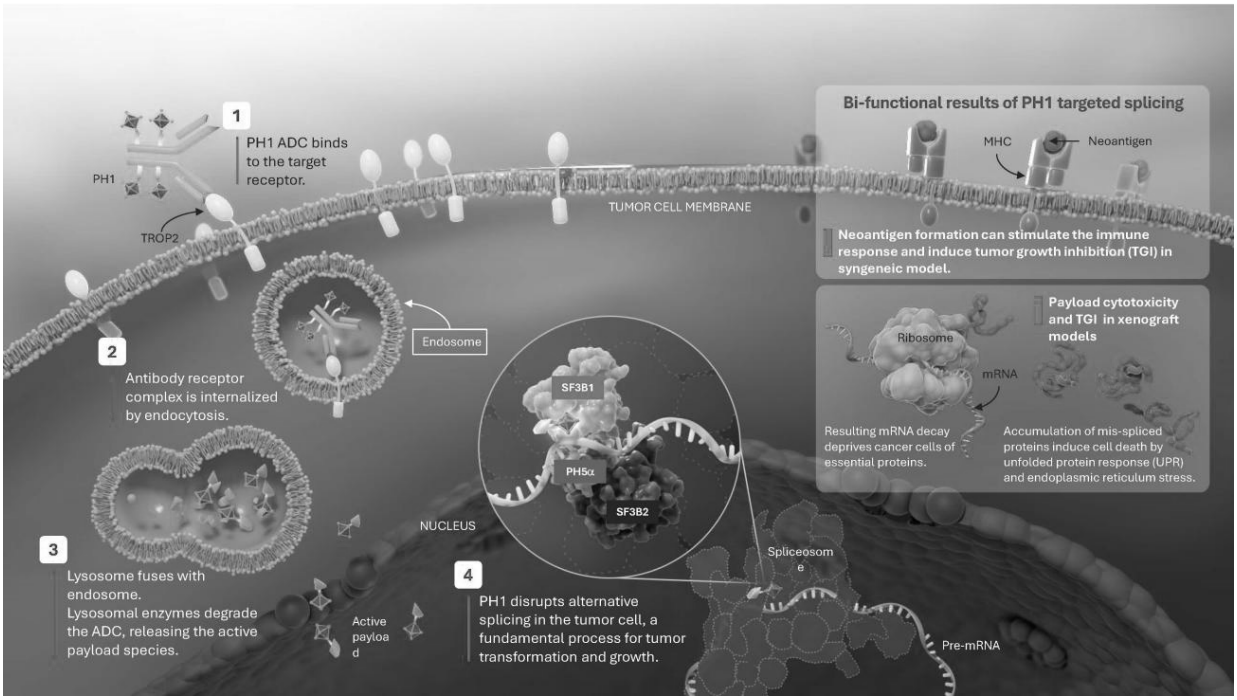
PH1, or Thailanstatin ThA13, is an analog of a toxin produced by the bacterium *Burkholderia thailandensis* MSMB43 with cytotoxic properties that stem from its ability to inhibit the ability of spliceosomes in eukaryotic cells to properly generate mature messenger mRNA ("mRNA") from pre-messenger RNA ("pre-mRNA") during the step of protein synthesis called splicing.

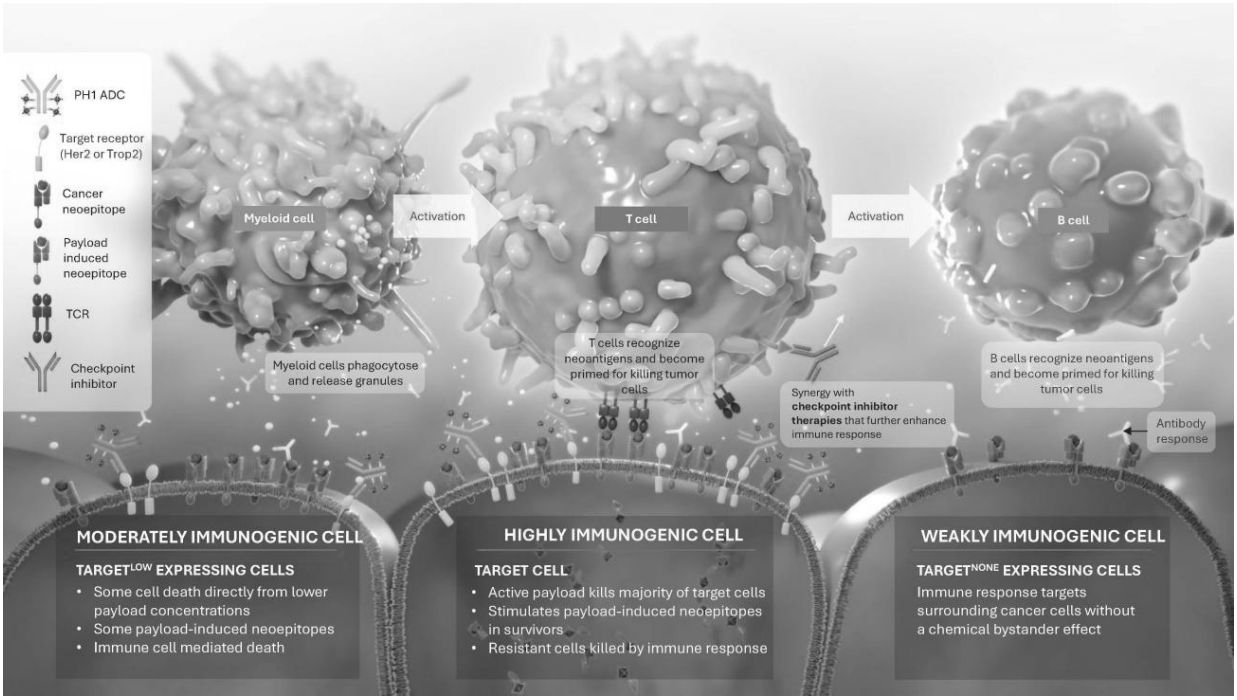
We believe spliceosomes are attractive targets for ADCs because the inhibition of spliceosomal function prevents cells from receiving critical information necessary for their continued survival. During splicing, pre-RNA is converted to mRNA via the removal of "junk" sequences of pre-mRNA called introns, and the stitching together of the meaningful parts of pre-mRNA called exons. After the introns have been removed and the exons stitched together, the resulting mRNA is then translated into proteins. The spliceosome is the machinery responsible for the correct splicing of pre-mRNA and resultant formation of mRNA.

Faulty spliceosome function, results in improper construction of exons, leading to faulty mRNA and resultant aberrant proteins. Accumulation of thousands of aberrant mis-spliced RNA sequences and misfolded unnatural proteins within the cell cause it to die by endoplasmic reticulum stress, unfolded protein response, and other various mechanisms. The accumulation of mis-spliced RNA also produces unnatural proteins called neoepitopes, which generate an immunostimulatory response that leads to further elimination by the immune system of cells that express similar neoepitopes. We believe the secondary cytotoxic effect of spliceosome malfunction that results from neoepitope formation makes the use of spliceosome inhibitors attractive in the development of potential ADC therapies due to their potential to exhibit a bifunctional MoA through which the payload targets and kills cancer cells and the resultant formation of neoepitopes triggers the body's immune system to do the same.

Preclinical data that we have gathered indicate that PH1 possesses the ability to induce neoepitope formation. In an *in vitro* study, we performed an unbiased comparison of PH1-, ravtansine ("DM4")- and dimethyl sulfoxide ("DMSO") (vehicle control)- treated human gastric cancer cells by performing RNA sequencing all genes and looking for sequences that would give rise to neoepitopes. After identifying the normal and novel RNA species, we highlighted the neoepitope-containing species that respectively increased in response to treatment with DM4 and PH1 as compared to the control treatment. We observed that PH1-treated cells contained 765 neoepitope-containing species, representing approximately 9 times the number of neoepitope-containing species created by DM4, which suggests that PH1 may be highly proficient at recruiting immune cells to the tumor and stimulating immune-cell mediated cancer cell death. When we looked for genes that were negatively impacted and reduced in quantity, we found 660 unique RNA species were depleted in PH1-treated cells which was over three times greater than the number found in DM4-treated cells.

This bifunctional MoA is described in the following two graphics:





Summary of Preclinical Studies of PH1

We have examined the cytotoxic and immunostimulatory effects of PH1 on multiple targets on several solid tumor types and examined PH1's potential synergies with checkpoint inhibitors in various *in vitro* and *in vivo* preclinical studies.

In *in vitro* gastric and breast cancer models, we compared the cytotoxicity of an ADC comprised of PH1 conjugated to a Her2 antibody ("Her2-PH1 ADC") with that of Kadcyla®, a Her2-targeting ADC commercially approved for use in the treatment of Her2-positive breast cancer. In both studies, the Her2-PH1 ADC demonstrated superior cytotoxic activity. We also studied PH1 conjugated to a novel target (undisclosed) in an *in vitro* preclinical model of non-small cell lung cancer (NSCLC) and found that the PH1 ADC showed increased anti-tumor activity in comparison to a vehicle comprised of the antibody target alone.

We have also studied PH1's bifunctional MoA and its potential synergies with checkpoint inhibitors in a mouse colon cancer model in which we examined tumor regression and survival rates in 76 mice that were injected subcutaneously with colon cancer cells expressing Her2. We compared a Her2-PH1 ADC with Kadcyla®, (Kadcyla® is not approved for colon cancer) both as single treatment agents and in combination with checkpoint inhibitor therapy ("I/O"). When administered as a combination with I/O therapy, the Her2-PH1 ADC induced 14 complete tumor regressions ("CRs") whereas 5 tumors rebounded after initial shrinkage (n=19 mice per arm). As a result, 73% of Her2-PH1 + I/O treated mice showed complete regressions and were still on study at 5 months, and median survival was not reached. In the Kadcyla® combination arm with I/O, there were 8 CRs and 11 tumor rebounds, and 42% of Kadcyla® + I /O treated mice were tumor-free at 5 months. The median survival of Kadcyla® + I/O treated mice was 149 days.

A second *in vivo* preclinical mouse study was performed using the identical mouse colon cancer model with the cancer cells expressing Her2. The mice developed measurable tumors and were then treated with two doses of a Her2-PH1 ADC, both as monotherapy and in combination with I/O. Of the eight mice treated with the Her2-PH1 ADC in combination with I/O, seven (87.5%) had achieved CR and survived at 150 days. These seven mice were subsequently rechallenged with colon cancer cells expressing Her2, similar to the cells administered at the onset of the study. No tumor growth was observed in any of the seven mice after they were rechallenged. This zero occurrence of cancer was found despite these mice not receiving any additional treatment with the Her2-PH1 ADC after being rechallenged, indicating that these mice retained immune memory against the colon cancer cells expressing Her2. Based on the results of these two combination studies, we believe that PH1 has the potential to generate an immunostimulatory effect and may possess synergies with checkpoint inhibitors, which could improve the longer term control of cancer after the completion of initial treatment.

We have also observed that PH1 may be less susceptible to multidrug resistance ("MDR"), which can occur when cancer cells develop resistance to chemotherapeutic agents. One mechanism by which MDR occurs is through the overexpression of what are referred to as MDR transporters, which have the ability to pump standard payloads out of the cell before the payload can kill the cell.

We evaluated PH1 and Monomethyl auristatin E's (MMAE) ability to kill mouse embryonic stem ("MES") cells with normal and high levels of MDR. We found that MMAE, but not PH1, was recognized by these pumps, and the presence of high levels of these pumps reduced the in vitro cytotoxicity (IC50) of MMAE 198-fold. The presence of high levels of these pumps had no significant effect on the cytotoxic potency of PH1, as the latter were not substrates and therefore not recognized by MDRs nor pumped out of the cell. The MDR-specific inhibitor Elacridar prevented MDR pumps in MDR-high MES cells from pumping MMAE payload out of the cell, allowing its accumulation, and returning MMAE's cell killing potency back to baseline. This finding confirmed that the loss of MMAE's potency was specific to the increase in the number of MDR pumps and did not occur even in the presence of increased numbers, when we blocked MDR's ability to pump out the payload using Elacridar. We believe this is important because MDR transporters are known to be implicated in the emergence of resistance against many chemotherapies, including some ADC payloads. Furthermore, if MDRs recognized PH1, it would have reduced its potency, and restricted its cytotoxicity to only targets that were highly expressed in cancer cells.

Our PH5 Payload

Our discovery stage PH5 payload targets MMR and/or DDR. Cancer cells are associated with uncontrolled cell division. Before cells divide, they replicate their DNA to forward one chromosome copy to each daughter cell. Largely, DNA replication is a robust process controlled by enzymes with precise fidelities, low error rates, and the presence of correction mechanisms (i.e., MMR). Due to rapid and frequent cell division, cancer cells tend to accumulate errors such as mutations and single- and double-stranded DNA breaks, that are corrected in real time by MMR enzymes. Errors left uncorrected trigger a set of cellular responses (i.e., DDR). DDR engages signaling pathways that regulate the recognition of DNA damage, the recruitment of DNA repair factors, the initiation and coordination of DNA repair pathways, and transition through the cell division cycle. If the cells are at a significant survival disadvantage, DDR processes activate apoptosis and trigger cell death.

When cancer cells are treated with DNA-damaging chemotherapeutic agents, such as the DNA alkylating agent platinum, cancer cells activate DDR and MMR processes, and when the errors are significant in terms of cellular liability and cannot be repaired, they are committed to programmed cell death.

In adult cancer patients, cancer cells are likely to be actively involved in cell division compared to normal differentiated cells. As a result, ADC payloads that target DNA DDR and/or MMR are likely to preferentially target proliferating cancer cells. If an ADC is able to prevent DDR or MMR from occurring, cancer cells are likely to be committed to cell death because of the errors they incorporate.

Conversely, mutations in MMR and DDR genes may provide a selective advantage to the cancer cell by not correcting the mutation that would offer a significant growth or survival advantage. MMR-deficiency ("dMMR") is common in many colorectal, gastrointestinal, and endometrial cancers and found in lower frequency in other solid cancers of breast, prostate, bladder and thyroid. Here, dMMR patients can have increasing numbers of microsatellite repeats, also called high microsatellite instability ("MSI-H"). Both dMMR and MSI-H are considered biomarkers and predict response to checkpoint therapy and are consistent with the neoepitopes that are formed when errors in DNA go uncorrected.

It is therefore likely that an ADC payload targeting MMR or DDR may also have a bifunctional MOA, inducing apoptosis in targeted cells as well as activating the immune system in parallel.

We are currently evaluating the first generation of PH5 linker-toxins against an undisclosed MMR/ DDR target. The payload is bystander-enabled for killing the neighboring cell and may be adapted for low and heterogenous target expression. This MoA is supplemented with the potential killing of cancer cells via the immune system which is also potentially activated by neoepitopes.

Our PH6 Payload

Our discovery stage PH6 payload targets immune suppression. Protein synthesis is integral to most biological functions. Even slow-growing, stem cell-like progenitors of tumor cells that divide less frequently synthesize proteins to support vital functions. Theoretically, both inhibitors of transcription and translation may function as ADC payloads if one can partition them selectively to cancer cells using target-specific antibodies that can differentiate them from a normal cell. PH6 is an undisclosed payload that prevents protein synthesis at the stage of transcription.

Tumors containing an active population of immune cells capable of responding to immunogenic stimuli and killing cancer cells are referred to as immune "hot" tumors. Conversely, those tumors that have a low population of immune cells or have immune cells that are actively suppressed or co-opted into working for the tumor are referred to as immune "cold". An extreme form of immune cold tumors called immune desert reflects tumors where immune cells are confined to the tumor periphery.

Immune cold tumors are hard to target and typically unresponsive to immunotherapy. Checkpoint inhibitor therapy and immune stimulation approaches have largely been unsuccessful due the immune cells being suppressed or co-opted. These tumors have regulatory T cells that suppress T cell activation or express soluble factors that induce immune deserts. In this case, we are testing payloads that (a) induce cytotoxicity of tumor cells, and (b) suppress immunosuppressive immune cells. This dual action protein synthesis inhibitor payload may potentially have a second function where tumor immunogenicity is increased by killing co-opted immune cells or suppressing function(s) of immunosuppressive cells.

We are planning to evaluate the first generation of PH6 linker-toxins against an undisclosed target and validating its bifunctional MoA. Due to the varied effects of new protein synthesis inhibition, this payload may also prevent the formation or recruitment of new blood vessels to the tumor.

AKTX-101: Our Lead ADC Product Candidate

We aim to establish a best-in-class Trop2-targeting ADC with our lead product candidate AKTX-101. AKTX-101 is designed to treat solid tumors by delivering PH1 into cells expressing Trop2. Trop2 is a cell surface antigen which is upregulated in a variety of malignant tumors, including breast, ovarian, prostate, gastric, colorectal, pancreatic and lung cancer, but has limited expression in normal human tissues, making it an ideal target in cancer.

We have studied AKTX-101 in a number of preclinical models, both *in vitro* and *in vivo*, as well as in a non-human primate ("NHP") toxicity study. Based on our preclinical experiments, we believe AKTX-101 may have the potential to offer advantages over existing therapies in terms of increased cytotoxicity, reduced resistance, better tolerance, and ability to combine with I/O therapies.

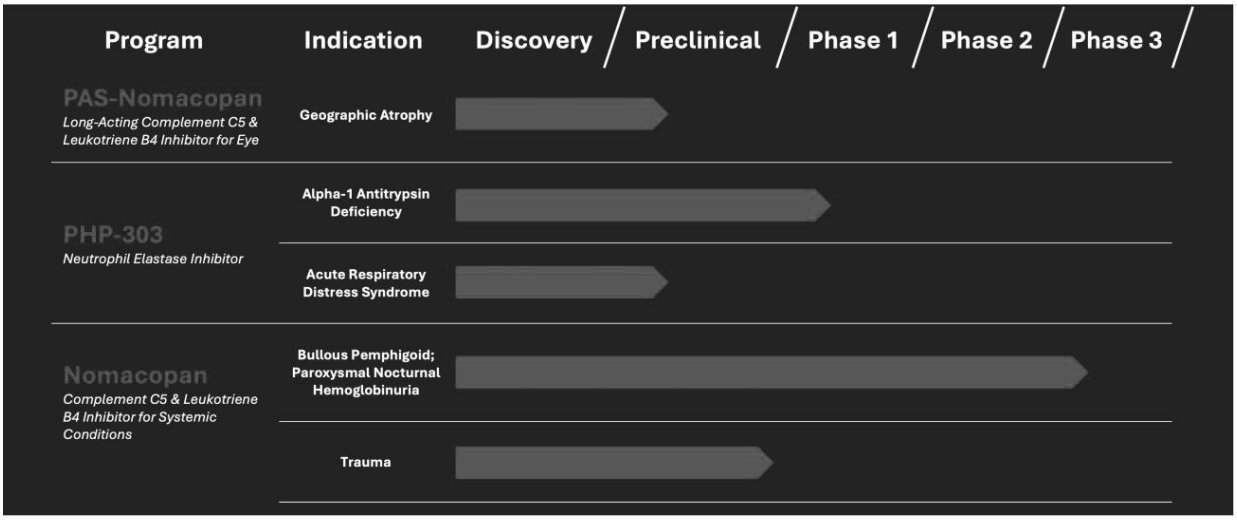
In *in vitro* preclinical studies, we compared AKTX-101 (drug antibody ratio ("DAR") 4) to a currently approved Trop2-targeting ADC (with DAR 8). We found that AKTX-101 showed greater cytotoxicity at lower drug doses in gastric, pancreatic and bladder cancer models. To further corroborate our *in vitro* observations, we evaluated AKTX-101 and the same currently approved ADC in an *in vivo* model against the same $Trop2^{high}$ gastric carcinoma cell-line derived xenograft grown as tumors in mice. Two doses of each agent were given with the currently approved ADC administered at 10 mg/kg while AKTX-101 (DAR 4) was administered at 3 mg/kg. Both treatments induced tumor regression at 3-6 weeks. At the conclusion of the study at 150 days, five out of ten mice (50%) treated with AKTX-101 experienced a tumor regression, as compared to two out of ten mice (20%) treated with currently approved Trop2 ADC.

To evaluate activity with checkpoint inhibition, mice that were administered bladder cancer cells expressing human Trop2 were treated with AKTX-101, I/O, a combination of both, or placebo. In these studies, AKTX-101 monotherapy was equivalent to I/O monotherapy for bladder cancer in terms of tumor growth inhibition (TGI), however the combination of AKTX-101 and I/O was significantly superior in terms of TGI ($p=0.01$) and prolonged overall survival ($p=0.013$) compared to single agent therapy with AKTX-101 or I/O at day 14. We believe the data suggests a synergistic effect between AKTX-101 and checkpoint inhibition.

The use of our proprietary L22 linker in AKTX-101 may contribute to a safety profile that has the potential to be superior to currently approved Trop2-targeting ADCs. As a non-cleavable linker, L22 causes PH1 to bind irreversibly to the spliceosome machinery, thereby eliminating the potential for PH1 to be released by the cancer cell and thus enter and kill normal, non-cancerous cells, which is referred to as the bystander effect. In pre-clinical *in vitro* models, AKTX-101 demonstrated minimal killing of normal human fibroblasts not expressing Trop2 in comparison to an approved Trop2-targeting ADC, which, due to its known bystander effect, is toxic to normal human fibroblasts. We believe this preclinical data suggests that a higher therapeutic index may be possible using AKTX-101 over current Trop2 ADCs available today.

We also studied the toxicity and tolerability of AKTX-101 in a NHP model. We evaluated AKTX-101 at DARs of two and four and performed a repeat-dose study wherein three ADC doses were intravenously administered every three weeks, followed by a three-week recovery period. To gain an understanding of the maximal cumulative effects of AKTX-101, animals were evaluated two days after receiving at the conclusion of all three doses being administered. Reversibility was addressed in another set of animals that received all three doses but were allowed a three-week recovery period. Histopathology was performed unilaterally for all tissues in both sets of animals. We found that AKTX-101 was well-tolerated at both dosages, with observed side effects (skin rash, mild thrombocytopenia and mild elevation of liver enzymes) resolving within weeks after administration. Importantly, there was no evidence of neutropenia, leukopenia, interstitial lung disease or mucosal inflammation, which have been associated with other Trop2-targeting ADCs that use standard payloads comprising of topoisomerase I inhibitors. We believe the absence of observed lung complications, colitis and hypothyroidism in this study may further support AKTX-101's potential suitability and feasibility for use in combination with checkpoint inhibitors, given these side effects are often common with checkpoint inhibitors.

Our Legacy Programs



Nomacopan

Prior to the Merger, our lead product candidate was nomacopan, a bi-specific complement C5 and leukotriene B4 inhibitor that we had advanced into Phase-3 trials for the treatment of paroxysmal nocturnal hemoglobinuria ("PNH"), a rare, acquired blood disorder characterized by the destruction of red blood cells, and pediatric hematopoietic stem cell transplantation-associated thrombotic microangiopathy ("HSCT-TMA"). HSCT-TMA is a rare but serious complication of hematopoietic stem cell transplant that appears to involve complement activation, inflammation, tissue hypoxia and blood clots, leading to progressive organ damage and death. Mortality in patients who develop severe transplant-related TMAs is 80%.

Nomacopan was also studied in a phase 2 trial in bullous pemphigoid, a chronic autoimmune skin condition, and preclinical testing for the treatment of trauma. We believe that nomacopan's dual inhibitory action may prevent proinflammatory and prothrombotic activities of two key pathways, and that its biophysical 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 suspended internal development of nomacopan in June 2024 to shift our resources to ADC development in connection with the Merger.

PAS-Nomacopan

We previously conducted preclinical studies on long-acting PAS-nomacopan for the potential treatment of geographic atrophy, an advanced form of age-related macular degeneration of the eye. We suspended internal development of PAS-nomacopan in November 2024.

PHP-303

We acquired PHP-303, a Phase-2-ready neutrophil elastase inhibitor that Peak Bio was advancing for the potential treatment of a genetic disorder known as alpha-1 antitrypsin disorder, in the Merger. Peak Bio was also conducting preclinical studies on PHP-303 as a potential treatment of acute respiratory distress syndrome. Peak Bio acquired the rights to PHP-303 and licensed associated know-how from Bayer Pharmaceuticals in March 2017.

Competition

The biotechnology and pharmaceutical industries, and the oncology subsector, are characterized by rapid technological evolution, fierce competition and strong defense of intellectual property. While we believe that our technology, the expertise of our team, and our development experience and scientific knowledge provide us with competitive advantages, we face competition from biotechnology and pharmaceutical companies, including companies that are larger and better funded than we are, academic institutions, governmental agencies and public and private research institutions, among others. Moreover, we may also compete with smaller or earlier-stage companies, universities and other research institutions that have developed, are or may be developing or may in the future develop current and future cancer therapeutics. Product candidates that we successfully develop and commercialize may compete with existing therapies and new therapies that may become available in the future.

We also face competition more broadly across the oncology market for cost-effective and reimbursable cancer treatments. The most common methods of treating patients with cancer are surgery, radiation and drug therapy, including chemotherapy, hormone therapy, biologic therapy such as monoclonal and bispecific antibodies, immunotherapy, cell-based therapy and targeted therapy, or a combination of any such methods. There is a variety of available drug therapies marketed for cancer. In many cases, these drugs are administered in combination to enhance efficacy. While our product candidates, if any are approved, may compete with these existing drugs and other therapies, to the extent they are ultimately used in combination with or as an adjunct to these therapies, our product candidates may not be competitive with them. Insurers may also encourage the use of generic products or specific branded products. As a result, obtaining market acceptance of, and gaining significant share of the market for, any product candidates that we successfully introduce to the market may pose challenges. In addition, many companies are developing new oncology therapeutics, and we cannot predict what the standard of care will be as our current and future product candidates progress through development.

AKTX-101 will compete with approved Trop2-targeting ADCs such as Trodelvy® and Datroway® as well as other programs in clinical trials that also target Trop2. If we are unable to effectively differentiate AKTX-101 from other products and product candidates or other common methods of treating cancer patients our ability to compete would be negatively impacted.

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 any other product candidates that may be approved in the future. If our lead product candidate is approved, we intend either to establish a sales and marketing organization with technical expertise and supporting distribution capabilities, 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 our product candidates. Analytical methods, compliant with GMP requirements, have been established and qualified for release and stability testing of drug substance and drug products.

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 any potential 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.

We have identified multiple CDMOs with the ability to produce the antibody component of our product candidates at different scales and have strong track records in GMP requirements. The production of all necessary elements for the manufacture of our ADC product candidates, and the final manufacture of the ADC drug product, will be handled entirely by CDMOs.

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 clinical 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, sponsors 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 a product.

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 an approval letter following its review process if it determines that the NDA or BLA has met all applicable requirements. Alternatively, 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. 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

With 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 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. 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 December 20, 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 whether FDA regulations, guidance or interpretations may change 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 replaced the Clinical Trials Directive 2001/20/EC, or the CT Directive and came into effect on January 31, 2022. 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, through the centralized EU portal called the Clinical Trials Information System (CTIS).
- 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.

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 (as set out below) must use the centralized authorization procedure to obtain marketing authorization.

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 (gene-therapy, somatic cell-therapy or tissue-engineered medicines);
- medicinal products containing a new active substance indicated for any of the following:
    - 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 for conditions other than those set out above, 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 public health 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 if additional information is requested, which triggers clock-stops in the procedural timelines. 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, which is issued within 67 days of the EMA opinion.

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 following grant of the market authorization, 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.

Market Authorizations Granted by Authorities of EU Member States

In general, if the centralized procedure is not mandatory or 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.

An EU marketing authorization may only be granted 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 an MAA 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 EMA (for a centrally authorized product) or the competent authority of the authorizing EU Member State (for a product with a national authorization). 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 nine 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 of a medicinal product 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 orphan medicinal product designation where the sponsor can establish that the product 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 for 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 grant of 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" for the same therapeutic indication as the authorized orphan 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 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, and Article 10(1) of Directive 2001/83/EC, upon receiving marketing authorization, new active substances 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 applicants for generic or biosimilar products from referencing the data contained in the dossier of the reference product when applying for a generic or biosimilar marketing authorization in the EU, for a period of eight years from the date on which the reference product was first authorized in the EU. During the additional two-year period of market exclusivity, a generic or biosimilar marketing authorization application 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 active substance 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.

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.

All of 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, and in April 2024, the European Parliament proposed amendments to the legislative proposals. 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, the UK has implemented previous EU legislation on the marketing, promotion and sale of medicinal products through the Human Medicines Regulations 2012. Except in respect of the EU Clinical Trials Regulation, the regulatory regime in the UK 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 the UK's regulatory system is independent from the EU and the TCA does not provide for mutual recognition of UK and EU pharmaceutical legislation.

As a result of the Northern Ireland protocol, following Brexit, the EMA remained responsible for approving novel medicines for supply in Northern Ireland under the EU centralized procedure, and a separate authorization was required to supply the same medicine in Great Britain (England, Wales and Scotland). On February 27, 2023, the UK government and the EC announced a political agreement in principle to replace the Northern Ireland Protocol with a new set of arrangements, known as the "Windsor Framework". The Windsor Framework was approved by the EU-UK Joint Committee on March 24, 2023, and the medicines aspects of the Windsor Framework have applied since January 1, 2025. This new framework fundamentally changes the previous system under the Northern Ireland Protocol, including with respect to the regulation of medicinal products in the UK. In particular, the MHRA is now responsible for approving all medicinal products destined for the UK market (i.e., Great Britain and Northern Ireland), and the EMA no longer has any role in approving medicinal products destined for Northern Ireland under the EU centralized procedure. A single UK-wide MA will be granted by the MHRA for all novel 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. In addition, the new arrangements require all medicines placed on the UK market to be labeled "UK only," indicating they are not for sale in the EU.

The MHRA has introduced changes to national licensing procedures, including procedures to prioritize access to new medicines that will benefit patients, an accelerated assessment procedure and new routes of evaluation for novel products and biotechnology products. On January 1, 2024, the MHRA put in place a new international recognition framework which means that the MHRA may have regard to decisions on the approval of marketing authorizations made by the EMA and certain other regulators when determining an application for a new UK marketing authorization.

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. There is now no pre-MA orphan designation in the UK. Instead, the MHRA reviews applications for orphan designation in parallel to the corresponding MAA. The criteria are essentially the same, but have been tailored for the UK market, i.e., the prevalence of the condition in the UK (rather than the European Union) must not be more than five in 10,000. Should an orphan designation be granted, the period of market exclusivity will be set from the date of first approval of the product in the UK.

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.

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 impact, among other things, sales, marketing and educational programs associated with approved products. In addition, patient privacy regulations by both the U.S. federal and state governments as well as pharmaceutical pricing and transparency requirements also apply to companies that market approved pharmaceutical products.

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.

In addition, there is significant interest in the United States in promoting changes in healthcare system 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. 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 31, 2025, we had 9 employees, 8 of which are full-time, including our Chief Financial Officer, Torsten Hombeck, Ph.D., our Executive Director, Head of Oncology, Satyajit Mitra, Ph.D., and 6 other individuals, 4 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.

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 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 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 ADSs. 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 ADSs could decline, and you may lose all or part of your investment in our securities.

Risks Related to Our Financial Position and Our Capital Requirements

We have a history of operating losses and cannot give assurance of future revenues or operating profits.

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 $19.8 million and $10.0 million for the years ended December 31, 2024 and 2023, respectively. In addition, our accumulated deficit as of December 31, 2024 and 2023 was $247.3 million and $227.5 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 public and private offerings 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 any of our current or future product candidates receive marketing authorization, sales and marketing activities.

We have not initiated clinical development of any of the product candidates in our active pipeline and expect that it will be many years, if ever, before any of our candidates is ready for commercialization. To become and remain profitable, we must develop and, either directly or through collaborators, commercialize products with market potential. This will require us to be successful in a range of activities, including identifying product candidates, completing preclinical studies and clinical trials of product candidates, obtaining marketing approval for these product candidates, manufacturing, marketing and selling products for which we may obtain marketing approval and satisfying any post-marketing requirements. We may never succeed in these activities and, even if we do, we may never generate revenues that are significant or large enough to achieve profitability. Additionally, we are unable to predict the extent of any future losses or when we will become profitable, if at all. Our failure to become and remain profitable could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. Accordingly, investors may not receive any return on their investment or may lose their entire investment.

We will require substantial 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, 2024, we had cash of approximately $2.6 million. We will require additional capital in order to develop and commercialize our current product candidates or any future product candidates that we may develop or acquire. 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.

We expect our expenses to increase in connection with our ongoing activities, particularly as we identify, continue the research and development of, initiate and carry out preclinical studies and clinical trials of, and seek marketing approval for product candidates. The amount and timing of any expenditure needed will depend on numerous factors, some of which are outside our control, including:

- the costs of developing our current products and any future product candidates that we may develop, in-license or acquire;
- the costs of obtaining, maintaining and enforcing our patents and other intellectual property rights;
- the costs and timing of future clinical trials or the need for additional clinical trials in any indications or product candidates which we are pursuing or may choose to pursue in the future;

- the costs and timing of initiating manufacturing for our product candidates, including commercial manufacturing if any product candidate is approved;
- the terms and timing of establishing and maintaining collaborations, license agreements and other partnerships;
- the costs and timing of enhanced internal controls over financial reporting;
- 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, potential collaborations or strategic partnerships with other companies, non-dilutive financings or the divestiture of programs and product candidates that we have ceased developing or may in the future cease developing. 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 the event that we decide to pursue divestiture of any of our legacy programs or product candidates, we may be unable to identify a potential buyer or to complete such a divestiture on favorable terms or at all. 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 research for our programs and we may be required to significantly curtail some or all of our activities. Additionally, any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize any product candidates we may develop. We cannot be certain that additional funding will be available on acceptable terms or at all. We have no committed source of additional capital and, if we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of any product candidates or other research and development initiatives. We could be required to seek collaborators for potential product candidates or complete divestitures of some or all of our legacy programs or product candidates earlier than we would otherwise plan or on terms that are less favorable than might otherwise be available. We could also be required to relinquish or license our rights to product candidates on unfavorable terms in certain markets where we otherwise would seek to pursue development or commercialization ourselves.

Raising additional capital may cause significant dilution to our shareholders or restrict our operations.

Until such time, as ever, as we are able to generate substantial product revenues, we expect to finance our capital needs at least in part through a combination of equity offerings and debt financings. To the extent that we do so, our shareholders may experience significant dilution, and the terms of these securities may contain preferential rights that adversely affect the rights of holders of ADSs representing our ordinary shares. 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-linked securities in the future at a time and at a price that we might otherwise desire. Additionally, 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, declaring dividends and other restrictions.

Our ability to use net operating losses to offset future income may be subject to certain limitations.

As of December 31, 2024, we had cumulative UK, U.S. federal, various U.S. state, Switzerland, and South Korea net operating loss carryforwards ("NOL") to offset future taxable income of approximately $145.7 million, $38.1 million, $71.8 million, less than $0.3 million, and $87.0 million, respectively. NOLs in certain jurisdictions do not expire, while NOLs in some jurisdictions are subject to expiration. A lack of future taxable income would adversely affect our ability to utilize these NOLs. In addition, under Section 382 of the Internal Revenue Code of 1986, as amended (the Code), a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its NOLs to offset future taxable income. We have already experienced ownership changes as defined under Section 382 of the Code. Depending on the timing of any future utilization of our NOLs, the amount that can be utilized each year may be limited as a result of such previous ownership changes. In addition, future changes in our stock ownership, including changes that may be outside of our control, could result in additional ownership changes under Section 382 of the Code. Our NOLs may also be impaired under similar provisions of state law. We maintain a full valuation allowance related to our NOLs and other deferred tax assets due to the uncertainty of the ultimate realization of the future benefits of those assets.

We have identified material weaknesses in our internal control over financial reporting. If our remediation of the material weaknesses are not effective, or if we experience additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our ADSs.

As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal control. Section 404 of the Sarbanes-Oxley Act of 2002 ("Sarbanes-Oxley") requires that we evaluate and determine the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. In connection with our year-end assessment as part of the preparation of this Form 10-K, we determined that, as of December 31, 2024, we did not maintain effective internal control over financial reporting due to material weaknesses identified relating to the lack of formalized information technology general controls, lack of formally designed and implemented "purchase to pay" controls, and lack of effective controls over business combination accounting, as more fully described in "Disclosure Controls and Procedures" in Item 9A of Part II of this Form 10-K. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim consolidated financial statements will not be prevented or detected on a timely basis.

While we are in the process of implementing changes to remediate the material weaknesses we have identified, we cannot assure you that these measures will significantly improve or remediate such material weaknesses. We may discover additional weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our consolidated financial statements. Our internal control over financial reporting will not prevent or detect all errors or fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are unable to maintain proper and effective internal controls over financial reporting, we may not be able to produce timely and accurate financial statements. If that were to happen, our investors could lose confidence in our reported financial information, the market price of our ADSs could decline, and we could be subject to sanctions or investigations by the SEC or other regulatory authorities.

Risks Related to Discovery, Development and Regulatory Approval of Our Product Candidates

We have not initiated clinical studies for any of the programs in our active pipeline or entered into any strategic partnerships regarding the continued development of our legacy pipeline assets. As a result, it may be years before we commercialize a product candidate, if ever. If we, alone or with a strategic partner, are unable to identify and advance product candidates through preclinical studies and clinical trials, obtain marketing approval and ultimately commercialize them, or experience significant delays in doing so, our business will be materially harmed.

The success of our business depends primarily upon our ability to identify, develop and commercialize product candidates, which are subject to the risks of failure inherent in the novel approaches, targets and mechanisms of action upon which we base our efforts. We are early in our development efforts, have not yet completed preclinical studies of AKTX-101, our lead product candidate, and our other current active programs are in the drug discovery stage. We recently suspended further development of our legacy pipeline assets nomacopan, PAS-nomacopan, and PHP-303, and we cannot guarantee that we will be able to enter into any strategic partnerships covering the continued development of such assets or that future strategic partnerships with respect to such assets that we may enter into, if any, will result in successful therapeutic products. Furthermore, our reliance on our ADC Platform in the identification and development of product candidates may not yield any viable pharmaceutical products.

Additionally, our ability to achieve and sustain profitability depends on obtaining regulatory approvals for, and successfully commercializing, our product candidates, either alone or with third parties, and we cannot guarantee that we will ever obtain regulatory approval for any of our product candidates. Before obtaining regulatory approval for the commercial distribution of any product candidates, we must conduct extensive preclinical studies followed by clinical trials to demonstrate the safety and efficacy of our product candidates in humans. We cannot be certain of the timely completion or outcome of our research and development activities, preclinical studies or any future clinical trials, and cannot predict if the FDA or other regulatory authorities will accept our proposed clinical programs or if the outcome of our preclinical studies will ultimately support the further development of our future product candidates.

We also may not have the financial resources to continue development of, or the ability to enter into collaborations or other strategic partnerships for, a product candidate if we experience any issues that delay or prevent regulatory approval of, or our ability to commercialize, product candidates, including:

- negative or inconclusive results from our preclinical trials, leading to a decision to conduct additional preclinical studies or abandon a program;
- negative or inconclusive results from clinical trials or the clinical trials of others for product candidates similar to ours, leading to a decision or requirement to conduct additional preclinical studies or clinical trials or abandon a program;
- our clinical safety data in humans not matching the safety evaluation in relevant animal models;
- our strategy of deploying payloads, including our PH-1 payload, as ADCs failing to mitigate known toxicities of those classes of small molecules delivered as systemic chemotherapies;
- our clinical data failing to match preclinical data supporting antibody selectivity, linker stability, pharmacokinetics, anti-tumor efficacy, or any other key attributes;
- product-related side effects experienced by participants in our clinical trials or by individuals using drugs or therapeutic antibodies similar to ours;
- delays in submitting IND applications or comparable foreign applications, or delays or failure in obtaining the necessary approvals from regulators to commence a clinical trial, or a suspension or termination of a clinical trial once commenced;
- conditions imposed by the FDA, or other regulatory authorities regarding the scope or design of our clinical trials;
- delays in clinical trials as a result of the limited number of patients with the diseases that some or all of our current or expected future product candidates target, patient enrollment taking longer than anticipated or patient withdrawal;
- high drop-out rates or high failure rates of research subjects;
- inadequate supply or quality of product candidate components or materials or other supplies necessary for the conduct of preclinical studies or clinical trials;
- greater-than-anticipated clinical trial costs;
- poor effectiveness of our product candidates during clinical trials;
- unfavorable FDA or other regulatory agency inspection and review of a clinical trial or manufacture site;
- failure of our third-party contractors or investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner, or at all;
- delays and changes in regulatory requirements, policies and guidelines;
- the FDA or other regulatory agencies interpreting our data differently than we do;
- or adverse impacts caused by any future pandemics or geopolitical considerations which could heighten any of the foregoing risks.

Our inability to complete development of, or commercialize, our product candidates, or significant delays in doing so due to one or more of these factors, or other factors, could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Preclinical and clinical drug development is a lengthy and expensive process, with uncertain timelines and outcomes. If preclinical studies or clinical trials of our product candidates are prolonged or delayed, we may be unable to obtain required regulatory approvals, and therefore be unable to commercialize our product candidates or any of our future product candidates on a timely basis or at all.

Successful development of pharmaceutical products involves a lengthy and expensive process, is highly uncertain, and is dependent on numerous factors, many of which are beyond our control. Product candidates that appear promising in the early phases of development may fail to reach the market for several reasons, including:

- clinical trial results may show the product candidates to be less effective than expected (for example, a clinical trial could fail to meet its primary or key secondary endpoint(s)) or have an unacceptable safety or tolerability profile;

- failure to receive the necessary regulatory approvals or a delay in receiving such approvals, which, among other things, may be caused by patients who fail the trial screening process, slow enrollment in clinical trials, patients dropping out of trials, patients lost to follow-up, length of time to achieve trial endpoints, additional time requirements for data analysis or application preparation, discussions with the FDA, EMA or other comparable foreign regulatory authorities (including FDA, EMA or other comparable foreign regulatory authorities requesting additional preclinical or clinical data, such as long-term toxicology studies), or encountering unexpected safety or manufacturing issues;

- preclinical study results may show the product candidate to be less effective than desired or to have harmful on-target or off-target side effects; or

- the proprietary rights of others and their competing products and technologies that may prevent our product candidates from being commercialized.

Furthermore, the length of time necessary to complete clinical trials and submit an application for marketing approval for a final decision by a regulatory authority varies significantly from one product candidate to the next and from one country or jurisdiction to the next and may be difficult to predict. Even if we are successful in obtaining marketing approval, commercial success of any approved products will also depend in large part on the availability of coverage and adequate reimbursement from third-party payors, including government payors such as the Medicare and Medicaid programs and managed care organizations in the United States or country-specific governmental organizations in foreign countries, which may be affected by existing and future healthcare reform measures designed to reduce the cost of healthcare. Third-party payors could require us to conduct additional studies, including post-marketing studies related to the cost effectiveness of a product, to qualify for reimbursement, which could be costly and divert our resources. If government and other healthcare payors were not to provide coverage and adequate reimbursement for our products once approved, market acceptance and commercial success would be reduced. Even if we are able to obtain coverage and adequate reimbursement for our products once approved, there may be features or characteristics of our products, such as dose preparation requirements, that prevent our products from achieving market acceptance by the healthcare or patient communities.

In addition, if any of our product candidates receive marketing approval, we will be subject to significant regulatory obligations regarding the submission of safety and other post-marketing information and reports and registration, and will need to continue to comply (or ensure that our third-party providers comply) with current Good Manufacturing Practice ("cGMPs") and Good Clinical Practice ("GCPs") for any clinical trials that we conduct post-approval. In addition, there is always the risk that we, a regulatory authority or a third party might identify previously unknown problems with a product post-approval, such as AEs of unanticipated severity or frequency. Compliance with these requirements is costly, and any failure to comply or other issues with our product candidates post-approval could adversely affect our business, financial condition and results of operations

We may encounter substantial delays in the commencement, enrollment or completion of clinical trials or we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities, which could prevent us from commercializing any product candidates we determine to develop on a timely basis, if at all.

The risk of failure in developing product candidates is high. It is impossible to predict when or if any product candidate would prove effective or safe in humans or receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical development, submit an IND or comparable foreign application to permit initiation of clinical studies, and then conduct extensive clinical trials to demonstrate the safety and efficacy of product candidates in humans. We have not yet commenced or completed a clinical trial of any of the product candidates in our active pipeline.

Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies that support our INDs and other regulatory filings. We cannot be certain of the timely identification of a product candidate or the completion or outcome of our preclinical testing and studies and cannot predict whether the FDA, EMA or other comparable foreign regulatory authorities will accept our proposed clinical programs or whether the outcome of our preclinical testing and studies will ultimately support the further development of any product candidates. Conducting preclinical testing is a lengthy, time-consuming and expensive process. The length of time may vary substantially according to the type, complexity and novelty of the program, and often can be several years or more per program. As a result, we cannot be sure that we will be able to submit INDs or other comparable foreign regulatory submissions for our preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs will result in the FDA, EMA, or other comparable foreign regulatory authority allowing clinical trials to begin.

Furthermore, product candidates are subject to continued preclinical safety studies, which may be conducted concurrently with our clinical testing. The outcomes of these safety studies may delay the launch of or enrollment in future clinical trials and could impact our ability to continue to conduct our clinical trials.

Clinical testing is expensive, is difficult to design and implement, can take many years to complete and is uncertain as to outcome. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, or at all. A failure of one or more clinical trials can occur at any stage of testing, which may result from a multitude of factors, including, but not limited to, flaws in trial design, dose selection issues, patient enrollment criteria and failure to demonstrate favorable safety or efficacy traits.

Patient enrollment depends on many factors, including the size and nature of the patient population, eligibility criteria for the trial, the proximity of patients to clinical sites, the design of the clinical protocol, the availability of competing clinical trials, the availability of new drugs or biologics approved for the indication the clinical trial is investigating, and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies. These factors may make it difficult to enroll enough patients to complete clinical trials in a timely and cost-effective manner.

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;
- 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 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.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs overseeing the conduct of such trials, by a Data Safety Monitoring Board for such trial or by the FDA, EMA, or other comparable foreign regulatory authorities. Such regulatory authorities may impose such a suspension or termination due to a number of factors, including 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 FDA, EMA, or other comparable regulatory foreign authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination and approval, which may impact the costs, timing or successful completion of a clinical trial.

Further, conducting clinical trials in foreign countries, as we may do for our product candidates, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocols as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory requirements, as well as political, currency exchange and other economic risks relevant to such foreign countries. We may face delays in meeting our anticipated timelines for our ongoing and planned clinical trials, which could adversely affect our business, financial condition, results of operations and growth prospects.

Any inability to successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to generate revenue from future product sales and regulatory and commercialization milestones. In addition, if we make manufacturing or formulation changes to our product candidates, we may need to conduct additional testing to bridge our modified product candidate to earlier versions. Clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates, if approved, or allow our competitors to bring comparable products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business, financial condition, results of operations and prospects.

Serious adverse events, undesirable side effects or other unexpected properties of our product candidates may be identified during development or after approval, which could lead to the discontinuation of our development programs, refusal by regulatory authorities to approve our product candidates or, if discovered following marketing approval, revocation of marketing authorizations or limitations on the use of our product candidates, any of which would limit the commercial potential of such product candidates.

To date, we have not commenced or completed the evaluation of any of our current ADC candidates in human clinical trials. It is impossible to predict when or if any product candidates we may develop will ultimately prove safe in humans. As is the case with pharmaceuticals generally, it is likely that there may be side effects and AEs associated with our product candidates' use. Often, it is not possible to determine whether or not the product candidate being studied caused these conditions. Regulatory authorities may draw different conclusions or require additional testing to confirm these determinations, if they occur. In addition, it is possible that as we test our product candidates in larger, longer and more extensive clinical trials with a broader group of patients, or as use of these product candidates becomes more widespread if they receive marketing approval, illnesses, injuries, discomforts and other AEs that were observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by participants. In some instances, certain side effects are only detectable after investigational product candidates are tested in large-scale, Phase 3 trials or after they are made available to patients on a commercial scale after approval. If additional clinical experience indicates that any of our current or future product candidates has serious or life-threatening side effects or other side effects that outweigh the potential therapeutic benefit, the development of the product candidate may fail or be delayed, or, if the product candidate has received marketing approval, such approval may be limited or revoked, which would harm our business, prospects, operating results and financial condition. If we elect, or are required, to delay, suspend or terminate any clinical trial of our product candidates, the commercial prospects of our product candidates may be harmed and our ability to generate revenue through their sale may be delayed or eliminated. Any of these occurrences may harm our business, financial condition and prospects significantly

Moreover, if our product candidates are associated with undesirable side effects in clinical trials or have characteristics that are unexpected, we may elect to abandon their development or limit their development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective, which may limit the commercial value for the product candidate if approved. We may also be required to modify our trial plans based on findings after we commence our clinical trials. Many compounds that initially showed promise in early-stage testing have later been found to cause side effects that prevented further development of the compound.

In addition, if any of our product candidates receive marketing approval, the FDA could require us to include a boxed warning in our label or adopt a REMS to ensure that the benefits outweigh its risks, which may include, among other things, a medication guide outlining the risks of the drug for distribution to patients, a communication plan to health care practitioners, or other elements to assure safe use. Furthermore, if we or others identify undesirable side effects caused by our product candidates, several other potentially significant consequences could result, including:

- regulatory authorities may suspend or withdraw approvals of any such product and require removal from the market;
- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies, specialty pharmacies and other pharmacy related distribution networks (for example, oncology therapies do have inherent risks and labeling considerations that in many instances require additional regulatory labeling requirements);
- regulatory authorities may require a medication guide outlining the risks of such side effects for distribution to patients, or that we implement a risk evaluation and mitigation strategy (REMS) plan to ensure that the benefits of the product outweigh its risks;
- we may be required to change the way a product is administered, including changes in dosing regimens, frequency of dose, or reduction in dosing and may require us to conduct additional clinical trials or change the labeling of a product;
- we may be subject to limitations on how we may promote the product leading to the potential for sales of the product to decrease significantly;
- third-party private or government payors may not offer, or may offer inadequate, reimbursement coverage for our product candidates, or reimbursement payments may be delayed or impossible to recover; and
- we may be subject to litigation or product liability claims; and our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of our product candidates or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenue from the sale of our product candidates.

Our proprietary ADC Platform is based on novel technologies that are unproven and may not result in approvable or marketable products, which exposes us to unforeseen risks and makes it difficult for us to predict the time and cost of product development and potential for regulatory approval, and we may not be successful in our efforts to expand our development portfolio of product candidates.

A key element of our strategy is to develop a robust and diverse portfolio of potentially first-in-class and best-in-class oncology therapies through the use of our proprietary ADC Platform to identify indications that are particularly suitable for the linkers and payloads that we have developed, including AKTX-101, or may in the future develop.

We have only recently commenced preclinical studies of AKTX-101, the lead program developed via our ADC Platform, and the scientific research that forms the basis of our efforts to develop product candidates with our ADC Platform is still ongoing. We are not aware of any FDA approved ADCs that involve the deployment of spliceosome inhibitors as payloads. Further, the scientific evidence to support the feasibility of developing therapeutic treatments based on our ADC Platform is both preliminary and limited. As a result, we are exposed to a number of unforeseen risks, and it is difficult to predict the types of challenges and risks that we may encounter during development of our product candidates. For example, we have not yet generated any clinical data on AKTX-101 or any other product candidate being developed using our ADC Platform, and our current data on AKTX-101 is limited to animal models and preclinical cell lines, the results of which may not translate into humans. Further, relevant animal models and assays may not accurately predict the safety and efficacy of our product candidates in humans, and we may encounter significant challenges creating appropriate models and assays for demonstrating the safety and purity of our product candidates.

Even if we obtain human data to support our product candidates, the FDA or comparable foreign regulatory authorities may lack experience in evaluating the safety and efficacy of product candidates like those developed using our ADC Platform, which could result in a longer than expected regulatory review process, increase our expected development costs, and delay or prevent commercialization of our product candidates. We cannot be certain that our approach will lead to the development of approvable or marketable products, alone or in combination with other therapies.

Although our research and development efforts to date have resulted in a development portfolio of potential programs and product candidates, our deployment of our ADC Platform may not prove reliable or effective in expanding our development portfolio. We may also pursue opportunities to acquire or in-license additional businesses, technologies or products, form strategic alliances or create joint ventures with third parties to complement or augment our existing business. However, we may not be able to identify any product candidates through such acquisition or in-license.

Even if we are successful in continuing to build and expand our development portfolio, the potential product candidates that we identify may not be suitable for clinical development. For example, they may be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be drugs that will be successful in clinical trials or receive marketing approval and achieve market acceptance. If we do not successfully develop and commercialize product candidates, we will not be able to obtain drug revenues in future periods, which likely would result in significant harm to our financial position.

Interim, initial, or preliminary results from our preclinical testing or clinical trials that we announce or publish from time to time may change 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 becomes 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 is 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.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product, product candidate or our business. If the preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

We or a future strategic partner may choose to, or may be required to, suspend, repeat, or terminate clinical trials of our assets if they are not conducted in accordance with regulatory requirements, the results are negative or inconclusive or the trials are not well designed.

Clinical trials must be conducted in accordance with GCPs and are subject to oversight by the FDA and institutional review boards at the medical institutions where the clinical trials are conducted. In addition, clinical trials must be conducted with product candidates produced under cGMPs and may require large numbers of test patients. Clinical trials may be suspended by the FDA at any time if the FDA finds deficiencies in the conduct of these trials or it is believed that these trials expose patients to unacceptable health risks.

In addition, we or the FDA might delay or halt our clinical trials of a product candidate for various reasons, including:

- the product candidate may have unforeseen adverse side effects;
- the time required to determine whether the product candidate is effective may be longer than expected;

- fatalities arising during a clinical trial due to medical problems that may not be related to clinical trial treatments;
- the product candidate may not appear to be more effective than standard of care therapies;
- insufficient statistical power due to significant patient dropout or crossover to other therapies;
- insufficient patient enrollment in the clinical trials; or
- we may not be able to produce sufficient quantities of the product candidate to complete the trials.

Furthermore, the process of obtaining and maintaining regulatory approvals for new products is lengthy, expensive, and uncertain. It can vary substantially, based on the type, complexity and novelty of the product involved. Accordingly, our current product candidates or any of our other future product candidates could take a significantly longer time to gain regulatory approval than we expect or may never gain approval, which would have a significant adverse impact on our business and results of operations.

Our employees, independent contractors, principal investigators, contract research organizations, consultants, vendors and collaboration partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards.

We are exposed to the risk of employees, independent contractors, principal investigators, contract research organizations, 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 applicable laws, including UK or 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). 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 rise to increased 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 Commercialization, Marketing and Competition

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 we do. Those companies and institutions also may 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, patent protection or regulatory exclusivity that could impede the commercialization of our product candidates, which could materially adversely affect our business.

If we are unable to establish sales, marketing and distribution capabilities 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 any of our product candidates is approved, we must establish a sales and marketing organization with technical expertise and supporting distribution capabilities or outsource this function to a third party. Either of these options could be expensive and time-consuming. 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 any existing or 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. If we do so, any future product revenue may be lower than if we directly marketed or sold any products that may be approved in the future. In addition, any revenue we receive will depend in whole or in part upon the efforts of these third parties, which may not be as diligent or successful as if we were to market and sell any products that may be approved in the future ourselves. 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 any products that may be approved in the future, our future product revenue will suffer and we may incur significant losses.

Even if any of our current or future product candidates receive marketing approval, such product candidates may fail to achieve market acceptance by physicians, patients, third-party payors or others in the medical community necessary for commercial success, in which case we may not generate significant revenues or become profitable.

We have never commercialized a product, and even if any of our current or future product candidates are approved by the appropriate regulatory authorities for marketing and sale, they may not gain market acceptance among physicians, patients, third-party payors or others in the medical community. Market participants with significant influence over acceptance of new treatments, such as clinicians and third-party payors, may not be able to convince the medical community and third-party payors to accept and use, or to provide favorable reimbursement for, any product candidates developed by us or our existing or future collaborators. If our current or future product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable. The degree of market acceptance of our current or future product candidates, if approved for commercial sale, will depend on a number of factors, including but not limited to:

- the clinical indications and patient populations for which the product candidate is approved;
- the safety, efficacy and potential advantages compared to alternative treatments and therapies;
- the timing of market introduction of the product as well as competitive products;
- effectiveness of sales and marketing efforts;
- the strength of our relationships with patient communities;
- the cost of treatment in relation to alternative treatments and therapies, including any similar generic treatments;
- our ability to offer such product for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments and therapies;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the availability of third-party coverage and adequate reimbursement;
- the willingness of patients to pay out-of-pocket in the absence of coverage and adequate reimbursement by third-party payors and government authorities;
- the strength of marketing and distribution support;
- the inclusion of any REMS program or other restrictions included by the regulators;
- the prevalence and severity of any side effects; and
- any restrictions on the use of the product together with other medications.

Our efforts to educate physicians, patients, third-party payors and others in the medical community on the benefits of our product candidates may require significant resources and may never be successful. Because we expect sales of our product candidates, if approved, to generate substantially all of our revenues for the foreseeable future, the failure of our product candidates, if approved, to find market acceptance would harm our business and could require us to seek additional financing.

Even if we are able to commercialize any product candidate, the third-party payor coverage and reimbursement status of newly-approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for our product candidates could limit our ability to market those products and decrease our ability to generate revenue.

The availability and adequacy of coverage and reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors in the United States are essential for most patients to be able to afford treatments such as our products or product candidates, if approved. Our ability to achieve acceptable levels of coverage and reimbursement for drug treatments by governmental authorities, private health insurers and other organizations will have an effect on our ability to successfully commercialize our products, and potentially attract additional collaboration partners to invest in the development of our product candidates. We cannot be sure that adequate coverage and reimbursement in the United States, the EU, Australia or elsewhere will be available for our products or any products that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

Third-party payors increasingly are challenging prices charged for pharmaceutical products, medical devices and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs when an equivalent generic drug is available. It is possible that a third-party payor may consider our products or product candidates, if approved, and the generic or biosimilar parent drug as substitutable and only offer to reimburse patients for the generic drug. Even if we show improved efficacy or safety or improved convenience of administration with our products or product candidates, if approved, pricing of the existing parent drug may limit the amount we will be able to charge for such product. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our products or product candidates, and may not be able to obtain a satisfactory financial return on products that we may develop.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs, biologics and medical devices will be covered. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs, biologics and medical devices. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our products or product candidates.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, Canada, and other countries has and will continue to put pressure on the pricing and usage of our products and product candidates, if approved, and on related parent drugs. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Many countries, including the EU Member States, established complex and lengthy procedures to obtain price approvals, coverage and reimbursement. These procedures vary from country to country but are commonly initiated after grant of the related marketing authorization. More particularly, in the EU, potential reductions in prices and changes in reimbursement levels could be the result of different factors, including reference pricing systems. It could also result from the application of external reference pricing mechanisms, which consist of arbitrage between low-priced and high-priced countries. Reductions in the pricing of our medicinal products in one EU Member State could affect the price in other EU Member States and, thus, have a negative impact on our financial results. Other countries allow companies to fix their own prices for medical products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our products or product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits. As an example, many EU Member States review periodically their decisions concerning the pricing and reimbursement of medicinal products. The outcome of these reviews cannot be predicted and could have adverse effects on the pricing and reimbursement of our medicinal products in the EU Member States.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for our products or product candidates. We expect to experience pricing pressures in connection with the sale of our products and product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs, medical devices and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

Our future growth may depend, in part, on our ability to commercialize products in foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future growth may depend, in part, on our ability to develop and commercialize our product candidates in foreign markets. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from applicable regulatory authorities in foreign markets, and we may never receive such regulatory approvals for any of our product candidates. To obtain separate regulatory approval in many other countries we must comply with numerous and varying regulatory requirements regarding safety and efficacy and governing, among other things, clinical trials, manufacturing, commercial sales, pricing and distribution of our product candidates. If we obtain regulatory approval of our product candidates and ultimately commercialize our products in foreign markets, we would be subject to additional risks and uncertainties, including

- different regulatory requirements for approval of drugs in foreign countries;
- reduced protection for intellectual property rights;
- the existence of additional third-party patent rights of potential relevance to our business;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- foreign reimbursement, pricing and insurance regimes;
- workforce uncertainty in countries where labor unrest is common;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires; and
- business interruptions resulting from pandemics or similar public health crises.

EU drug marketing and reimbursement regulations may materially affect our ability to market and receive coverage for our products in the EU Member States.

We intend to seek approval to market our product candidates in both the United States and in selected foreign jurisdictions, including the EU. If we obtain approval in one or more foreign jurisdictions for our product candidates, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in the EU, the pricing of products is subject to governmental control and other market regulations which could put pressure on the pricing and usage of our product candidates. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. In addition, market acceptance and sales of our product candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for our product candidates and may be affected by existing and future healthcare reform measures.

Much like the federal Anti-Kickback Statute prohibition in the United States, the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the EU. The provision of benefits or advantages to reward improper performance is typically governed by the national anti-bribery laws of EU Member States and the Bribery Act 2010 in the United Kingdom. Infringement of these laws could result in substantial fines and imprisonment. EU Directive 2001/83/EC, which is the EU Directive governing medicinal products for human use, further provides that, where medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or

promised to such persons unless they are inexpensive and relevant to the practice of medicine or pharmacy. This provision has been transposed into the Human Medicines Regulations 2012 and so remains applicable in the United Kingdom despite its departure from the EU.

Payments made to physicians in certain EU Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual EU Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

In addition, in some foreign countries, including some countries in the EU, the proposed pricing for a product must be approved before it may be lawfully marketed. The requirements governing product pricing and reimbursement vary widely from country to country. For example, some EU Member States have the option to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. Reference pricing used by various EU Member States and parallel distribution, or arbitrage between low-priced and high-priced EU Member States, can further reduce prices. An EU Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. In some countries, we may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of any of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. 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 United States and generally prices tend to be significantly lower. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If pricing is set at unsatisfactory levels or if reimbursement of our products is unavailable or limited in scope or amount, our revenues from sales and the potential profitability of any of our product candidates in those countries would be negatively affected.

Obtaining and maintaining marketing approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining marketing approval of our product candidates in other jurisdictions.

Obtaining and maintaining marketing approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain marketing approval in any other jurisdiction. For example, even if the FDA grants marketing approval of a product candidate, comparable foreign regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion and reimbursement of the product candidate in those countries, and they may not do so. A failure or delay in obtaining marketing approval in one jurisdiction may negatively impact the marketing approval process in others. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

Obtaining foreign marketing approvals and establishing and maintaining compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we or any future collaborator fail to comply with the regulatory requirements in international markets or fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed, which would adversely affect our business, prospects, financial condition, and results of operations.

If the market opportunities for any of our product candidates are smaller than we estimate, even assuming approval of a product candidate, our revenue may be adversely affected, and our business may suffer.

The precise incidence and prevalence for all the conditions we aim to address with our product candidates are unknown. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations or market research, and may prove to be incorrect. Further, new information may change the estimated incidence or prevalence of these diseases. The total addressable market across all of our product candidates will ultimately depend upon,

among other things, the diagnosis criteria included in the final label for each of our product candidates approved for sale for these indications, the availability of alternative treatments and the safety, convenience, cost and efficacy of our product candidates relative to such alternative treatments, acceptance by the medical community and patient access, drug pricing and reimbursement. The number of patients in the United States and other major markets and elsewhere may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our products or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business.

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.

Risks Related to Intellectual Property

Our success depends in part on our ability to protect our intellectual property and 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. Although we have issued composition-of-matter patents in the United States and other countries, 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.

Further, the patent prosecution process is subject to numerous risks and uncertainties, expensive and time-consuming, and we or our licensors may not be able to prepare, file and successfully prosecute all necessary or desirable patent applications for a commercially reasonable cost or in a timely manner or in all jurisdictions. It is also possible that we or our licensors may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection for them.

Moreover, depending on the terms of any future in-licenses to which we may become a party, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology in-licensed from third parties. Therefore, these patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

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.

With respect to certain patents, we enjoy only limited geographical protection, and as a consequence we may not be able to protect our intellectual property rights throughout the world.

It would be prohibitively expensive to file and prosecute patent applications and maintain and defend patents covering our product candidates in all countries throughout the world and competitors may use our and our licensors' technologies in jurisdictions where we have not obtained patent protection to develop their competitor's own product candidates and, further, may export otherwise infringing product candidates to territories where we and our licensors have patent protection, but enforcement rights are not as strong as that in the United States or Europe.

As a result, these product candidates may compete with our product candidates, and our and our licensors' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Further, national and regional patent authorities may restrict the scope and coverage of our PCT applications before grant. The examination of each national or regional patent application is an independent proceeding. As a result, patent applications in the same family may issue as patents in some jurisdictions, such as in the United States, but may issue as patents with claims of different or limited scope or may even be refused in other jurisdictions, such as in China and India, which have different requirements for patentability and it is also quite common that depending on the country, the scope of patent protection may vary for the same product or technology.

As maintaining patents in multiple countries over their lifetimes (usually a period of 20 years) is expensive, we may decide to abandon pending or granted national and regional patent applications for financial considerations, or, strategically, when projects are reprioritized, or for any other reason. In hindsight, these decisions may hurt us, our revenue stream from licensing activities, and ultimately profitability.

In addition, the laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws or rules and regulations in the United States, The UK and Europe, and many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions.

The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing product candidates in violation of our proprietary rights generally.

Proceedings to enforce our patent rights in other jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing as patents, and could provoke third parties to assert claims against us. Should we seek legal redress, we may not prevail or if we do prevail, the damages or other remedies awarded may not be meaningful. As a result, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

While we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize our product candidates in all of our expected significant foreign markets.

If we or our licensors encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished, and we may face additional competition from others in those jurisdictions.

Another risk we face is that some countries in Europe and China have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties and some countries limit the enforceability of patents against government agencies or government contractors. As a result, in those countries, the patent owner may have limited remedies, which could materially diminish the value of such patents. 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.

Our intellectual property rights may not adequately protect our technologies and product candidates and may not necessarily address all potential threats to our competitive advantage.

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

- others may be able to make compounds that are the same as or similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed;
- the patents of third parties may impair our ability to develop or commercialize our product candidates;
- the patents of third parties may be extended beyond the expected patent term and thus may impair our ability to develop or commercialize our product candidates;
- we or our licensors or any future strategic collaborators might not have been the first to conceive or reduce to practice the inventions covered by the issued patents or pending patent applications that we own or have exclusively licensed;
- we or our licensors or any future strategic collaborators might not have been the first to file patent applications covering our inventions, our product candidates, or uses of the product candidates in the indications under our development or to be developed;
- it is possible that the pending patent applications that we own or have exclusively licensed may not lead to issued patents;
- issued patents that we own or have exclusively licensed may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;

- issued patents that we own or have exclusively licensed may not provide coverage for all aspects of our product candidates in all countries, such as for uses of our product candidates in the indications under our development or to be developed;

- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;

- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive product candidates for sale in our major commercial markets;

- others performing manufacturing or testing for us using our product candidates or technologies could use the intellectual property of others without obtaining a proper license; or

- our or our licensors' inventions or technologies may be found to be not patentable; and we may not develop additional technologies that are patentable.

We may become subject to third parties' claims alleging infringement of third-party patents and proprietary rights, or we may be involved in lawsuits to protect or enforce our patents and other proprietary rights, which could be costly and time consuming, delay or prevent the development and commercialization of our product candidates, or put our patents and other proprietary rights at risk.

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

We may be subject to claims by third parties asserting that we or our employees have misappropriated third-party intellectual property or claiming ownership of what we regard as our own intellectual property. These claims may be costly to defend and if we do not successfully do so, we may be required to pay monetary damages and lose valuable intellectual property rights or personnel.

Some of our employees, including our senior management, were previously employed at other biopharmaceutical or pharmaceutical companies, including our competitors or potential competitors. Some of these employees executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees do not use the know-how, trade secrets, or other proprietary information of others in their work for us, we may be subject to claims that we or these employees have used or disclosed confidential information or intellectual property, including know-how, trade secrets, or other proprietary information, of any such employee's former employer. Litigation may be necessary to defend against these claims. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel.

A loss of key research personnel or their work product could hamper or undermine our ability to develop and commercialize our product candidates, which would severely harm our business. In addition, if such intellectual property rights were to be awarded to a third party, we could be required to obtain a license from such third party to commercialize our technology or product candidates. Such a license may not be available on commercially reasonable terms or at all, which could hamper or undermine our ability to develop and commercialize our product candidates, which would severely harm our business. Even if we successfully prosecute or defend against such claims, litigation could result in substantial costs and distract management from the development and commercialization of our product candidates.

Our proprietary information may be lost or we may suffer security breaches. In the ordinary course of our business, we collect and store sensitive data, including intellectual property, clinical trial data, proprietary business information, personal data and personally identifiable information of our clinical trial subjects and employees, in our data centers and on our networks. The secure processing, maintenance and transmission of this information is critical to our operations. Despite our security measures, our information technology and infrastructure and those of our CROs or other contractors or consultants may be vulnerable to attacks by hackers or breached due to employee error, malfeasance, or other disruptions. While the maintenance of HIPAA-compliance and deidentification of clinical trial personal data is the responsibility of our CROs, breach of planned and future trials at our CRO sites may result in costly lawsuits, stiff penalties from governmental agencies, and may also result in disbarment from operating within some socio-geographic regions, such as the UK and the EU, where personal data is considered paramount. Furthermore, the loss of clinical trial data from completed, ongoing, or planned trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Although, to our knowledge, we have not experienced any such material security breach to date, any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost, or stolen. Any such access, disclosure, or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, and significant regulatory penalties; disrupt our operations; damage our reputation; and cause a loss of confidence in us and our ability to conduct clinical trials, which could adversely affect our reputation and delay our clinical development of our product candidates. This could increase our cyber security risk, create data accessibility concerns, and make us more susceptible to communication disruptions.

Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations or prospects.

Risks Related to Our Reliance on Third Parties

We rely on third parties to conduct, supervise and monitor our preclinical studies and clinical trials, and if those third parties perform in an unsatisfactory manner it may harm our business.

We do not currently have the ability to independently conduct preclinical studies or clinical trials required to develop our product candidates. We rely upon CROs, clinical trial sites and other third parties to ensure the proper and timely conduct of our preclinical studies, and we expect to have limited influence over their actual performance. We intend to rely upon CROs and others for the execution of future nonclinical studies and to monitor, manage and report data any future clinical trials.

We and our CROs and other third parties are required to comply with good clinical practice and good manufacturing practice (collectively, "GxP") requirements, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area, and comparable foreign regulatory authorities for all of our product candidates in clinical development. Regulatory authorities enforce these GxP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. At any point in time, the FDA may revoke or suspend the license of our contract manufacturer for failure to maintain standards resulting in business losses for us. Further, if we fail to exercise adequate oversight over any of our CROs or other third parties, or if we or any of our CROs or other third parties fail to comply with applicable GxP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, the EMA, or foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon a regulatory inspection of us or our CROs or other third parties, such regulatory authority will determine that any of our clinical trials complies with GxP requirements. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

Further, while we may only control certain aspects of these parties' activities, we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. Such standards may change, affecting the ability of contract manufacturers to produce our product candidates on the schedule we require for our clinical trials.

These CROs and other third parties are not our employees and we are not able to control, other than by contract, the amount of resources, including time, which they devote to our clinical trials. If our CROs or other third parties fail to devote sufficient resources to the development of our product candidates, or if their performance is substandard, it may delay or compromise the prospects for approval and commercialization of our product candidates. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information is misappropriated. If any of our relationships with our CROs or other third parties terminate, we may not be able to enter into arrangements with alternative CROs or other third parties or to do so on commercially reasonable terms. Switching or adding additional investigators or CROs involves additional cost and potential delays and requires our management's time and focus. In addition, there is a natural transition period when a new independent investigator or CRO commences work. As a result, delays could occur, which could materially impact our ability to meet our desired clinical development timelines.

If our CROs or other third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to a failure to adhere to our clinical protocols, regulatory requirements, or for other reasons, our clinical trials may be extended, delayed, or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

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, particularly with respect to our legacy product candidates for which we have suspended development. 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 intend to 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 intend to use and rely on CROs to conduct and/or oversee future clinical trials of our product candidates. Nonetheless, we will be responsible for confirming that each of our future clinical trials is conducted in accordance with the FDA's, MHRA's or EMA's requirements and general investigational plans and protocols, as may be applicable. Our expected reliance on third parties will 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.

The process of manufacturing pharmaceuticals and biological products is complex, time-consuming, highly regulated and subject to multiple risks. 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 for our product candidates. Our strategy is to outsource all manufacturing of our product candidates and products to third parties.

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 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 develop and commercialize our product. 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 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. While we provide oversight of manufacturing activities, we do not and will not control the execution of our manufacturing activities by, and are or will be essentially dependent on, our CDMOs for compliance with cGMP requirements for the manufacture of our product candidates. 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 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.

Risks Related to our Business Operations

We only have a limited number of employees to manage and operate our business. Our business could suffer if we are unable to attract and retain key employees.

As of March 31, 2025, we had 9 employees, 8 of which are full-time. Our limited financial resources have led us to focus on the development of our ADC Platform and to manage and operate our business in a highly efficient manner.

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 preclinical and clinical experiments, 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 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 skilled personnel in the biopharmaceutical industry. There can be no assurance that we will be able to continue to attract and retain such personnel or train new hires to the skill level required for completing our preclinical/ clinical objectives.

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.

If we or any third-party manufacturers we engage fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs or liabilities that could harm our business.

We and third-party manufacturers we engage are and will be subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. Liability under certain environmental laws governing the release and cleanup of hazardous materials is joint and several and could be imposed without regard to fault. We also could incur significant costs associated with civil or criminal fines and penalties or become subject to injunctions limiting or prohibiting our activities for failure to comply with such laws and regulations.

Although we maintain general liability insurance as well as workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Further, with respect to the operations of our current and any future third-party contract manufacturers, it is possible that if they fail to operate in compliance with applicable environmental, health and safety laws and regulations or properly dispose of wastes associated with our products, we could be held liable for any resulting damages, suffer reputational harm or experience a disruption in the manufacture and supply of our product candidates or products. In addition, our supply chain may be adversely impacted if any of our third-party contract manufacturers become subject to injunctions or other sanctions as a result of their non-compliance with environmental, health and safety laws and regulations.

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 brought on by the effects of a 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.

We are currently operating in a period of economic uncertainty and capital markets disruption, which has been significantly impacted by geopolitical instability. Our business, financial condition and results of operations could be materially adversely affected by any negative impact on the global economy and capital markets resulting from the geopolitical tensions or high inflation.

U.S. and global markets are experiencing volatility and disruption following the escalation of geopolitical tensions between Russia and Ukraine as well as the ongoing conflict between Israel and Hamas. Although the length and impact of the ongoing military conflict is highly unpredictable, the conflicts could lead to market disruptions, including significant volatility in commodity prices, credit and capital markets, as well as supply chain interruptions, which has led to high inflation globally. We are continuing to monitor inflation and global capital markets and assess the potential impacts on our business.

Although our business has not been materially impacted by these geopolitical tensions to date, it is impossible to predict the extent to which our operations, or those of our suppliers and manufacturers, will be impacted in the short and long term, or the ways in which the conflict may impact our business. The extent and duration of the conflicts, geopolitical tensions, record inflation, sanctions and resulting market disruptions are impossible to predict, but could be substantial. Any such disruptions may also magnify the impact of other risks described herein.

Disruptions at the FDA, the SEC and other government agencies caused by the change in presidential administration, funding shortages or potential funding shortages could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner, or otherwise prevent those agencies from performing normal business functions, which could negatively impact our business and our timelines.

The ability of the FDA to review and clear or approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, shifting policy priorities as a result of changes in the presidential administration and its appointees tasked to oversee the agency, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in the past as a result of these factors, and government funding of the SEC, and other government agencies on which our operations may rely, is subject to the impacts of political events, which are inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may slow the time necessary for review and approval (including any applications we may file with respect to our current and future product candidates), which could adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical employees and stop critical activities. If a prolonged government shutdown or other disruption occurs, it could significantly impact the ability of the FDA and the SEC to timely review and process our submissions, which could have a material adverse effect on our business.

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 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 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. Especially since the merger, cyber-security needs have grown as the combined company has offices in London and San Francisco Bay area with employees operating out of UK, US East and West Coasts. 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.

Our business is subject to risks associated with conducting business internationally.

We source research and development, manufacturing, consulting, and other services from companies based throughout the United States, the UK, the EU, and select Asian countries. Accordingly, our future results could be harmed by a variety of factors, including: economic weakness, including inflation, or political instability in varying economies and markets; differing regulatory requirements for drug approvals in non-European Union (EU) countries; differing jurisdictions could present different issues for securing, maintaining, or obtaining freedom to operate for our intellectual property in such jurisdictions; such jurisdictions; potentially reduced protection for intellectual property rights; difficulties in compliance with non- US laws and regulations; changes in non-U.S. regulations and customs, tariffs, and trade barriers; changes in non-U.S. currency exchange rates of the USD and currency controls; changes in a specific country's or region's political or economic environment, trade protection measures, import or export licensing requirements or other restrictive actions by the USA or non-U.S. governments; differing reimbursement regimes and price controls in certain non-U.S. markets; negative consequences from changes in tax laws; compliance with tax, employment, immigration, and labor laws for employees living or traveling outside of the USA; business interruptions resulting from geo-political actions, including war and terrorism, health epidemics and other widespread outbreaks of contagious disease, or natural disasters, including earthquakes, typhoons, hurricanes, floods and fires.

Risks Related to our Ordinary Shares and ADSs

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 of the global economies remain uncertain or continue to be volatile, or if they deteriorate, including because 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 Silicon Valley Bank ("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 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 and financial performance 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 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 passive foreign investment company ("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.

The market price of our ADSs 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 AE 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 AEs 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 European Commission approval or non-approval of our product candidates or delays in or AEs 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, European Commission 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 31, 2025, our directors and executive officers, together with their affiliates and related persons, beneficially own, in the aggregate, approximately 40% of our outstanding ordinary shares. Our Chairman, Hoyoung Huh, MD, PhD, our President and Chief Executive Officer, Dr. Samir Patel, and our director Dr. Ray Prudo, each beneficially own approximately 18%, 12% and 10% of our outstanding ordinary shares, respectively. Accordingly, these shareholders, if acting together, or Dr. Huh, Dr. Patel or Dr. Prudo, 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 EU (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-please see *Item 1. Business—UK Regulation* for more details. The regulatory regime in the UK 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 the UK's regulatory system is independent from the EU.

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, the UK is no longer covered by centralized marketing authorizations and a separate authorization is required to market a product in the UK. 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 have in the past and may in the future fail to meet the requirements for continued listing on Nasdaq. If we fail to maintain compliance with the minimum listing requirements, our ADSs may be delisted, which could have a material adverse effect on the liquidity of our ADSs.

We have in the past received notices from The Nasdaq Stock Market relating to a failure to comply with the minimum $2,500,000 stockholders' equity requirement for continued listing set forth in Listing Rule 5550(b) (the "Stockholders' Equity Requirement").

Most recently, in April 2024, we received a written notice from the Nasdaq Listing Department notifying us that we were in noncompliance with the Stockholders' Equity Requirement and we regained compliance in November 2024. There can be no assurance that we will continue to meet the Stockholders' Equity Requirement, or any other Nasdaq requirements, in the future.

Furthermore, we may also be unable to meet other applicable Nasdaq listing requirements, including maintaining minimum levels of stockholders' equity or market values of our ADSs, in which case our ADSs could be delisted. If our ADSs were to be delisted, the liquidity of our ADSs would be adversely affected, and the market price of our ADSs could decrease.

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

We 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 spend 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 Sarbanes-Oxley, 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 we are 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 of 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.

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 our risk management controls, including controls in connection with risks from cybersecurity threats.

The Audit Committee of our Board of Directors (the "Audit Committee") is primarily responsible for overseeing our 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 our information system and cybersecurity controls.

On a quarterly basis, the Audit Committee discusses with senior management, our processes for assessing, identifying, and managing material risks from cybersecurity threats and the state of our cybersecurity processes. The Audit Committee also receives updates on, and monitors, our 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 July 2025, 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 also lease laboratory space, located in San Francisco, CA, which expires in September 2025 and is cancellable anytime with 60 days' notice. We are not party to any material lease agreements. We believe that our current facilities are adequate to meet our needs and that suitable additional alternative spaces will be available in the future on commercially reasonable terms, if required.

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.

Refer to Note 10 of the Notes to our consolidated financial statements related to commitments and contingencies, which is incorporated herein by reference.

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 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.

Holders of Record

As of March 31, 2025, we had approximately 415 shareholders of record registered on our books, excluding shares held through banks and brokers. Of the approximate 415 shareholders, 114 hold our ordinary shares through ADSs.

Dividends

We have never declared or paid cash dividends on our ordinary shares, and we do not expect to pay any cash dividends on our ordinary shares 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.

November 2024 Private Placement

In November 2024, we entered into a definitive purchase agreement with certain investors, Dr. Prudo and Dr. Patel, pursuant to which we sold and issued in a private placement an aggregate of 1,713,402 ADSs, and Series D Warrants (the "Series D Warrants") to purchase up to 1,713,402 ADSs, at a per unit price of $2.26 for aggregate gross proceeds of $3.2 million (the "November 2024 Private Placement"). The Series D Warrants have 3-year terms ranging from December 2, 2027 to June 2, 2028 and have cashless exercise provisions in limited circumstances.

At close of the November 2024 Private Placement, we incurred a total of $204,000 in placement agent fees with Paulson Investment Company, LLC ("Paulson"). Net proceeds from the November 2024 Private Placement were approximately $2.8 million after deducting placement agent fees and other expenses. In April 2025, we issued 408,000,000 ordinary shares to Paulson in lieu of $204,000 in cash payment.

March 2025 Private Placement

On March 2, 2025, we entered into a securities purchase agreement (the "March 2025 Purchase Agreement"), pursuant to which we sold an aggregate of (i) 2,283,031 ADSs, each representing 2,000 of our ordinary shares (the "Shares"), (ii) 2,283,031 Series A warrants to purchase ADSs ("Series A Warrants") and (iii) 2,283,031 Series B warrants to purchase ADSs ("Series B Warrants"). The initial closing took place on March 6, 2025. For information on the price per share for each of the Shares, Series A Warrants and Series B Warrants, see "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations—Recent Developments—March 2025 Private Placement."

The net proceeds from the March 2025 Offering, after deducting placement agent fees and other expenses, through the filing of this Form 10-K were approximately $3.3 million. We expect to receive the remaining cash proceeds of $3.0 million in April 2025.

Issuer Purchases of Equity Securities

We did not repurchase any of our equity securities during the fiscal year ended December 31, 2024.

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 audited consolidated 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 an oncology company developing next-generation ADCs designed around novel payloads, which we believe may have the potential to transform the efficacy and safety outcomes of ADCs as cancer therapies beyond options that are currently available or in development.

ADCs are a class of cancer therapies that combine the precision targeting of antibodies with payload toxins that attack cancer cells. To date, innovation in the field of ADC therapies has focused primarily on the development of novel antibodies linked to existing classes of payload toxins. For example, there is a range of approved ADCs with antibodies that target the Her2, Trop2, CD19, CD22, CD30, Nectin-4, Tissue Factor, and FR alpha antibodies. But there is a surprising lack of diversity in the payload toxins to which those antibodies are linked, as all of these marketed products, and more than 90% of ADCs in late-stage clinical development of which we are aware, utilize payloads from just two standard classes: (1) microtubule inhibitors or (2) DNA-damaging agents such as topoisomerase I inhibitors.

Our ADC Platform enables us to generate a range of ADC product candidates that pair our novel payloads with biologically validated antibody targets prevalent in cancer tumors. We believe that our focus on the development of ADCs that utilize our novel payloads may allow us to develop ADCs with benefits that include:

- more effective cancer-killing properties, or cytotoxicity;
- generation of greater numbers of neoepitopes than currently available ADCs, leading to activation of both B-cells and T-cells in the tumor microenvironment to generate an immune response that has the potential to continue to kill cancer cells in the tumor microenvironment and throughout the body;
- ability to be used in combination with checkpoint inhibitors to potentially deliver synergistic efficacy results (more than additive);
- sustained duration of response of tumor regression or elimination;
- reduced tumor resistance; and
- improved safety and tolerability relative to ADCs that are currently available.

Our lead product candidate is AKTX-101, a preclinical stage Trop2-targeting ADC that combines PH1 with the Trop2 antibody, which is expressed in the highest number of solid tumor cancer types, including lung, breast, colon and prostate. We aim to establish AKTX-101 as a best-in-class Trop2-targeting ADC for the treatment of a variety of solid tumors.

We acquired the proprietary rights to our ADC discovery and development platform in connection with the Merger. Prior to that time, we were primarily focused on advancing our former product candidates nomacopan and PAS-nomacopan (longer-acting nomacopan that is PASylated). Since the closing of the Merger, we have focused substantially all of our efforts on the development of ADCs and our ADC Platform. We have suspended further internal development of our legacy programs, nomacopan and PAS-nomacopan, and intend to seek strategic partners to advance their development externally. For our PHP-303 program, a program that Peak Bio had advanced prior to the closing of the Merger, we intend to seek strategic partners for it as well to further its development externally.

Our activities since inception have consisted of performing research and development activities and raising capital.

We do not have any products available for commercial sale, and we have not generated any product revenue from our portfolio of product candidates or other sources. Our ability to generate revenue sufficient to achieve profitability, if ever, will depend on the successful development and eventual commercialization of our potential therapies, which we expect, if it ever occurs, will take a number of years. The research and development efforts require significant amounts of additional capital and adequate personnel infrastructure. There can be no assurance that our research and development activities will be successfully completed, or that our potential therapies will be commercially viable.

Recent Developments

Appointment of New President and Chief Executive Officer

On March 14, 2025, we entered into an Executive Offer of Employment Agreement (as amended by a subsequent Chief Executive Officer Letter Agreement, dated March 18, 2025) with Mr. Abizer Gaslightwala pursuant to which Mr. Gaslightwala will serve as our President and Chief Executive Officer, effective on or around April 21, 2025. Mr. Gaslightwala will earn a base salary, which includes an annual cash bonus target, and receive share-based payment compensation based on time service and the achievement of specific performance criteria.

March 2025 Private Placement

On March 2, 2025, we entered into the March 2025 Purchase Agreement, pursuant to which we agreed to sell and issue in a private placement (the "March 2025 Offering") the Shares as described above, or prefunded warrants in lieu thereof ("Pre-Funded Warrants"), and, in each case, Series A Warrants and Series B Warrants, together with the Pre-Funded Warrants and Series A Warrants, the "Warrants," and together with the ADSs or Pre-Funded Warrants, the "Units")). The Units consist of (i) for investors committing less than $1.0 million in the March 2025 Offering ("Tier 1 Investors") one ADS or Pre-Funded Warrant plus a Series A Warrant to purchase one ADS and a Series B Warrant to purchase one ADS, (ii) for investors committing at least $1.0 million but less than $3.0 million in the March 2025 Offering ("Tier 2 Investors") one ADS or Pre-Funded Warrant plus a Series A Warrant to purchase 1.25 ADSs and a Series B Warrant to purchase one ADS, and (iii) for investors committing $3.0 million or more in the March 2025 Offering ("Tier 3 Investors"), one ADS or Pre-Funded Warrant plus a Series A Warrant to purchase 1.5 ADSs and a Series B Warrant to purchase one ADS. The purchase price per Unit for investors purchasing ADSs is equal to $0.87 plus (a) $0.25 for Tier 1 Investors, (b) $0.28125 for Tier 2 Investors, or (c) $0.3125 for Tier 3 Investors (the "ADS Unit Purchase Price"). The purchase price per Pre-Funded Warrant and accompanying Series A Warrant and Series B Warrant is equal to $0.67 (which represents the ADS purchase price minus the $0.20 exercise price for such Pre-Funded Warrant) plus (a) $0.25 for Tier 1 Investors, (b) $0.28125 for Tier 2 Investors, or (c) $0.3125 for Tier 3 Investors (the "Pre-Funded Unit Purchase Price").

As part of the March 2025 Offering, Dr. Huh agreed to purchase $1 million of Units, with the purchase price thereof to be satisfied through his agreement to cancel and extinguish $1.0 million of notes previously issued to him by the Company (the "Note Termination") for an equal amount of ordinary shares and warrants.

The net proceeds from the March 2025 Offering, after deducting placement agent fees and other offering expenses payable by us, through the filing of this Form 10-K were approximately $3.3 million. We expect to receive the remaining cash proceeds of $3.0 million in April 2025.

The placement agent was paid three percent (3%) of the total number of ADSs issued in the March 2025 Offering, including any of the ADSs issuable upon exercise of the Pre-Funded Warrants (excluding the ADSs issued to Dr. Huh in respect to the Note Termination).

Pipeline Prioritization of the Merged Companies

In May 2024, we announced the completion of a joint portfolio prioritization review pursuant to which the anticipated combined entity, following completion of the proposed Merger (as defined below), will focus on Peak Bio's ADC platform technology. As a result, our nomacopan program in HSCT-TMA was suspended, with enrollment in our pediatric clinical study discontinued due to cost and timeline. Our PAS-nomacopan GA program has also been suspended and we are looking for an external licensing partner. Following the closing of the Merger on November 14, 2024, we expanded our pipeline of assets spanning early and late development stages with the addition of Peak Bio's ADC technology platform with novel payload and linker technologies, as well as the Peak Bio PHP-303 small molecule selective and reversible neutrophil elastase inhibitor. The ADC program includes a novel pre-clinical ADC candidate AKTX-101 targeting TROP-2. By combining our ADC program with immunotherapy strategies, we aim to develop cutting-edge solutions for cancer patients. Further, related to PHP-303, we expect to emphasize partnering/collaboration and licensing opportunities with broad potential impact on patients. We also plan to work closely with the FDA to define the best path for this platform and will pursue opportunities for external partnering/collaboration and licensing for nomacopan, including as a potential treatment for pediatric HSCT-TMA.

Restructuring and Reduction-in-Force

In May 2024, we implemented a reduction-in-force (the "RIF") of approximately 67% of our total workforce, as a result of the recently announced program prioritization under which our nomacopan HSCT-TMA program was suspended. The RIF is part of an operational restructuring plan and includes the elimination of certain senior management positions and was completed by the end of the second quarter of 2024. The purpose of the restructuring plan, including the RIF, was to reduce HSCT-TMA related operating costs, while supporting the execution of our long-term strategic plan. For additional information, refer below to our "Results of Operations" discussion under the heading "Restructuring and Other Costs" and to Note 2 of our consolidated financial statements included in this Form 10-K.

Merger Agreement

On November 14, 2024, we completed the previously announced business combination contemplated by the Agreement and Plan of Merger (the "Merger Agreement") by and among us, Peak Bio and Pegasus Merger Sub, Inc., a Delaware corporation and a wholly-owned subsidiary of Akari (the "Merger Sub"), as amended by a side letter dated August 15, 2024, pursuant to which, upon the terms and subject to the conditions thereof, Merger Sub was merged with and into Peak Bio, with Peak Bio surviving such merger as our wholly owned subsidiary.

For additional information on our acquisition of Peak Bio, please refer to Note 3 of our consolidated financial statements included in this Form 10-K.

Results of Operations

Comparison of the Years Ended December 31, 2024 and 2023

Overview

During the year ended December 31, 2024, our loss from operations totaled $21.6 million, a 29% increase, compared to a loss from operations of $16.8 million for the year ended December 31, 2023. General and administrative expenses, merger related costs and restructuring costs comprise the majority of our total operating expenses, as shown in the table below:

	Year Ended December 31,			
($ in thousands)	**2024**	**2023**	**$ Change**	**%**
Operating expenses:				
Research and development	$ 6,983	$ 5,450	$ 1,533	28%
General and administrative	9,664	11,356	(1,692)	-15%
Merger-related expenses	3,273	—	3,273	100%
Restructuring and other expenses	1,723	—	1,723	100%
Total operating expenses	21,643	16,806	4,837	29%
Loss from operations	$ (21,643)	$ (16,806)	$ (4,837)	29%

Research and development expenses

Our research and development expenses are charged to operations as incurred, and we incur both direct and indirect expenses for all 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, 2024, total research and development expenses increased by approximately $1.5 million, or 28%, compared to the year ended December 31, 2023. The following sets forth research and development expenses for the years ended December 31, 2024 and 2023 by category:

	Year Ended December 31,			
($ in thousands)	**2024**	**2023**	**$ Change**	**%**
Clinical Trials:				
HSCT-TMA clinical development (AK901)	$ 1,896	$ 1,802	$ 94	5%
BP clinical development (AK802)	—	(1,073)	1,073	-100%
ADC preclinical development	47	—	47	100%
Chemistry, manufacturing and control	3,497	2,684	813	30%
Other external development expenses	837	1,498	(661)	-44%
Personnel costs	1,988	3,110	(1,122)	-36%
Tax credits	(1,282)	(2,571)	1,289	-50%
Total research and development expenses	$ 6,983	$ 5,450	$ 1,533	28%

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 5% increase in expenses incurred during the year ended December 31, 2024, as compared to the year ended December 31, 2023, were primarily due to clinical trial close-out costs. In May 2024, following the completion of a pipeline prioritization review, we decided to suspend our HSCT-TMA program. Accordingly, we expect future HSCT-TMA costs to decrease following completion of the wind-down and close-out of the clinical trial.

Bullous Pemphigoid ("BP") clinical development (AK802)

These expenses previously included external expenses that we incurred in connection with the development of nomacopan for the treatment of BP and primarily consisted 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 during the year ended December 31, 2023. We do not expect to incur material additional costs related to this program.

ADC preclinical development

These expenses include external expenses that we incurred in connection with the research and discovery of our ADC platform and program(s), and primarily consist of payments to CROs and other vendors. In 2024, we announced our strategic prioritization of our ADC technology and programs and expect to incur material additional costs related to this program as we will invest in additional ADC related preclinical research and discovery activities.

Chemistry, manufacturing and control

These expenses include external expenses incurred related to the development and manufacturing of nomacopan for use in clinical trials and preclinical development of PAS-nomacopan. In general, such expenses primarily consist of payments to contract manufacturing organizations and other vendors for manufacturing of drug substance (including raw materials), drug product, supplies, and validation, quality assurance and other manufacturing development activities. The $0.8 million, or 30%, increase in expenses incurred during the year ended December 31, 2024, as compared to the year ended December 31, 2023, is primarily due to the timing of manufacturing and development activities, including increased spending on the development of and preparation for manufacturing 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, discontinued programs and unallocated expenses. The $0.7 million, or 44%, decrease in expenses incurred during the year ended December 31, 2024, as compared to the year ended December 31, 2023, is primarily related to lower costs incurred related to preclinical studies and other development work investigating PAS-nomacopan for the treatment of GA.

Personnel costs

These expenses include compensation and related costs associated with employees, independent consultants and staffing firms. The $1.1 million, or 36%, decrease in expenses incurred during the year ended December 31, 2024, as compared to the year ended December 31, 2023, is primarily due to the impact of the RIF which was announced in May 2024, along with lower costs incurred for consultants. Separation benefits paid to impacted employees are classified separately under "Restructuring and other expenses", as discussed below.

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 post-Merger, including program prioritization.

General and administrative expenses

During the year ended December 31, 2024, total general and administrative costs decreased by approximately $1.7 million, or 15%, as compared to the year ended December 31, 2023. The decrease was primarily due to decreases in (i) personnel costs of approximately $1.0 million resulting from the impact of the RIF which was announced in May 2024 (excluding separation benefits paid to impacted employees classified separately under "Restructuring and other expenses" below), (ii) director and officer insurance premiums of approximately $0.3 million, and (iii) consulting and professional fees of approximately $1.2 million. These decreases were partially offset by increases in other expenses of approximately $0.8 million related to regulatory and legal fees.

Merger-related expenses

Merger-related expenses consist of direct expenses incurred in connection with the completed Merger and are comprised primarily of legal and professional fees. No such expenses were incurred during the year ended December 31, 2023.

Restructuring and other expenses

Restructuring and other expenses consist primarily of severance and related benefit costs related to workforce reductions incurred in connection with the RIF, which we implemented in May 2024. Restructuring and other expenses includes $0.3 million of non-cash stock-based compensation expense. No restructuring expenses were incurred during the year ended December 31, 2023.

Interest income

During each of the years ended December 31, 2024 and 2023, interest income was less than $0.1 million and not material. The nominal decrease in interest income during the year ended December 31, 2024, as compared to the year ended December 31, 2023, was primarily due to lower cash deposits in interest bearing accounts. Amounts may fluctuate from period to period due to changes in average cash balances and prevailing interest rates.

Interest expense

Interest expense primarily consists of interest incurred on the May 2024 Convertible Notes, the financing of director and officer insurance premiums and the notes assumed in the acquisition of the Peak Bio, Inc., which include the April 2023 Convertible Notes, the November 2023 Note, the September 2024 Note and the Notes Payable, Related Party. Refer to Note 6 and Note 9 of our consolidated financial statements included in this Form 10-K.

Interest expense may fluctuate from period to period due to changes in average interest-bearing loans and related interest rates. No interest expense was recognized during the year ended December 31, 2023.

Change in fair value of warrant liabilities

Change in fair value of warrant liabilities represents non-cash warrant revaluation gains or losses related to the remeasurement of our liability-classified instruments, namely our September 2022 Warrants and the warrants we assumed on November 14, 2024 in connection with our acquisition of Peak Bio (the "Peak Bio Warrants"), which are more fully described in Note 4 of our consolidated financial statements included in this 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 and Peak Bio Warrants, it is not unusual 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.

During the years ended December 31, 2024 and 2023, we recorded a change in the fair value of warrant liabilities, representing a non-cash warrant revaluation gain of approximately $2.1 million and $6.6 million, respectively. Change in the fair value of the warrant liabilities and resulting warrant revaluation gain for the year ended December 31, 2024 was driven by the decrease in our stock price and decreases in the expected term and expected volatility assumptions during the reporting period, offset by the recognition of warrant liabilities relating to the assumed warrants resulting from the acquisition of Peak Bio. Change in the fair value of the warrant liabilities and resulting warrant revaluation gain for the year ended December 31, 2023 was driven primarily by the decrease in our stock price and decreases in the expected term and expected volatility assumptions during the reporting period.

Foreign currency exchange gain, net

During each of the years ended December 31, 2024 and 2023, we recorded a net foreign currency exchange gain of approximately less than $0.1 million. 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 each of the years ended December 31, 2024 and 2023, we recorded a net other expense of less than $0.1 million. 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, 2024 and 2023 was $19.8 million and $10.0 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, and convertible notes. At December 31, 2024, we had $2.6 million in cash and an accumulated deficit of $247.3 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 discovery, research and development activities;
- the costs associated with the integration activities related to the Merger;
- 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 and current or future 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 arrangements 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.

March 2025 Private Placement

In March 2025, we entered into the March 2025 Purchase Agreement with certain investors, pursuant to which we agreed to sell and issue in a private placement an aggregate of a combination of Units. For more information, see "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations—Recent Developments—March 2025 Offering."

November 2024 Private Placement

In November 2024, we sold Series D Warrants in connection with the November 2024 Private Placement. For more information, see "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations— Recent Sales of Unregistered Securities— November 2024 Private Placement."

May 2024 Private Placement

In May 2024, we entered into a definitive purchase agreement with certain investors, Dr. Prudo and Dr. Patel, pursuant to which we sold and issued in a private placement an aggregate of 4,029,754 ADSs, and Series C Warrants (the "Series C Warrants") to purchase up to 4,029,754 ADS, at a per unit price of $1.885 per ADS and Series C Warrant for aggregate gross proceeds of approximately $7.6 million (the "May 2024 Private Placement"). The Series C Warrants have 3-year terms ranging from May 31, 2027 to June 21, 2027 and have cashless exercise provisions in limited circumstances. The Series C Warrants (other than those issued to Dr. Prudo and Dr. Patel) have an exercise price of $1.76 per ADS. The Series C Warrants issued to Dr. Prudo and Dr. Patel have an exercise price of $1.79 per ADS. Net proceeds from the May 2024 Private Placement were approximately $7.0 million after deducting placement agent fees and other expenses.

May 2024 Convertible Notes

In May 2024, we entered into unsecured convertible promissory notes (the "May 2024 Notes") with Dr. Prudo, our Chairman at the time, and our then Interim President and Chief Executive Officer and director, Dr. Patel, for an aggregate of $1.0 million in gross proceeds. The May 2024 Notes bear interest at 15% per annum, which may be increased to 17% upon the occurrence of certain events of default as described therein, and the principal and all accrued but unpaid interest is due on the date that is the earlier of (a) ten (10) business days following our receipt of a U.K. research and development tax credit from HM Revenue and Customs, and (b) November 10, 2024. Provided, however, at any time or times from the date of the note and until the tenth business day prior to closing of the acquisition, the note holders are entitled to convert any portion of the outstanding and unpaid amount, including principal and accrued interest, into our ADSs at a fixed conversion price equal to $1.59, representing the Nasdaq official closing price of our ADSs on the issuance date, subject to certain restrictions.

In October 2024, Drs. Prudo and Patel each elected to convert $125,000 of principal and accrued interest into our ADSs at a conversion price of $1.59 per ADS. These ordinary shares remain unissued as of December 31, 2024 and are expected to be issued during the second quarter of 2025. The remaining unconverted aggregate principal balance of the May 2024 Notes, or $750,000, was repaid in cash with proceeds from our U.K. research and development tax credit from HM Revenue and Customs.

March 2024 Private Placement

In March 2024, we entered into a definitive purchase agreement with certain existing investors, pursuant to which we 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 (the "March 2024 Private Placement"). Net proceeds from the March 2024 Private Placement were approximately $1.7 million after deducting placement agent fees and other expenses.

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 at the time, and our then Interim President and Chief Executive Officer and director, Dr. Patel, (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 were 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 at the time, and Ms. Rachelle Jacques, our then President and Chief Executive Officer (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.

March 2023 Registered Direct Offering

In March 2023, we sold to certain accredited and institutional investors, led by our existing investors, including Dr. Prudo, our Chairman at the time, 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 from the "March 2023 Registered Offering" were approximately $3.5 million after deducting placement agent fees and other expenses.

Funding Requirements

As of the date of this report, we expect our existing cash, which includes gross proceeds of approximately $6.6 million received in connection with the March 2025 Private Placement (as defined above), will be sufficient to fund our operations into September 2025. While we have additional funding activities in progress to fund our operations, 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, pre-clinical and 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 11 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 pre-clinical and 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; and
- the cost, timing, and outcome of regulatory reviews.

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 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:

	Year Ended December 31,	
(In thousands)	**2024**	**2023**
Net cash (used in) provided by:		
Net cash used in operating activities	$ (12,552)	$ (16,432)
Net cash provided by investing activities	382	—
Net cash provided by financing activities	10,988	7,020
Effect of exchange rates on cash	(4)	7
Net decrease in cash	$ (1,186)	$ (9,405)

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, 2024, as compared to the year ended December 31, 2023, was primarily due to increases in accounts payable and accrued expenses resulting from the timing of cash outlays.

Investment Activities. The net cash provided by investing activities during the year ended December 31, 2024 is solely related to the Merger. There were no investing activities during the year ended December 31, 2023.

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

- For the year ended December 31, 2024, an aggregate of $11.8 million in net proceeds received from the issuance of debt and equity securities, including (i) $1.7 million in net proceeds from the March 2024 Private Placement, (ii) $1.0 million in net proceeds from the issuance of the May 2024 Convertible Notes, (iii) $7.0 million in net proceeds from the May 2024 Private Placement, and (iv) $2.8 million in net proceeds from the November 2024 Private Placement, partially offset by repayment of $0.75 million towards the May 2024 Convertible Notes and $1.1 million in payments related to our short-term insurance premium financing arrangement; and
- 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.

Material Cash Requirements

Insurance Financing Obligations

In January 2025, 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 $0.5 million which is scheduled to be paid in monthly installments through November 2025.

Debt Obligations

In November 2024 as part of the Merger, we assumed convertible notes and notes payable with third parties, and notes payable with a related party, through the acquisition of Peak Bio Inc., as more fully described in Note 6 and Note 9, respectively, to our consolidated financial statements appearing elsewhere in this Form 10-K. These obligations are expected to result in payments of approximately $2.2 million.

Other

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, (iv) the valuation allowance for deferred income taxes, (v) accounting for the acquisition of Peak Bio Inc., and (vi) the valuation of intangible assets. 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. The 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 and the Peak Bio 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 warrant liabilities 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 and the Peak Bio 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 and the Peak Bio Warrants. The expected life of the September 2022 Warrants and the Peak Bio Warrants is assumed to be equivalent to their remaining contractual term. The dividend rate is based on our 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 unusual 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.

Income Tax

When determining if the realization of a deferred tax asset is likely to assess the need to record a valuation allowance, estimates and judgment are required. We consider all available evidence, both positive and negative, including estimated future taxable earnings, ongoing planning strategies, future reversals of existing temporary differences and historical operating results. Additionally, changes to tax laws and statutory tax rates can have an impact on our determination. Our intention is to evaluate the realizability of our deferred tax assets quarterly.

We follow the provisions of ASC 740 "*Accounting for Uncertainty in Income Taxes*" ("ASC 740"), 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, 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.

Peak Bio Inc. Acquisition

On March 4, 2024, we entered into the Merger Agreement with Peak Bio and Merger Sub. On November 14, 2024, we completed the business combination contemplated by the Merger Agreement, pursuant to which, Merger Sub merged with and into Peak Bio, with Peak Bio surviving the acquisition as a wholly-owned subsidiary of Akari.

In connection with the acquisition, we issued a total of 12,613,942 Akari American Depositary Shares ("Akari ADSs") which reflected the conversion of each issued and outstanding share of Peak Bio common stock, par value $0.0001 ("Peak Bio Common Stock") into the right to receive Akari ADSs representing a number of Akari ordinary shares, par value $0.0001 per share ("Akari Ordinary Shares") equal to the exchange ratio calculated in accordance with the Merger Agreement (the "Exchange Ratio"). Each warrant to purchase capital stock of Peak Bio ("Peak Warrant") and option to acquire shares of Peak Common Stock ("Peak Option") was converted into warrants to purchase a number of Akari Ordinary Shares or Akari ADSs,

as determined by Akari ("Adjusted Warrants") and options to purchase a number of Akari Ordinary Shares or Akari ADSs, as determined by Akari ("Adjusted Options"), respectively, to purchase a number of Akari Ordinary Shares or Akari ADSs, based on the Exchange Ratio. The Adjusted Warrants and the Adjusted Options have substantially similar terms and conditions as were applicable to such Peak Warrants and Peak Options immediately prior to the Closing.

The estimated fair value of the Adjusted Warrants of $1.8 million at the acquisition closing date was calculated using the Black Scholes Option Pricing Model. The following assumptions were used to determine the fair value of the assumed warrants as of November 14. 2024:

	Peak Bio Assumed Warrants	
	November 2022	April 2023
Stock (ADS) price	$ 2.23	$ 2.23
Exercise price	$ 39.18	$ 2.04
Expected term (in years)	3.0	3.5
Expected volatility	86.4%	84.1%
Risk-free interest rate	4.3%	4.3%
Expected dividend yield	—	—

We assumed Peak Bio's outstanding stock option awards and granted options to purchase 1,618,081 ADSs as replacement awards for the Peak Bio Adjusted Options. We determined the Peak Bio Adjusted Options were not probable of vesting prior to the consummation of the Merger Agreement. For this reason, the fair value of the replacement awards was not included as consideration transferred in the business combination. Instead, the entire fair value of the adjusted options will be recognized as compensation cost in the post-combination period. The estimated fair value of the Adjusted Options of $1.8 million at the acquisition closing date was calculated using the Black Scholes Option Pricing Model. The valuation assumptions used in the Black Scholes Option Pricing Model include our stock price on the date of closing of $2.23, volatility ranging from 84.1% to 86.4%, an expected dividend yield of 0.0%, an expected term ranging from 0.20 years to 5.32 years, and a risk-free interest rate ranging from 4.3% to 4.6%.

We recognized in-process research and development ("IPR&D") in connection with the acquisition. The fair value of the acquired IPR&D was determined based upon the income approach using a multi period excess earnings model which included a forecast of the expected cash flows, as discussed in more detail under "Valuation of Intangible Assets."

Valuation of Intangible Assets

In a business combination, the fair value of acquired IPR&D is capitalized and accounted for as indefinite-lived intangible assets, and not amortized until the underlying project receives regulatory approval, at which point the intangible assets will be accounted for as definite-lived intangible assets or discontinued. If discontinued, the intangible assets will be written off. R&D costs incurred after the acquisition are expensed as incurred.

The estimated fair values of identifiable intangible assets were determined using the multi-period excess earnings method, which is a valuation methodology that provides an estimate of the fair value of an asset based on market participant expectations of the cash flows an asset would generate over its remaining useful life. The projected discounted cash flow models used to estimate the fair value of assets of our IPR&D reflect significant assumptions and are level 3 unobservable data regarding the estimates a market participant would make in order to evaluate a drug development asset, including the following:

- Probability of clinical trial success and obtaining regulatory approval;
- Forecasted gross sales from up-front and milestone payments, royalties and product sales; and
- A discount rate reflecting our weighted average cost of capital and specific risk inherent in the underlying assets.

The valuation of our acquired IPR&D has significant measurement uncertainty given the lack of historical data on which to base assumptions. We engaged a third-party valuation firm to assist us with the valuation of the IPR&D. Assumptions are difficult to make accurately and were mainly derived from life science studies, industry data, and peer company information that our management believes represent appropriate comparable data.

We test indefinite-lived intangible assets for impairment by first assessing qualitative factors to determine whether it is more likely than not that the fair value is less than its carrying amount. If we conclude it is more likely than not that the fair value is less than its carrying amount, a quantitative impairment test is performed.

Intangible Assets Impairment

We recognized goodwill and other intangible assets comprised of IPR&D during the year ended December 31, 2024 in connection with our acquisition of Peak Bio (collectively, our "Intangible Assets").

For our Intangible Assets, we have the option to first assess qualitative factors to determine whether the fair value of our reporting unit is "more likely than not" less than its carrying value. For IPR&D, the qualitative assessment focuses on key inputs, assumptions and rationale utilized in the establishment of the carrying value. When performing a quantitative analysis, we use our overall market capitalization as a basis to determine the fair value of our reporting unit. When the carrying value of our reporting unit exceeds its fair value, an impairment charge is recorded in current earnings for the difference up to the carrying value of the Intangible Assets recorded.

We manage our operations as a single operating segment for the purposes of assessing performance, making operating decisions and allocating resources, resulting in a single reportable segment, or reporting unit. Subsequent to our acquisition of Peak Bio, the fair market value of our ADSs experienced a significant decline. As a result, we performed a qualitative assessment as of December 31, 2024 to determine whether our Intangible Assets were impaired.

In our qualitative assessment, we considered relevant facts and circumstances for our reportable segment, including (i) overall financial performance, including recent fundraising activities and our strategic acquisition of Peak Bio (ii) industry and market conditions in which we operate, (iii) changes in the reporting unit carrying value since prior year, (iv) macroeconomic conditions, and (v) changes in the fair market value of our ADSs.

Based on the results of our qualitative assessment, we concluded that it is not more likely than not that the fair value of our reporting unit is less than its carrying value.

Recent Accounting Pronouncements

We periodically monitor and review all current accounting pronouncements and standards from the Financial Accounting Standards Board ("FASB") for applicability to our operations. We do not expect the adoption of accounting pronouncements recently issued to have a material impact on our results of operations, financial position or cash flow.

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 U.S. 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, Swiss Franc and Korean Won 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 U.S. 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 short-term promissory notes, related party debt requiring interest payment and our short-term insurance premium financing arrangement we entered into in January 2025, 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, 2024.

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, 2024. 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 our disclosures controls and procedures were not effective at a reasonable assurance level as of December 31, 2024, due to the material weaknesses described below in Management's Annual Report on Internal Control over Financial Reporting.

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, our principal executive and principal financial officers and effected by our 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 our assets;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our 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, 2024. 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, 2024, our internal control over financial reporting was not effective at the reasonable assurance level due to the material weaknesses described below.

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

During 2024, we migrated our ERP system to QuickBooks and our payables management to Bill.com with the intention of introducing manual controls to mitigate the known control deficiencies inherent in such systems. In addition, we acquired Peak Bio in November 2024. Due to the reduction-in-force announced in May 2024 and other personnel changes during the year, we did not have sufficient personnel available to lead the implementation of the necessary manual controls relating to QuickBooks, Bill.com and the accounting for the business combination. As a result of these 2024 initiatives, and the business combination that closed in November 2024, management identified three material weaknesses.

Lack of Formalized Controls over Information Technology General Controls (QuickBooks)

We did not design and maintain effective IT general controls ("ITGCs") for information systems that are relevant to the preparation of our financial statements. Specifically, we did not design and maintain:

(i) Program and data change management controls to ensure that program and data changes are identified, tested, authorized, and implemented appropriately;

(ii) User access controls to ensure a secure access environment through appropriate segregation of duties that adequately restrict user and privileged access to appropriate personnel;

(iii) Computer operations controls to maintain data integrity and ensure that processing and transfer of data, and data backups and data recovery are monitored; and

(iv) Program development controls to ensure that new software development/enhancements are tested, authorized, and implemented appropriately.

Lack of Formally Designed and Implemented Internal Controls – Purchase to Pay (Bill.com)

We have not adequately designed or maintained effective internal controls in the purchase to pay process, specifically to monitor the completeness and accuracy of vendor data, the approval and release of vendor payments, and appropriate segregation of duties.

Lack of Effective Controls over Business Combination Accounting

We have not adequately designed or maintained effective internal controls associated with our recent business combination, specifically, to monitor the completeness of due diligence procedures, estimates and assumptions used in the valuation of acquired intangible assets, technical accounting matters and the review and approval process of reconciliations and journal entries.

Management's Plan to Remediate the Material Weaknesses

Management, with oversight from the Audit Committee, is taking steps to remediate the control deficiencies which resulted in the material weaknesses described above by implementing changes to our internal control over financial reporting. Our plans for remediation include, but are not limited to, the efforts summarized below, which are in the process of being implemented:

Information Technology Controls

We will focus on the following areas to mitigate the material weakness associated with QuickBooks:

- **Access Security**: For user account creation and provisioning to in-scope systems, a designated system administrator will grant access only upon request. The designated system administrator and appropriate approvers will consider segregation of duties access conflicts when granting new access. For de-provisioning, the system administrator will remove users in a timely manner upon appropriate notification. Further, to maintain integrity of access privileges, the appropriate personnel will perform periodic user access reviews of in-scope systems to ensure access remains appropriate, ensure any inappropriate access is identified regularly, and perform lookback procedures as needed to identify the impact of inappropriate activity.

- **Program Changes**: Management will identify a system administrator who will manage change management to enforce appropriate segregation of duties and change management controls.

Purchase to Pay Controls

We will perform the following over the subsequent reporting periods to mitigate the material weakness associated with Bill.com:

- We will design and implement control activities related to vendor data and vendor payment reviews which will be completed on a periodic basis (at least quarterly).

- Perform a segregation of duties assessment to identify the systematic conflicts and/or operational incompatible duties and evaluate the impact on our internal control environment.

- Design and implement controls over the review of service organization control reports for key service organizations (as available) and map the complementary user entity controls to our controls. This includes evaluating any control deficiencies identified at the service organization and the impact on our control environment.

Business Combination Accounting

We are in the process of designing and implementing control activities to ensure that there is an appropriate periodic assessment of our business combination accounting policies and procedures, and other complex technical accounting matters. Additionally, we are consulting with accounting experts to provide appropriate guidance in connection with accounting for business combinations. Our Chief Executive Officer, Chief Financial Officer, and management will continue to monitor the effectiveness of this remediation plan and refine it as appropriate.

We expect to expend efforts to remediate the material weaknesses as described above through fiscal year 2025. We believe that the implementation of the above steps will allow us to address the deficient controls within our internal control environment, which will facilitate the remediation of the material weaknesses. As we continue to evaluate and work to improve our internal control over financial reporting, we will take additional measures to address control deficiencies, and we may modify certain of the remediation measures described above. Following our design and implementation of our remediation efforts, we will need to demonstrate their operating effectiveness. We will not be able to consider the material weaknesses remediated until the applicable remedial controls operate for a sufficient period of time and management has concluded, through testing, that our controls are operating effectively.

b) Attestation Report of the Registered Public Accounting Firm

Not Applicable.

c) Changes in Internal Control over Financial Reporting

Other than the material weaknesses described above, there have been no changes in our internal control over financial reporting occurred during the fiscal quarter ended December 31, 2024 that has materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

Not applicable.

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 our 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 31, 2025, (c) their positions and offices with us, (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 identifies our directors and their ages as of March 31, 2025:

			Committee Memberships (1)			
Name	**Age**	**Relationship**	**Audit**	**Comp**	**N&CG**	**Class – Election Year**
Hoyoung Huh, M.D.	55	Chair of the Board			X	Class A Director - 2025
Ray Prudo, M.D.	80	Director			X	Class C Director - 2025
Samir R. Patel, M.D.	55	Director				Class A Director - 2025
Robert Bazemore	57	Director	X	X	C	Class A Director - 2025
James Neal	69	Director	X	C		Class A Director - 2025
Sandip I. Patel	58	Director	C	X		Class A Director - 2025
Abizer Gaslightwala	51	Director				Class A Director - 2025

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

Hoyoung Huh, MD, PhD, has served as Chairman of our board of directors since November 2024, following our merger with Peak Bio, Inc. Dr. Huh is the founder of Peak Bio Inc. (f/k/a pH Pharma) and has held positions of Chief Executive Officer and Board Chairman since founding pH Pharma in 2015. Dr. Huh is a Silicon Valley-based entrepreneur and investor in healthcare and technology-based businesses and has served as Lead Director of Pliant Therapeutics since December 2017. Dr. Huh has been involved in the formation and management of multiple biotechnology and innovation-based companies, including holding board positions. He previously served as the Chairman of the board of directors of Geron Corporation from September 2011 to December 2018 and CytomX Therapeutics, Inc. from February 2012 to December 2018, and served as a member of the board of directors of Rezolute, Inc. (f/k/a AntriaBio, Inc.) from 2013 to January 2019. He holds an A.B. in Biochemistry from Dartmouth College, an M.D. from Cornell University Medical College and a Ph.D. in Cell Biology and Genetics from Cornell University Sloan Kettering Institute.

Raymond Prudo-Chlebosz, M.D., has served as a member of our board of directors since September 2015, and has previously served as our Executive Chairman from September 2015 through December 2022 and Chairman of our board of directors from January 1, 2023 through November 14, 2024. 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.

James Neal, MS, MBA, has served as a member of our board of directors since November 2024, following our merger with Peak Bio, Inc. He comes to our board of directors as an experienced business professional serving as XOMA Corporation's Chief Executive Officer and Chairman of the Board, joining that company in 2009. Mr. Neal has more than 25 years' experience in forming and maximizing business and technology collaborations globally and in bringing novel products and technologies to market. Prior to XOMA, Mr. Neal was Acting Chief Executive Officer of Entelos, Inc., a leading biosimulation company that acquired Iconix Biosciences, a privately held company where Mr. Neal was Chief Executive Officer. At Iconix, Mr. Neal established multi-year collaborations with Bristol-Myers Squibb, Abbott Labs, Eli Lilly and the U.S. Food and Drug Administration. Mr. Neal earned his B.S. in Biology and his M.S. in Genetics and Plant Breeding from the University of Manitoba, Canada, and holds an Executive MBA degree from Washington University in St. Louis, Missouri.

Sandip I. Patel JD, BBA, has served as a member of our board of directors since November 2024, following our merger with Peak Bio, Inc. Mr. Patel has been involved in the formation, development, growth, and successful exits of several companies in the healthcare services and technology sector, insurance, and financial services. He has served on numerous boards including AtlasClear Holdings, Inc. (NYSE: ATCH), Quantum Fintech (NYSE: QFTA), Monterey Bio (NASDAQ: MTRY), Anderen Bank, Avatar Property & Casualty, and Morton Plant Mease Hospital as a trusted advisor and entrepreneur. Additionally, he has served in executive roles with leading organizations, including American Managed Care, Orion Communities, and WellCare. Mr. Patel received his law degree from the Stetson University College of Law, and a B.B.A in Finance from the University of Georgia.

Robert Bazemore has served as a member of our board of directors since September 2024. Mr. Bazemore has spent over 30 years on the development and commercialization of novel medicines. From 2015 to 2021, Mr. Bazemore served as the President, Chief Executive Officer and member of the Board of Directors of Epizyme, Inc., developing and launching TAZVERIK ® for patients with Follicular Lymphoma and Sarcoma while building on the company's pipeline of promising epigenetic candidates in oncology. Prior to that, Mr. Bazemore served as the Chief Operating Officer of Synageva BioPharma Corp., where he established the company's global commercial and medical organization to support the first product launch, helping lead the broader transition to a sustainable commercial enterprise through the company's acquisition by Alexion Pharmaceuticals, Inc. Mr. Bazemore served in increasing levels of responsibility at Johnson & Johnson including Vice President of Centocor Ortho Biotech Sales & Marketing from 2008 to 2010 and President of Janssen Biotech, where he led the successful launches of numerous products and indications, including the US launches of the oncology therapies ZYTIGA ® and IBRUVICA ®. He was also Vice President of Global Surgery at Ethicon. Prior to Johnson & Johnson, Mr. Bazemore worked at Merck & Co. Inc., where he served in a variety of roles in medical affairs, sales and marketing, including supporting the launch of SINGULAIR ® in the U.S. Mr. Bazemore previously served on the board of Neon Therapeutics prior to its acquisition by BioNTech and served as Board Chairman for Pennsylvania BIO. Mr. Bazemore received a B.S. in Biochemistry from the University of Georgia.

Abizer Gaslightwala has served as a member of our board of directors since December 2024. Mr. Gaslightwala is a well-established leader in the biotechnology and pharmaceutical industry. He has a successful track record spanning over 25 years in the development and commercialization of novel medicines across a range of companies and therapeutic areas. Mr. Gaslightwala serves as the Senior Vice President and Franchise Head for Oncology at Jazz Pharmaceuticals, where he manages a portfolio of products spanning both solid and hematological malignancies. Mr. Gaslightwala has led and driven growth in several leadership roles at Amgen, Pfizer, and Johnson & Johnson. His experience spans business unit leadership, brand marketing, sales leadership, commercial pipeline planning, advanced analytics and insights, and business development. Mr. Gaslightwala also helped lead R&D strategic planning within the autoimmune/inflammation portfolio at Johnson & Johnson, as well as lead commercial planning for Remicade® and several novel pipeline molecules focused on rheumatoid arthritis, inflammatory bowel disease, psoriasis, and atopic dermatitis. Additionally, Mr. Gaslightwala advised several life science companies through his time at the Boston Consulting Group. Mr. Gaslightwala holds a BS in Chemical Engineering from Cornell University, and an MBA from the Sloan School of Management, and a MS in Chemical Engineering from the Massachusetts Institute of Technology.

Samir R. Patel, M.D., has served as a member of our board of directors since November 2023 and as President and Chief Executive Officer since December 16, 2024, after previously serving as Interim President and Chief Executive Officer effective May 1, 2024. 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, since May 2019. Dr. Patel has more than 20 years of experience in life sciences including co-founding SPEC Pharma, LLC, a company that develops and manufactures injectables used in rheumatology, obstetric, orthopedic, and veterinary applications. 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 (now University of Toledo) in Toledo, Ohio, and completed his internal medicine internship and residency, as well as rheumatology fellowship, at University of New Mexico School of Medicine Affiliated Hospitals.

Information about our Executive Officers

Our 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
Samir R. Patel, M.D.[(1)]	55	President and Chief Executive Officer
Torsten Hombeck	55	Chief Financial Officer

(1) Dr. Patel is a member of our board of directors. See "Information about our Directors" above for more information about Dr. Patel.

Torsten Hombeck, Ph.D., has served as our Chief Financial Officer since December 2024. Dr. Hombeck has more than 20 years of experience in the life sciences industry, finance, capital markets and M&A transactions. Prior to joining Akari, Dr. Hombeck served as the CFO, Corporate Secretary and SVP at Aspira Women's Health. Prior to that, Dr. Hombeck served as the Chief Financial Officer of Akari Therapeutics from June 2020 – June 2023. Additionally, his previous positions include Chief Commercial and Strategy Officer and Managing Director at Promethera Biosciences, and Co-Chief Executive Officer and Chief Business Officer at Cytonet where he played an integral role in its acquisition by Promethera. Dr. Hombeck also served as Chief Financial Officer at both Agennix and GPC Biotech. Dr. Hombeck holds a Masters in Business Administration and a Ph.D. in Finance from the EBS University of Business and Law, Ostrich-Winkel, Germany.

Corporate Governance

Audit Committee

Our board has established a formal standing Audit Committee. The current members of our Audit Committee are Mr. Patel (Chair), Mr. Neal, and Mr. Bazemore. Our board has determined that Mr. Patel 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. Neal (Chair), Mr. Patel, and Mr. Bazemore, 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. Bazemore (Chair), Dr. Huh, and Dr. Prudo, 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, we have elected to avail itself of the scaled disclosure requirements available to smaller reporting companies.

This section discusses the material components of our executive compensation program for our named executive officers ("NEOs") for the fiscal year ended December 31, 2024:

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

Summary Compensation Table

The following table sets forth information concerning the compensation of our NEOs during the years ended December 31, 2024 and 2023:

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards (S)(3)	Option Awards ($)(4)	All Other Compensation ($)(5)	Total ($)
Samir R. Patel	2024	–	–	127,497	308,270	–	435,767
President and Chief Executive Officer	2023	–	–	–	–	–	–
Torsten Hombeck[1]	2024	12,500	–	–	–	–	12,500
Chief Financial Officer	2023	138,945	–	–	–	28,561	167,506
Rachelle Jacques	2024	207,582	–	658,216	–	535,375	1,401,173
Former President and Chief Executive Officer	2023	615,750	–	729,393	198,498	16,500	1,560,141
Wendy DiCicco[2]	2024	440,000	15,000	140,249	–	265,595	860,844
Former Interim Chief Financial Officer	2023	226,184	45,000	–	6,480	–	277,664

(1) Dr. Hombeck serves as our Chief Financial Officer, effective December 16, 2024, having previously served as our Chief Financial Officer until June 15, 2023.

(2) Ms. DiCicco served as our Interim Chief Financial Officer from July 17, 2023 through December 6, 2024.

(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 FASB Accounting Standards Codification ("ASC") Topic 718, disregarding estimated forfeitures related to service-based vesting. See Note 8 to our consolidated financial statements included elsewhere in this 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 8 to our consolidated financial statements included elsewhere in this Form 10-K regarding assumptions we made in determining the fair value of option awards.

(5) For 2024, all other compensation includes the following amounts:

Name	Company 401(k) Plan Match ($)	Separation ($) [a]	Other ($) [b]	Total ($)
Dr. Patel	—	—	—	—
Dr. Hombeck	—	—	—	—
Ms. Jacques	11,563	450,000	73,812	535,375
Ms. DiCicco	—	265,595	—	265,595

For 2023, all other compensation includes the following amounts:

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

(a) Amounts reported in the table above represent an accrued and unpaid one time payment due to Ms. Jacques pursuant to her Separation Agreement (defined below). For Ms. DiCicco, the amount reported in the table above represents an accrued and unpaid payment due to be paid in nine equal monthly installments beginning in March 2025 relating to claims for unpaid wages, wages owed due to improper termination notice, unpaid bonuses and severance.

(b) Amounts reported as "Other" in the table above represent earned and unused vacation paid upon termination of their 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 Dr. Patel and Ms. DiCicco). All employee NEOs are at-will employees.

Samir Patel Consulting Services Agreement

We are a party to a consulting services agreement, effective May 1, 2024, with Dr. Patel, who served as our Interim President and Chief Executive Officer (the "Patel Agreement"). Pursuant to the Patel Agreement, Dr. Patel is to be paid $50,000 per month which would be in the form of fully vested Ordinary Shares, and valued based on the closing price of the Ordinary shares on the Nasdaq Capital Market on the last day of each month (or partial month) Dr. Patel serves as President and Chief Executive Officer.

On September 16, 2024, we entered into an amendment to the Patel Agreement (the "Amended Patel Agreement") to revise the compensation to be received. Pursuant to the Amended Patel Agreement, in lieu of receiving his stated monthly compensation of $50,000 in the form of fully vested Ordinary Shares, Dr. Patel shall be paid in the form of fully vested non-qualified stock options to purchase Ordinary Shares ("NQSOs"), with the number of ADSs underlying each such monthly NQSOs grant to be equal to two times the number determined by dividing (i) $50,000 by (ii) the closing price of our ADSs on the Nasdaq Capital Market on the last day of each month (or partial month) Dr. Patel serves as our President and Chief Executive Officer.

The Amended Patel Agreement includes no annual bonus provisions, no eligibility for employee benefits and no severance entitlements. Further, the Amended Patel Agreement can be terminated by us immediately for any reason.

There were no changes to the Amended Patel Agreement following Dr. Patel's appointment as President and Chief Executive Officer on December 16, 2024.

Rachelle Jacques Employment Agreement

Ms. Jacques stepped down as our President and Chief Executive Officer, effective May 1, 2024 (the "Separation Date"). On August 19, 2024, we entered into a separation agreement with Ms. Jacques (the "Separation Agreement"). The Separation Agreement, in exchange for a release of claims and other agreements, acknowledgements and representations of Ms. Jacques set forth therein, provides for: (i) a one-time lump sum payment in the amount of $450,000 to be paid to Ms. Jacques on the earlier of (a) within 30 days of the closing date of our anticipated merger with Peak Bio, Inc. and (b) December 2, 2024; (ii) vesting of a portion of RSUs held by Ms. Jacques representing 276,000,000 ordinary shares; and (iii) forfeiture of a portion of RSUs held by Ms. Jacques representing 482,250,000 ordinary shares.

Prior to her departure in May 2024, we were a party to an executive employment agreement, effective February 28, 2022, with Ms. Jacques (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, we are 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 we 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 our 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 us and our affiliates in a form provided by us (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 our benefit and Ms. Jacques is required to maintain the confidentiality of our confidential information.

Wendy DiCicco Consulting Services Agreements

Prior to her departure in December 2024, we were a party to a consulting services agreement, dated January 15, 2024, and amended on April 26, 2024, with an entity controlled by Ms. DiCicco, our former interim Chief Financial Officer (the "DiCicco Agreement"). The DiCicco Agreement provides for (i) a $40,000 per month fee (the "Consulting Base Pay") 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; (ii) a 2024 target bonus percentage of 45% of the Consulting Base Pay; (iii) a transaction bonus of 10% of the Consulting Base Pay upon the successful closing of the planned merger between us and Peak Bio Inc.; and (iv) a one-time grant of RSUs on May 1, 2024 totaling 1% of our outstanding ordinary shares, which shall vest in full on May 1, 2025, subject to Ms. DiCicco's continued service to us.

Pursuant to the DiCicco Agreement, if we terminated Ms. DiCicco's services without cause and subject to Ms. DiCicco signing a separation agreement and release in a form and manner satisfactory to us (the "Separation Agreement and Release"), and (ii) the Separation Agreement and Release becoming irrevocable, all within 60 days after the Date of Termination (as defined in the DiCicco Agreement), Ms. DiCicco is entitled to a severance equal to nine months of her Consulting Base Rate plus eligible Target Bonus, prorated for the year of termination and for the same time period, payable as lump-sum.

Prior to entering into the DiCicco Agreement, we were 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

We are party to an executive employment agreement, effective December 16, 2024, with Dr. Hombeck (the "Hombeck Agreement"). Pursuant to the Hombeck Agreement, Dr. Hombeck's initial annual base salary is $300,000, which is subject to review and increase on an annual basis and he is eligible to receive an annual cash bonus with a target of 100% of base salary based on the achievement of performance goals established by the board of directors, in consultation with Dr. Hombeck. Further, the Hombeck Agreement provides for participation in employee benefit plans and no severance for termination of services with or without cause.

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

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 "Original Hombeck Agreement"). The Original 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 Original 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 Original Hombeck Agreement, upon termination of Dr. Hombeck's employment without "cause" (as defined in the Original Hombeck Agreement), or by Dr. Hombeck for "good reason" (as defined in the Original Hombeck Agreement) or upon non-renewal by us of the term of the Original 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 us, 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 our share of the premium paid by Dr. Hombeck while he was an active employee for medical insurance coverage under our 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 Original Hombeck Agreement), and subject to Dr. Hombeck's execution and the effectiveness of a release of claims in a form acceptable to us, 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.

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 us.

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 2024 and 2023, our compensation committee utilized the services of Amplify Strategy & Consulting LLC ("Amplify"), an independent compensation consultant. During 2024 and 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 2024, Dr. Hombeck received an annual salary of $300,000, and prior to her departure in May 2024, Ms. Jacques received an annual salary of $615,750. Ms. DiCicco is a non-employee consultant and received a monthly fee of $40,000 from January 1, 2024 through November 30, 2024 prior to her departure.

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 2024 for employees, including our NEOs, were based on corporate goals related to financing, pipeline advancement, reputation, and strengthening our capabilities. For 2024, 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 100% of his base salary. However, Ms. Jacques was not eligible to receive an incentive bonus because her employment terminated in May 2024 and Dr. Hombeck was not eligible to receive an incentive bonus because he had recently joined our Company. 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, 2024.

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, (ii) $25,000 upon resolving Nasdaq non-compliance on minimum bid price and shareholders' equity by October 23, 2023, and (iii) $20,000 upon achievement of internal finance capability improvements by December 31, 2023. In 2024, Ms. DiCicco received total bonuses of $15,000 for achievement of milestone (iii).

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 2024, prior to their separation, we awarded equity compensation under the 2023 Plan to Dr. Patel in accordance with the Patel Agreement. We also awarded Ms. Jacques and Ms. DiCicco in the form equity compensation of time-vesting stock options and/or time-based RSUs. However, unvested RSUs granted to Ms. DiCicco were forfeited in connection with her separation. No awards of equity compensation were made to Dr. Hombeck.

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 2024 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, 2024.

	Option Awards				Stock Awards	
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($)(1)
Samir R. Patel	1,666,667	3,333,333 (2)	0.0012	12/29/2033		
	175,080,000	—	0.0015	9/30/2034		
	79,684,000	—	0.0013	10/31/2034		
	162,604,000	—	0.0006	11/30/2034		
Torsten Hombeck (3)	—	—				
Rachelle Jacques (4)	103,817,200	—	0.0124	5/1/2025		
	14,881,150	—	0.0124	5/1/2025		
	19,086,338	—	0.0016	5/1/2025		
Wendy DiCicco (5) (6)	5,000,000	—	0.0017	12/6/2025	158,473,915	96,669

(1) Market Value is calculated based on a price per ADS of $1.22 (equivalent to $0.00061 per ordinary share), which was the closing price of our ADSs on December 31, 2024.

(2) Represents the unvested portion of a stock option award that vests in three equal installments of 1,666,667 ordinary shares on the annual general meeting anticipated to be held June 30, 2025 and June 30, 2026, subject to Dr. Patel's continued employment with us through the applicable vesting date.

(3) 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. No new awards were granted in 2024.

(4) All options (vested and unvested) held by Ms. Jacques on her employment termination date of May 1, 2024 were allowed to expire on May 1, 2025. No new awards were granted to Ms. Jacques in 2024. In connection with Ms. Jacques's termination, she received accelerated vesting on RSUs representing 276,000,000 ordinary shares, while a portion of RSUs representing 482,250,000 ordinary shares were forfeited.

(5) In connection with Ms. DiCicco's departure in December 2024, her stock option award was allowed to expire on the one-year anniversary of her departure date, December 6, 2025.

(6) On March 3, 2025, we signed a Settlement Agreement and Mutual Release with Ms. DiCicco. In connection with the settlement, Ms. DiCicco's RSU award will continue to vest through the first anniversary of the grant date (i.e., the award will vest 100% on May 1, 2025).

Equity Grant Timing

Our compensation committee has generally granted equity awards on an annual basis. During 2024, our compensation committee did not take into account any material nonpublic information when determining the timing and terms of equity incentive awards, and we did not time the disclosure of material nonpublic information for the purpose of affecting the value of executive compensation. During fiscal year 2024, we did not grant stock options to our named executive officers during any period beginning four business days before and ending one business day after the filing or furnishing of a Form 10-Q, 10-K or 8-K that discloses material nonpublic information.

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 2024 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 2024, 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, 2024 regarding the compensation of our non-employee directors.

	Fees Earned or Paid in Cash ($)(1)	Option Awards ($)(2)	Total ($)
Hoyoung Huh, M.D.	13,770	529,857	543,627
Ray Prudo, M.D.	93,059	10,853	103,912
Samir R. Patel, M.D.	15,138	11,233	26,371
Robert Bazemore	15,104	6,527	21,631
James Neal	7,868	220,774	228,642
Sandip I. Patel	8,511	176,619	185,130
Abizer Gaslightwala	1,796	-	1,796
Michael Grissinger[3]	63,203	5,427	68,630
Wa'el Hashad[3]	47,609	5,427	53,036
Donald Williams[3]	66,425	5,427	71,852

(1) Represents cash fees earned (paid and unpaid) for service as a non-employee director for 2024.

(2) Represents the aggregate grant date fair value of option awards made to each listed director in 2024, as computed in accordance with FASB ASC Topic 718, disregarding estimated forfeitures related to service-based vesting. See Note 8 to our consolidated financial statements included elsewhere in this Form 10-K regarding assumptions we made in determining the fair value of option awards. As of December 31, 2024, our non-employee directors held options to purchase our ordinary shares as follows: Dr Huh: 704,400,000 shares; Dr. Prudo: 10,000,000 shares; Dr. Patel: 5,000,000 shares; Mr. Bazemore: 5,000,000 shares; Mr. Neal: 293,500,000 shares; Mr. Patel: 234,800,000 shares; Mr. Grissinger: 5,000,000 shares; Mr. Hasad: 5,000,000 shares; and Mr. Williams: 5,000,000 shares. Mr. Gaslightwala did not hold any outstanding options as of December 31, 2024. Dr. Patel's options to purchase 5,000,000 shares were granted prior to his appointment as Interim CEO in May 2024. Messrs. Huh, Neal and Patel options were assumed from the acquisition of Peak Bio Inc., which closed on November 14, 2024.

(3) Former director.

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 31, 2025 (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 ordinary shares;
- each of our current directors and director nominees;
- each of our NEOs, as set forth in the Summary Executive Compensation Table set forth in Item 11 of this 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 after March 15, 2025, 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 57,752,981,523 ordinary shares issued and outstanding on March 31, 2025. 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 our ordinary shares.

Name and Address of Beneficial Owner (1)	Ordinary Shares Beneficially Owned (2)	Ordinary Shares Beneficially Owned (%)
5% Shareholders:		
Hoyoung Huh and Affiliates	10,179,008,000 (3)	17.5%
PranaBio Investments LLC	6,725,112,667 (4)	11.5%
Ray Prudo and Affiliates	5,819,456,800 (5)	10.1%
Named Executive Officers and Directors:		
Samir Patel	6,725,112,667 (4)	11.5%
Torsten Hombeck	400,000	*
Hoyoung Huh	10,179,008,000 (3)	17.5%
Ray Prudo	5,819,456,800 (5)	10.1%
Robert Bazemore	89,284,000 (6)	*
James Neal	254,424,000 (7)	*
Sandip Patel	1,179,182,000 (8)	2.0%
Abizer Gaslightwala	362,856,000 (9)	*
All current directors and executive officers as a group (8 individuals)	24,609,723,467 (10)	41.5%

* 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, ADSs 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." Each ADS represents 2,000 ordinary shares.

(3) Consists of (i) 9,391,708,000 shares held of record by Dr. Huh, (ii) 464,904,000 shares underlying options exercisable within 60 days of March 31, 2025 granted to Dr. Huh, (iii) 103,482,000 shares underlying warrants exercisable within 60 days of March 31, 2025 and (iv) 218,914,000 shares held of record by Hannol Ventures LLC ("Hannol"). Excludes up to 3,571,428,000 shares underlying warrants exercisable within 60 days of March 31, 2025 issued to Dr. Huh which are subject to a 9.99% beneficial ownership limitation and with respect to which Dr. Huh disclaims beneficial ownership to the extent that any exercise of such warrants would exceed such percentage. Dr. Huh is the sole member of Hannol and exercises voting and dispositive power over the shares held of record by Hannol and may be deemed the beneficial owner of such shares. The principal office address of Hannol is 16703 Early Riser Avenue, Suite 563, Land O Lakes, FL 34638.

(4) Consists of (i) 91,396,000 shares held of record by Dr. Patel, (ii) 6,062,010,000 shares held of record by PranaBio Investments LLC ("PranaBio") and (iii) 571,706,667 options exercisable within 60 days of March 31, 2025 granted to Dr. Patel. Excludes up to (i) 96,774,000 shares underlying prefunded warrants exercisable within 60 days of March 31, 2025 to PranaBio and (ii) 3,855,918,000 shares underlying warrants exercisable within 60 days of March 31, 2025 issued to Dr. Patel which are subject to a 9.99% beneficial ownership limitation and with respect to which Dr. Patel disclaims beneficial ownership to the extent that any exercise of such warrants would exceed such percentage. Dr. Patel is the manager of PranaBio and may be deemed the beneficial owner of the shares held of record by PranaBio. The principal office address of PranaBio is 1701 Chicon Street, Austin, TX 78745.

(5) Consists of (i) 4,969,980,600 shares held of record by Dr. Prudo, (ii) 10,000,000 shares underlying options exercisable within 60 days of March 31, 2025 granted to Dr. Prudo, (iii) 800,766,600 shares held of record by RPC Pharma Limited ("RPC") and (iv) 38,709,600 ordinary shares held of record by Praxis Trustees Limited as trustee of The Sonic Healthcare Holding Company ("Praxis"). Excludes up to 3,710,799,500 shares underlying warrants exercisable within 60 days of March 31, 2025 issued to Dr. Prudo which are subject to a 9.99% beneficial ownership limitation and with respect to which Dr. Prudo disclaims beneficial ownership to the extent that any exercise of such warrants would exceed such percentage. Dr. Prudo controls the voting and investment decisions with respect to the shares held of record by RPC and Praxis and thereby may be deemed the beneficial owner of such shares. The principal office address of RPC is c/o Landmark Fiduciare (Suisse) SA, 6 Place des Eaux-Vives, P.O. Box 3461, Geneva, V8 1211, Switzerland. The principal office address of Praxis is P.O. Box 296, Regency Court, Glategny Esplanade, St. Peter Port, Guernsey, GY1 4NA.

(6) Represent shares held of record by Mr. Bazemore.

(7) Consists of (i) 41,144,000 shares held of record by Mr. Neal, (ii) 193,710,000 shares underlying options exercisable within 60 days of March 31, 2025 and (iii) 19,570,000 shares underlying warrants exercisable within 60 days of March 31, 2025.

(8) Includes (i) 903,714,000 shares held of record by Mr. Patel, (ii) 154,968,000 shares underlying options exercisable within 60 days of March 31, 2025, (iii) 12,500,000 shares held of record by TT Insurance Investment LLC ("TTI"), (iv) 27,802,000 ordinary shares held of record by Innovative Lifesci Investments LLC ("Innovative Lifesci"), (v) 39,760,0000 ordinary shares held of record by Quest Bio LLC ("Quest") and (vi) 40,438,000 ordinary shares held of record by Davis Island Ventures LLC ("Davis Island"). Mr. Patel, as the managing member of TTI, Innovative Lifesci, Quest Bio and Davis Island, exercises voting and dispositive power with respect to the ordinary shares held by such entities and therefore may be deemed to beneficially own the shares held of record by such entities. The principal office address of each of TTI, Innovative Lifesci and Quest is 4631 W El Prado Blvd., Tampa, FL 33629.

(9) Represent shares held of record by Mr. Gaslightwala.

(10) Includes (i) 1,395,288,667 shares underlying options exercisable within 60 days of March 31, 2025, and (ii) 123,052,000 shares underlying warrants exercisable within 60 days of March 31, 2025.

Equity Compensation Plan Information

We have three compensation plans under which our equity securities are authorized for issuance. The 2014 Equity Incentive Plan, the 2023 Equity Incentive Plan and the Peak Bio Inc. Long Term Incentive Plan. The following table sets forth certain information relating to these equity compensation plans as of December 31, 2024:

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	253,434,688	$ 0.01	—
2023 Equity Incentive Plan	726,191,815	0.00	8,148,713,522
Peak Bio Inc. Long Term Incentive Plan	3,236,162,000	0.00	—
Total	4,215,788,503	$ 0.01	8,148,713,522
Equity compensation plans not approved by shareholders	N/A	N/A	N/A

(1) Consists of our 2014 Plan and 2023 Plan and the awards granted under the incentive plan of Peak Bio Inc. assumed at closing of the acquisition. As of December 31, 2024, new awards are only available for issuance under our 2023 Plan.

(2) There were no RSUs outstanding and there was no impact to the calculation of the weighted-average exercise price.

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

Transactions with Related Persons

Since January 1, 2023, 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.

Interim CEO Agreement

On December 12, 2024, our board of directors approved the appointment of Dr. Patel to Chief Executive Officer and principal executive officer, effective December 16, 2024. There were no changes to Dr. Patel's revised compensation as provided for under the September 16, 2024 Interim CEO Amendment Agreement, described below, following Dr. Patel's appointment as President and Chief Executive Officer on December 16, 2024.

On May 31, 2024, we and Dr. Patel entered into an Interim Chief Executive Officer Agreement, effective as of May 1, 2024 (the "Interim CEO Agreement"). Pursuant to the Interim CEO Agreement, Dr. Patel served as our Interim President and Chief Executive Officer as an independent contractor on an at-will basis. The Interim CEO Agreement could be terminated by us immediately for any reason. As the sole compensation for services provided under the Interim CEO Agreement, Dr. Patel was paid $50,000 per month in the form of fully vested ordinary shares. On September 16, 2024, we entered into an amendment to the Interim CEO Agreement (the "Amendment"), effective July 1, 2024, to revise Dr. Patel's compensation in connection with the services as Interim President and Chief Executive Officer. Pursuant to the Amendment, in lieu of receiving the stated monthly compensation of $50,000 in the form of fully vested ordinary shares, Dr. Patel is paid in the form of fully vested NQSOs, with the number of ADSs underlying each such monthly NQSOs grant equal to two times the number determined by dividing (i) $50,000 by (ii) the closing price of our ADSs on the Nasdaq Capital Market on the last day of each month (or partial month) Dr. Patel serves as our Interim President and Chief Executive Officer.

During the year ended December 31, 2024, we recognized approximately $0.3 million in non-cash stock-based compensation costs pursuant to the Interim CEO Agreement, as amended, pertaining to (i) NQSOs granted to Dr. Patel to purchase 422,368,000 ordinary shares at an exercise price of less than $0.01 per ordinary share with a grant date fair value of approximately $0.3 million, and (ii) 91,396,000 fully vested ordinary shares granted to Dr. Patel.

Notes Payable Due to Dr. Huh

Pursuant to the acquisition of Peak Bio, which closed on November 14, 2024, we assumed three notes payable due to Dr. Huh, our Chairman of the Board.

January 2024 Note

We assumed a note in the amount of $0.75 million owed to Dr. Huh, which was entered into in January 2024 (the "January 2024 Note"). The January 2024 Note has a maturity date of January 23, 2025, and carries an interest rate of 15% per annum. In connection with the closing of the acquisition, Dr. Huh released Peak Bio of its rights to any security interest in all of the assets of Peak Bio and its subsidiaries.

As of the closing date, and as of December 31, 2024, the outstanding balance of the January 2024 Note was $0.75 million. We recognized interest expense of less than $0.1 million subsequent to the acquisition date, through December 31, 2024. As of December 31, 2024, accrued interest of $0.1 million is presented within accrued expenses in our consolidated balance sheets.

2021 Notes

We assumed a note in the amount of $0.9 million owed to Dr. Huh, which was entered into at various dates in 2021 (the "2021 Notes"). The 2021 Notes, which matured at various dates in 2022, carried an interest rate of 1.0% per annum.

As of the closing date, and as of December 31, 2024, the outstanding balance of the 2021 Notes was $0.9 million. We recognized interest expense of less than $0.1 million subsequent to the acquisition date, through December 31, 2024. As of December 31, 2024, accrued interest of $0.1 million is presented within accrued expenses in our consolidated balance sheets.

In connection with the March 2025 Purchase Agreement, Dr. Huh's 2021 Notes and a portion of his January 2024 Note aggregating to $1.0 million were cancelled, extinguished and paid in full for an equal amount of ordinary shares and warrants.

May 2024 Convertible Notes

On May 10, 2024, we entered into the May 2024 Notes For more information, see "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations—Sources of Liquidity—May 2024 Convertible Notes."

The Doctors Laboratory

We lease 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, 2024 and 2023, respectively. Dr. Ray Prudo, our Director, is the non-Executive Chairman of the Board of Directors of TDL.

We 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, 2024 and 2023.

We recorded payable balances owed to TDL of less than $0.1 million as of December 31, 2024 and 2023.

Other

In November 2024, we assumed an amount due to an entity in which our Chairman, Dr. Hoyoung Huh, is a director. As of December 31, 2024, the amounts due totaled less than $0.1 million and are included in accounts payable in our consolidated balance sheets.

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 ordinary shares;
- 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 ordinary shares; 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. Huh, Dr. Prudo, Mr. Bazemore, Mr. Neal, Mr. Patel, and Mr. Gaslightwala 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 Mr. Grissinger, Mr. Hashad, and Mr. Williams, each of whom served on the board during 2023, were independent. As Dr. Patel is our President and Chief Executive Officer, he 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. during the years ended December 31, 2024 and 2023:

Fee Category	2024	2023
Audit Fees	$ 527,845	$ 344,384
Tax Fees	—	40,000
Total Fees	$ 527,845	$ 384,384

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 10-Q 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 the year ended December 31, 2023 primarily related to the conduct of an IRS Section 382 study. No such services were provided by BDO during the year ended December 31, 2024.

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 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, 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 (incorporated by reference to Exhibit 10.6 to the Registrant's 2023 Form 10-K, as filed with the SEC on March 29, 2024).
10.7†	Form of Restricted Stock Unit Agreement Granted Under the 2023 Equity Incentive Plan (incorporated by reference to Exhibit 10.7 to the Registrant's 2023 Form 10-K, as filed with the SEC on March 29, 2024).
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).

Exhibit Number	Description
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, 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 (incorporated by reference to Exhibit 10.24 to the Registrant's 2023 Form 10-K, as filed with the SEC on March 29, 2024).
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.

Exhibit Number	Description
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).
10.32	Form of Series C Warrant issued under the Securities Purchase Agreement dated as of June 4, 2024 between Akari Therapeutics, Plc and the investors listed therein (incorporated by reference to Exhibit 4.1 to Registrant's Current Report on Form 8-K, as filed with the SEC on June 4, 2024).
10.33	Form of Securities Purchase Agreement dated as of June 4, 2024 between Akari Therapeutics, Plc and the investors listed therein (incorporated by reference to Exhibit 10.1 to the Registrant's Report on Form 8-K, as filed with the SEC on June 4, 2024).
10.34	Form of Placement Agent Warrant issued under the Securities Purchase Agreement dated as of June 4, 2024 between Akari Therapeutics, Plc and the investors listed therein (incorporated by reference to Exhibit 4.2 to Registrant's Current Report on Form 8-K, as filed with the SEC on June 4, 2024).
10.35	Amendment No. 2 to Consulting Services Agreement, by and between the Company and Board Advantage LLC, dated April 26, 2024 (incorporated by reference to Exhibit 10.1 to Registrant's Current Report on Form 8-K, as filed with the SEC on May 1, 2024).
10.36	Form of Convertible Promissory Note, dated May 10, 2024, by and between Akari Therapeutics, Plc and the purchasers party thereto (incorporated by reference to Exhibit 10.3 to Registrant's Quarterly Report on Form 10-Q, as filed with the SEC on August 19, 2024).
10.37	Interim Chief Executive Officer Agreement, dated as of May 31, 2024, by and between the Company and Samir Patel, M.D. (incorporated by reference to Exhibit 10.1 to Registrant's Current Report on Form 8-K, as filed with the SEC on June 5, 2024).
10.38	Amendment to Interim Chief Executive Officer Agreement, between Akari Therapeutics, Plc and Samir R. Patel, M.D., dated as of September 16, 2024 (incorporated by reference to Exhibit 10.1 to Registrant's Current Report on Form 8-K, as filed with the SEC on September 18, 2024).
10.39	Side Letter Agreement, dated August 15, 2024, by and among Akari Therapeutics, Plc, Pegasus Merger Sub, Inc. and Peak Bio, Inc. (incorporated by reference to Exhibit 10.3 to Registrant's Quarterly Report on Form 10-Q, as filed with the SEC on August 19, 2024).
10.40*	Separation Agreement, dated August 18, 2024, by and between Akari Therapeutics, Plc and Rachelle Jacques.
10.41	Form of Warrant Certificate of the Company (incorporated by reference to Exhibit 4.1 to of the Company's Current Report on Form 8-K filed with the SEC on November 7, 2022).
10.42	Form of Amended and Restated Warrant Agreement, dated as of October 31, 2022, by and between Ignyte Acquisition Corp. and Continental Stock Transfer & Trust Company, as warrant agent (incorporated by reference to Exhibit 10.4 of the Company's Current Report on Form 8-K filed with the SEC on November 2, 2022).
10.43	Form of Convertible Note and Warrant Subscription Agreement, dated April 28, 2023, by and between Peak Bio, Inc. and the Investors party thereto (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on May 1, 2023).
10.44	Form of Convertible Note, dated April 28, 2023 (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed with the SEC on May 1, 2023).
10.45	Form of Warrant, dated April 28, 2023 (incorporated by reference to Exhibit 10.3 of the Company's Current Report on Form 8-K filed with the SEC on May 1, 2023).

Exhibit Number	Description
10.46	Warrant, dated April 28, 2023, issued to Paulson Investment Company, LLC (incorporated by reference to Exhibit 10.5 of the Company's Current Report on Form 8-K filed with the SEC on May 1, 2023).
10.47	Form of Senior Secured Promissory Note, dated January 23, 2024, by and between Peak Bio, Inc. and the Hoyoung Huh (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on January 29, 2024).
19.1	Insider Trading Policy.
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: April 15, 2025

/s/ Samir R. Patel, M.D.

Samir R. Patel, M.D.
President and Chief Executive Officer

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/ Samir R. Patel, M.D. **Samir R. Patel, M.D.**	President and Chief Executive Officer *(principal executive officer)*	April 15, 2025
/s/ Torsten Hombeck, Ph.D. **Torsten Hombeck, Ph.D.**	Chief Financial Officer *(principal financial officer and principal accounting officer)*	April 15, 2025
/s/ Hoyoung Huh, M.D., Ph.D. **Hoyoung Huh, M.D., Ph.D.**	Chairman	April 15, 2025
/s/ Ray Prudo, M.D. **Ray Prudo, M.D.**	Director	April 15, 2025
/s/ James Neal **James Neal**	Director	April 15, 2025
/s/ Sandip I. Patel **Sandip I. Patel**	Director	April 15, 2025
/s/ Robert Bazemore **Robert Bazemore**	Director	April 15, 2025
/s/ Abizer Gaslightwala **Abizer Gaslightwala**	Director	April 15, 2025

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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, 2024 and 2023, the related consolidated statements of operations and comprehensive loss, changes in shareholders' equity (deficit), 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, 2024 and 2023, 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, defaults on debt obligations 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 Matters

The critical audit matters communicated below are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate 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 matters 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 matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Valuation of Intangible Assets Related to In-process Research and Development (IPR&D)

As disclosed in Note 3 to the consolidated financial statements, the Company completed its acquisition of Peak Bio, Inc. in November 2024. As a result of the acquisition, the Company recognized approximately $34.0 million of AKTX-101 IPR&D and $5.2 million of PHP 303 IPR&D, both valued using the multi-period excess earnings method. Significant assumptions used in determining the fair value of the IPR&D include forecasted gross product sales, discount rates and probability of clinical trial success and obtaining regulatory approval.

We identified the valuation of intangible assets related to acquired IPR&D as a critical audit matter. The principal considerations for our determination are the significant judgments and subjectivity required in assessing the fair value of the acquired IPR&D and certain significant assumptions related to: (i) the forecasted gross product sales for AKTX-101 IPR&D, and (ii) discount rates and probability of clinical trial success and obtaining regulatory approval for both AKTX-101 and PHP 303 IPR&D. Auditing these elements involved especially challenging and subjective auditor judgment due to the nature and extent of audit effort required to address this matter, including the involvement of professionals with specialized skills or knowledge.

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

- Evaluating the reasonableness of forecasted gross product sales for AKTX-101 IPR&D by comparing them against relevant life science studies, market and industry data, and historical sales trend of comparable products.

- Utilizing professionals with specialized skills and knowledge in valuation to assist in: (i) evaluating the reasonableness of the discount rates used in the valuation models; (ii) developing independent estimates of the discount rates and comparing those to the discount rates selected by management; and (iii) assessing the reasonableness of the probability of clinical trial success and obtaining regulatory approval used in the valuation models.

Classification of Warrants

As described in Note 3 to the consolidated financial statements, in connection with the acquisition of Peak Bio, Inc., the Company assumed the April 2023 Peak Warrants issued to investors. The Company determined that the April 2023 Peak Warrants met the criteria for liability classification and recorded them as derivative liabilities within its consolidated balance sheet.

In addition, as described in Note 7 to the consolidated financial statements, in November 2024 and in May 2024, the Company sold to certain investors its American Depository Shares ("ADSs") in private placement offerings. In connection with these offerings, the Company also issued registered warrants to the investors (the "Series D Warrants" and "Series C Warrants"). The Company determined that the Series D Warrants and the Series C 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 transactions in November 2024 and May 2024.

We identified the evaluation of the consolidated financial statement classification for the April 2023 Peak Warrants, the Series D Warrants, and the Series C Warrants as a critical audit matter. Our principal considerations included the existence of accounting complexities related to certain provisions of the warrant agreements, including settlement provisions and derivative elements. Auditing these elements involved especially complex auditor judgment due to the terms of the relevant agreements, including the extent of expertise 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 agreements, (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 expertise in relevant technical accounting to assist in: (i) evaluating relevant terms of the warrant agreements in relation to the appropriate accounting literature, and (ii) assessing the appropriateness of conclusions reached by the Company related to the Series C Warrants and the April 2023 Peak Warrants.

Convertible Notes, Related Party

As described in Note 2 and Note 9 to the consolidated financial statements, the Company entered into unsecured convertible promissory notes with certain related parties in May 2024 (the "May 2024 Notes"). In accounting for the issuance of the May 2024 Notes, the Company concluded that there were no potential derivatives that should be accounted for separately.

We identified the accounting evaluation of the May 2024 Notes as a critical audit matter. The principal considerations for our determination were: (i) the evaluation of the contract terms and conditions in accordance with the appropriate existing and recently adopted accounting literature, and (ii) the evaluation of the potential derivatives that may require bifurcation from the debt instrument and evaluation of the appropriate accounting treatment. Auditing these elements involved especially complex auditor judgment due to the terms of the relevant agreements, including the extent of expertise needed.

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

- Utilizing personnel with expertise in relevant technical accounting to assist in: (i) evaluating relevant contract terms and conditions of the May 2024 Notes in relation to the relevant accounting literature, and (ii) assessing the appropriateness of conclusions reached by the Company with respect to the evaluation of potential derivatives, bifurcation, and accounting treatment for the May 2024 Notes.

/S/ BDO USA, P.C.

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

New York, New York

April 15, 2025

AKARI THERAPEUTICS, PLC

Consolidated Balance Sheets

(amounts in thousands, except share and per share data)

	December 31,	
	2024	**2023**
ASSETS		
Current assets:		
Cash	$ 2,599	$ 3,845
Restricted cash	60	—
Prepaid expenses	92	299
Other current assets	201	197
Total current assets	2,952	4,341
Goodwill	8,430	—
Other intangible assets	39,180	—
Patent acquisition costs, net	—	14
Total assets	$ 50,562	$ 4,355
LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 12,407	$ 1,671
Accrued expenses	3,137	1,566
Convertible notes	700	—
Convertible notes, related party	250	—
Notes payable	659	—
Notes payable, related party	1,651	—
Warrant liabilities	1,012	1,253
Other current liabilities	94	94
Total current liabilities	19,910	4,584
Other non-current liabilities	383	—
Deferred tax liability	8,040	—
Total liabilities	28,333	4,584
Commitments and contingencies (Note 10)		
Shareholders' equity (deficit):		
Share capital of $0.0001 par value		
Authorized: 245,035,791,523 and 45,122,321,523 ordinary shares at December 31, 2024 and 2023, respectively; issued and outstanding: 53,186,919,523 and 13,234,315,298 at December 31, 2024 and 2023, respectively	5,319	1,324
Additional paid-in capital	212,706	174,754
Capital redemption reserve	52,194	52,194
Accumulated other comprehensive loss	(738)	(1,040)
Accumulated deficit	(247,252)	(227,461)
Total shareholders' equity (deficit)	22,229	(229)
Total liabilities and shareholders' equity (deficit)	$ 50,562	$ 4,355

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

AKARI THERAPEUTICS, PLC

Consolidated Statements of Operations and Comprehensive Loss

(amounts in thousands, except share and per share data)

	Year Ended December 31,	
	2024	**2023**
Operating expenses:		
Research and development	$ 6,983	$ 5,450
General and administrative	9,664	11,356
Merger-related expenses	3,273	—
Restructuring and other expenses	1,723	—
Total operating expenses	21,643	16,806
Loss from operations	(21,643)	(16,806)
Other income (expense):		
Interest income	8	82
Interest expense	(244)	—
Change in fair value of warrant liabilities	2,085	6,599
Foreign currency exchange gains (losses), net	6	136
Other expense, net	(3)	(19)
Total other income, net	1,852	6,798
Net loss	$ (19,791)	$ (10,008)
Net loss per share — basic and diluted	$ (0.00)	$ (0.00)
Weighted-average number of ordinary shares used in computing net loss per share — basic and diluted	23,888,010,485	9,788,980,193
Comprehensive loss:		
Net loss	$ (19,791)	$ (10,008)
Other comprehensive income, net of tax:		
Foreign currency translation adjustment	302	(269)
Total other comprehensive income, net of tax	302	(269)
Total comprehensive loss	$ (19,489)	$ (10,277)

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

AKARI THERAPEUTICS, PLC

Consolidated Statements of Changes in Shareholders' Equity (Deficit)

(amounts in thousands, except share data)

	Share Capital $0.0001 par value		Additional Paid-in-	Capital Redemption	Accumulated Other Comprehensive	Accumulated	Total Shareholders'
	Shares	Amount	Capital	Reserve	Income (Loss)	Deficit	Equity (Deficit)
Balance, December 31, 2022	**7,444,917,123**	**$ 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 shares for 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)**
Issuance of share capital related to financing, net of issuance costs	14,127,540,000	1,413	10,054	—	—	—	11,467
Issuance of share capital related to acquisition of Peak Bio, Inc., net of issuance costs	25,227,884,000	2,523	25,606	—	—	—	28,129
Issuance of shares for services	334,396,000	33	238	—	—	—	271
Vesting of restricted shares	383,275,400	38	(10)	—	—	—	28
Shares withheld for payroll taxes	(120,491,175)	(12)	(181)	—	—	—	(193)
Stock-based compensation	—	—	2,245	—	—	—	2,245
Foreign currency translation	—	—	—	—	302	—	302
Net loss	—	—	—	—	—	(19,791)	(19,791)
Balance, December 31, 2024	**53,186,919,523**	**$ 5,319**	**$ 212,706**	**$ 52,194**	**$ (738)**	**$ (247,252)**	**$ 22,229**

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

AKARI THERAPEUTICS, PLC

Consolidated Statements of Cash Flows

(amounts in thousands)

	Year Ended December 31,	
	2024	**2023**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (19,791)	$ (10,008)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	14	4
Stock-based compensation	2,245	1,150
Issuance of shares for services	271	142
Change in fair value of warrant liabilities	(2,085)	(6,599)
Unrealized foreign currency exchange losses (gains)	255	(255)
Change in assets and liabilities, net of acquisition of Peak Bio:		
Prepaid expenses and other current assets	1,316	70
Accounts payable and accrued expenses	5,223	(936)
Net cash used in operating activities	(12,552)	(16,432)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Cash acquired in Peak Bio Acquisition	382	—
Net cash provided by investing activities	382	—
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of shares, net of issuance costs	11,815	7,016
Proceeds from issuance of convertible notes	1,000	—
Repayment of convertible notes	(750)	—
Proceeds from issuance of restricted shares	26	—
Proceeds from employee vesting of restricted shares	2	4
Payments on short-term financing arrangement	(1,105)	—
Net cash provided by financing activities	10,988	7,020
Effect of exchange rates on cash	(4)	7
Net decrease in cash	(1,186)	(9,405)
Cash and restricted cash at beginning of period	3,845	13,250
Cash and restricted cash at end of period	$ 2,659	$ 3,845
Components of cash and restricted cash		
Cash	$ 2,599	$ 3,845
Restricted cash	60	—
Total cash and restricted cash	$ 2,659	$ 3,845
SUPPLEMENTAL DISCLOSURES OF NON-CASH ACTIVITIES:		
Financing costs in accounts payable and accrued expenses	$ 348	$ 55
Seller-financed purchases	$ 1,105	$ —
Payroll taxes on stock-based compensation in accrued expenses	$ 193	$ —
Issuance of ordinary shares for Peak Bio Acquisition	$ 28,129	$ —
Warrants assumed in connection with Peak Bio Acquisition	$ 1,844	$ —
SUPPLEMENTAL CASH FLOW DISCLOSURES:		
Cash paid for interest	$ 143	$ —

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 developing next-generation antibody-drug conjugates, or ADCs, through its proprietary technology platform that enables Akari to generate a range of ADC candidates and optimize them to target a range of cancers. Since the Company's acquisition of Peak Bio in November 2024, Akari has focused substantially all of its efforts on the ADC platform and pipeline of novel anti-cancer payloads with mechanisms of action that differ from existing therapies and the application of those payloads against clinically validated targets. Through its platform, the Company aims to establish a pipeline of ADC candidates that target and kill cancer cells and stimulate the immune system, or bifunctional ADCs, all while overcoming the limitations inherent in existing therapies. 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 preclinical and 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, preclinical and regulatory activities, and clinical trials. 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 its preclinical studies or other discovery and research activities.

Agreement and Plan of Merger with Peak Bio Inc.

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 "acquisition"), with Peak Bio surviving the Acquisition as a wholly-owned subsidiary of Akari.

On November 14, 2024, the Company completed the previously announced strategic business combination contemplated by the Merger Agreement ("Closing"), pursuant to which, Merger Sub merged with and into Peak Bio, with Peak Bio surviving the acquisition as a wholly owned subsidiary of Akari.

At the Closing, the Company issued a total of 12,613,942 Akari American Depositary Shares ("Akari ADSs" or "ADSs") which reflected the conversion of each issued and outstanding share of Peak Bio Common Stock into the right to receive Akari ADSs representing a number of Akari Ordinary Shares equal to 0.2935 (the "Exchange Ratio"). The Exchange Ratio was calculated in accordance with the terms of the Merger Agreement and is such that the total number of shares of Akari ADSs issued in connection with the acquisition is approximately 48.4% of the outstanding shares of Akari on a fully diluted basis.

At the Closing, each warrant to purchase capital stock of Peak Bio ("Peak Warrant") that was outstanding immediately prior to the Closing was converted into 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 conditions as were applicable to such Peak Warrant immediately prior to the Closing. The number of Akari Ordinary Shares (or the number of Akari Ordinary Shares underlying Akari ADSs, as applicable) subject to each Adjusted Warrant is equal to the number of shares of Peak Bio Common Stock issuable upon exercise of such Peak Warrant immediately prior to the Closing 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 equal to the exercise price of such Peak Warrant immediately prior to the Closing divided by the Exchange Ratio.

Further, at the Closing, each option to acquire shares of Peak Bio Common Stock ("Peak Option") that was outstanding and unexercised immediately prior to the Closing, whether or not vested, was 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 is equal to the product of (i) the total number of shares of Peak Common Stock subject to such Peak Option immediately prior to the Closing 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 equal to the exercise price of such Peak Option immediately prior to the Closing divided by the Exchange Ratio.

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 $247.3 million as of December 31, 2024. The Company's cash balance of $2.6 million as of December 31, 2024 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 research and 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 preclinical research outcomes, uncertainty of additional funding, and history of operating losses. Substantial additional financing will be needed by the Company to fund its operations. Management is currently evaluating different strategies to obtain the required funding for future operations. These strategies may include, but are not limited to: 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.

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 impacted 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, Akari Malta Limited, a private Maltese company, Peak Bio, Inc, a Delaware corporation, Peak Bio Co., Ltd, a private Republic of Korea corporation, and Peak Bio, Inc., a California corporation, 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), net.

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, the valuation of goodwill and indefinite-lived intangible assets, 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.

Segment information – The Company manages its operations as a single operating segment, or reporting unit, for the purposes of assessing performance, making operating decisions and allocating resources, resulting in a single reportable segment. The Company has determined that its Chief Operating Decision Maker ("CODM") is its Chief Executive Officer. The Company's CODM reviews the Company's financial information on a consolidated basis for purposes of allocating resources and assessing financial performance. All of the Company's tangible assets are held in the United States. See Note 12, Segment Information, for additional details.

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 4.

Business combinations – The Company includes the results of operations of the acquired business in the consolidated financial statements prospectively from the acquisition date. The Company allocates the purchase consideration to the assets acquired and liabilities assumed in the acquired entity based on their fair values at the acquisition date. The excess of the fair value of purchase consideration over the fair value of these assets acquired and liabilities assumed in the acquired entity is recorded as goodwill. Management's estimates of fair value are based upon assumptions believed to be reasonable, but which are inherently uncertain and unpredictable and, as a result, actual results may differ from estimates. During the measurement period, which is one year from the acquisition date, we may record adjustments to the assets acquired and liabilities assumed, with the corresponding offset to goodwill. Upon the conclusion of the measurement period, any subsequent adjustments are recorded to earnings.

Transaction expenses are recognized separately from the business combination and are expensed as incurred. These charges primarily include direct third-party professional fees for advisory and consulting services and other incremental costs related to the acquisition.

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, 2024 or 2023.

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, 2024 and 2023 were principally comprised of Value Added Tax ("VAT") receivables.

Restricted cash – Restricted cash of $60,000 and $0 as of December 31, 2024 and 2023, respectively, is a restricted bank account established to secure the Company's credit cards.

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, 2024 and 2023 was less than $0.1 million.

Goodwill and intangible assets – The Company recognized goodwill and other intangible assets comprised of in-process research and development ("IPR&D") during the year ended December 31, 2024, in connection with its acquisition of Peak Bio (Note 3), which closed on November 14, 2024.

The fair value of acquired IPR&D was capitalized and accounted for as an indefinite-lived intangible asset and is not subject to amortization. Subsequent to the acquisition, the Company will assess goodwill and the IPR&D assets (collectively, the "Intangible Assets") for impairment at least annually or whenever changes in circumstances indicate the carrying amount may not be recoverable. Acquired IPR&D is subject to impairment testing until completion or abandonment of the associated R&D efforts. If abandoned, the carrying value of the IPR&D asset is written off. Once the associated R&D efforts are completed, the carrying value of the acquired IPR&D is reclassified as a finite-lived asset and amortized over its useful life. Incremental R&D costs incurred subsequent to the acquisition are expensed as incurred.

For its Intangible Assets, the Company has the option to first assess qualitative factors to determine whether the fair value of its reporting unit is "more likely than not" less than its carrying value. For IPR&D, the qualitative assessment focuses on key inputs, assumptions and rationale utilized in the establishment of the carrying value. When performing a quantitative analysis, the Company uses its overall market capitalization as a basis to determine the fair value of its reporting unit. When the carrying value of its reporting unit exceeds its fair value, an impairment charge is recorded in current earnings for the difference up to the carrying value of the Intangible Assets recorded.

The Company manages its operations as a single operating segment for the purposes of assessing performance, making operating decisions and allocating resources, resulting in a single reportable segment, or reporting unit. Subsequent to the Company's acquisition of Peak Bio, the fair market value of the Company's ADSs experienced a significant decline. As a result, the Company performed a qualitative assessment as of December 31, 2024 to determine whether its Intangible Assets were impaired.

In its qualitative assessment, the Company considered relevant facts and circumstances for its reporting unit, including (i) overall financial performance, including recent fundraising activities and its strategic acquisition of Peak Bio (ii) industry and market conditions in which the Company operates, (iii) changes in the reporting unit carrying value since prior year, (iv) macroeconomic conditions, and (v) changes in the fair market value of the Company's ADSs.

Based on the results of its qualitative assessment, the Company concluded that it is not more likely than not that the fair value of its reporting unit is less than its carrying value.

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 5.

Convertible notes and notes payable – The Company accounts for convertible promissory notes in accordance with ASC Topic 470-20, *Debt with Conversion and Other Options* ("ASC 470-20") and has not elected the fair value option as provided for within ASC Topics 815 and 825. Accordingly, the Company evaluated the embedded conversion and other features within the May 2024 Notes (Note 9) to determine whether any of the embedded features should be bifurcated from the host instrument and accounted for as a derivative at fair value. Based on management's evaluation, the Company determined that the May 2024 Notes were not issued at a substantial premium and none of the embedded features were required to be bifurcated and accounted for separately. Accordingly, the May 2024 Notes are accounted for as a single liability measured at its amortized cost. Issuance costs incurred in connection with the issuance of the May 2024 Notes were immaterial. Interest expense incurred on the May 2024 Notes was less than $0.1 million for the year ended December 31, 2024. As of December 31, 2024, accrued interest of less than $0.1 million is included within "Accrued expenses" in the Company's consolidated balance sheets.

In November 2024, the Company assumed convertible promissory notes issued by Peak Bio in April 2023 in the principal amount of $0.7 million. The Company evaluated the embedded conversion and other features within the April 2023 Convertible Notes (Note 6) to determine whether any of the embedded features should be bifurcated from the host instrument and accounted for as a derivative at fair value. Based on management's evaluation, the Company determined that the April 2023 Convertible Notes were not issued at a substantial premium and none of the embedded features were required to be bifurcated and accounted for separately. The April 2023 Convertible Notes are in default and the Company concluded their fair value approximates their carrying value. Accordingly, the April 2023 Convertible Notes are accounted for at carrying value as of December 31, 2024. Subsequent to the acquisition date, through December 31, 2024, interest expense of less than $0.1 million was recognized. As of December 31, 2024, accrued interest of less than $0.1 million is included within "Accrued expenses" in the Company's consolidated balance sheet.

Warrant liabilities – 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 and 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 liabilities" 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' equity (deficit) at the time of issuance and are not subject to remeasurement.

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 a derivative liability in its consolidated balance sheets. In September 2024, all outstanding Series A Warrants expired unexercised.

In connection with the acquisition of Peak Bio, the Company assumed warrants issued to investors to purchase an aggregate of 1,577,566 ADSs at $39.18 per ADS ("November 2022 Peak Bio Warrants") and an aggregate of 1,187,013 ADSs at $2.04 per ADS ("April 2023 Peak Bio Warrants"). The Company determined that the November 2022 Peak Bio Investor Warrants and the April 2023 Peak Bio Investor 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 assumed warrants as derivative liabilities in its consolidated balance sheets.

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.

Merger-related expenses – Merger-related expenses include direct expenses incurred in connection with the acquisition of Peak Bio, as more fully described in Note 3, and are comprised primarily of legal and professional fees and other incremental costs directly associated to the acquisition.

Restructuring and other expenses – In May 2024, the Company implemented a reduction-in-force of approximately 67% of its total workforce as a result of the recently announced program prioritization under which the Company's nomacopan HSCT-TMA program was suspended. The reduction-in-force was part of an operational restructuring plan (the "May 2024 Plan") which included the elimination of certain senior management positions and was completed in the third quarter of 2024. The purpose of the restructuring plan, including the reduction-in-force, was to reduce HSCT-TMA related operating costs, while supporting the execution of the Company's long-term strategic plan. As of December 31, 2024, the Company does not expect to incur additional restructuring-related expenses related to the May 2024 Plan.

The following table presents the restructuring reserve and accrual activity for the year ended December 31, 2024:

(In thousands)	Severance and Employee Benefit Costs	Other Restructuring Charges	Total
Balance at December 31, 2023	$ —	$ —	$ —
Restructuring charges	1,645	78	1,723
Cash payments	(910)	(78)	(988)
Non-cash stock-based compensation	(285)	—	(285)
Balance at December 31, 2024	$ 450	$ —	$ 450

No restructuring activities existed for the year ended December 31, 2023.

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 8). The Company estimates its expected stock price volatility based on the historical volatility of its ADSs, considering the expected term of the

options. 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, 2024 and 2023, 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, 2024 or 2023.

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. A valuation allowance against deferred tax assets is recorded if, based on the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

The Company follows the provisions of ASC 740 "*Accounting for Uncertainty in Income Taxes*" ("ASC 740"), 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, 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, 2024 and 2023, 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, 2024 and 2023.

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:

	As of December 31,	
	2024	**2023**
Stock options	3,963,964,688	651,237,400
Restricted stock units	—	385,954,925
Warrants	20,518,595,300	4,240,447,500
Convertible notes	406,236,000	—
Total	24,888,795,988	5,277,639,825

Loss contingencies, legal matters – Akari is involved from time to time in various claims, proceedings, and litigation, including those described in Note 10. The Company establishes reserves for specific legal proceedings when we determine that the likelihood of an unfavorable outcome is probable and the amount of loss can be reasonably estimated.

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 Standards

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*. The objective of ASU 2023-09 is to enhance disclosures related to income taxes, including specific thresholds for inclusion within the tabular disclosure of income tax rate reconciliation and specified information about income taxes paid. ASU 2023-09 is effective for public companies starting in annual periods beginning after December 15, 2024. The amendments should be applied on a prospective basis, with retrospective application permitted. The Company is currently assessing the impact of ASU 2023-09 on its consolidated financial statements and related disclosures.

In February 2024, the FASB issued ASU 2024-03, *Income Statement Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40)*. The objective of ASU 2024-03 is to require entities to provide enhanced disclosures of income statement expenses through disaggregation of specific expense captions. ASU 2024-03 is effective for public companies starting in annual periods beginning after December 15, 2026 and in interim periods beginning after December 15, 2027. The Company is currently evaluating ASU 2024-03 and the impact of the disclosures to its consolidated financial statements.

Recently Adopted Provisions of U.S. GAAP

On January 1, 2024, the Company adopted ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*. The objective of ASU 2023-07 is to require entities to provide enhanced disclosures on significant segment expenses. ASU 2023-07 is effective for public companies in annual periods beginning after December 15, 2023, and interim periods beginning after December 15, 2024. Refer to Note 12, Segment Information, for additional details.

Note 3. Agreement and Plan of Merger

On November 14, 2024, the Company completed its previously announced strategic combination contemplated by the Merger Agreement (the "Closing"), pursuant to which, Merger Sub merged with and into Peak Bio, Inc. with Peak Bio surviving the acquisition as a wholly owned subsidiary of Akari. Peak Bio, organized under the laws of Delaware, is a biotechnology company with a portfolio of potential therapies focused on cancer and immunological diseases. The Company acquired all outstanding equity interests in Peak Bio, Inc., which includes Peak Bio's therapeutic pipeline consisting of one clinical stage and one pre-clinical stage asset supported by an intellectual property portfolio consisting of various granted and pending patents in various jurisdictions worldwide.

Peak Bio's pipeline includes an ADC Platform for oncology and PHP-303 program for genetic disease, liver disease and inflammation, specifically for Alpha-1 antitrypsin deficiency (AATD).

Per the terms of the Merger Agreement, at the Closing, the Company issued a total of 12,613,942 Akari ADSs which reflected the conversion of each issued and outstanding share of Peak Bio Common Stock into the right to receive Akari ADSs representing a number of Akari Ordinary Shares equal to 0.2935 (the "Exchange Ratio"). The Exchange Ratio was calculated in accordance with the terms of the Merger Agreement and is such that the total number of shares of Akari ADSs issued in connection with the acquisition is approximately 48.4% of the outstanding shares of Akari on a fully diluted basis.

At the Closing, each Peak Warrant and Peak Option was converted into an Adjusted Warrant and Adjusted Option to purchase a number of Akari ordinary shares or Akari ADSs, based on the Exchange Ratio. The Adjusted Warrants and the Adjusted Options have substantially similar terms and conditions as were applicable to such Peak Warrants and Peak Options immediately prior to the Closing.

Consideration Paid

The following table summarizes the total consideration paid pursuant to the Merger Agreement, which was based on the closing market price of Akari's ADS as of the November 14, 2024 acquisition date:

($ in thousands)	Number of ADSs issued and issuable on exercise	Consideration
Company ADSs issued to Peak Bio Inc. shareholders	12,613,942	$ 28,129
Company ADSs issuable on exercise of November 2022 Peak Investor Warrants and April 2023 Peak Investor Warrants	2,764,569	1,844
Company ADSs issuable on exercise of Peak Bio Adjusted Options	1,618,081	—
Total consideration	16,996,592	$ 29,973

The fair value of the 12,613,942 ADS issued in connection with the acquisition is based on the closing price of the Company's ADSs on the Closing Date multiplied by the number of ADSs issued.

In connection with the acquisition of Peak Bio, the Company assumed (i) warrants issued to investors ("November 2022 Peak Warrants") to purchase an aggregate of 1,577,556 ADSs at $39.18 per ADS, and (ii) warrants issued to investors ("April 2023 Peak Warrants") to purchase an aggregate of 1,187,013 ADSs at $2.04 per ADS. The assumed Peak Bio warrants are fully vested, and thus are included in the consideration transferred.

The Company determined that the November 2022 Peak Warrants and the April 2023 Peak Warrants are not indexed to the Company's own stock in the manner contemplated by the relevant accounting standard (Note 2). Accordingly, on the Closing of the acquisition, the Company classified these warrants as derivative liabilities in its consolidated balance sheets.

The estimated fair value of the Adjusted Warrants of $1.8 million at the acquisition closing date was calculated using the Black Scholes Option Pricing Model. The following assumptions were used to determine the fair value of the assumed warrants as of November 14, 2024:

	Peak Bio Assumed Warrants	
	November 2022	April 2023
Stock (ADS) price	$ 2.23	$ 2.23
Exercise price	$ 39.18	$ 2.04
Expected term (in years)	3.0	3.5
Expected volatility	86.4%	84.1%
Risk-free interest rate	4.3%	4.3%
Expected dividend yield	—	—

The Company assumed Peak Bio's outstanding stock option awards and granted options to purchase 1,618,081 ADSs as replacement awards for the Peak Bio Adjusted Options. The Company determined the Peak Bio Adjusted Options were not probable of vesting prior to the consummation of the Merger Agreement. For this reason, the fair value of the replacement awards was not included as consideration transferred in the business combination. Instead, the entire fair value of the adjusted options will be recognized as compensation cost in the post-combination period. The estimated fair value of the Adjusted Options of $1.8 million at the acquisition closing date was calculated using the Black Scholes Option Pricing Model. The valuation assumptions used in the Black Scholes Option Pricing Model include the Company's stock price on the date of closing of $2.23, volatility ranging from 84.1% to 86.4%, an expected dividend yield of 0.0%, an expected term ranging from 0.20 years to 5.32 years, and a risk-free interest rate ranging from 4.3% to 4.6%.

Total Assets Acquired and Liabilities Assumed

The acquisition of Peak Bio has been accounted for as a business combination using the acquisition method of accounting. The fair value of the purchase price was allocated to the assets acquired and liabilities assumed at their respective fair values. Management estimated the fair value of the IPR&D intangible assets using a multi-period excess earnings method. The significant assumptions used in the valuation are the probability of clinical trial success and obtaining regulatory approval, forecasted gross sales from up-front and milestone payments, royalties and product sales, and the discount rate reflecting the Company's weighted average cost of capital. This acquisition method requires, among other things, that assets acquired, and liabilities assumed in a business combination be recognized at their fair values as of the acquisition date.

The following table summarizes the final fair values of assets acquired and liabilities assumed as of the acquisition date (in thousands):

Assets acquired		
Cash and restricted cash	$	382
Prepaid expenses and other current assets		10
Acquired in-process research and development		39,180
Total assets acquired		39,572
Liabilities assumed		
Accounts payable and accrued expenses		6,979
Convertible notes		700
Notes payable		659
Notes payable, related party		1,651
Deferred tax liability		8,040
Total liabilities assumed		18,029
Total assets acquired and liabilities assumed		21,543
Goodwill		8,430
Net assets acquired	**$**	**29,973**

Intangible assets of approximately $38.1 million and $9.5 million were recorded related to the value of IPR&D from Peak Bio's therapeutic pipeline, consisting of two separate pipelines supported by intellectual property, and goodwill, respectively. The recognized goodwill is attributable primarily to the expected synergies and other benefits from the merger and the deferred tax liability associated with the Company's acquired IPR&D, which is not deductible for income tax purposes.

The fair value of IPR&D intangible assets were as follows (in thousands):

In-Process Research and Development		
AKTX 101	$	34,000
PHP 303		5,180
Acquired intangible assets	**$**	**39,180**

The Company assumed convertible notes and notes payable with third parties, and notes payable with a related party, which are described in Note 6 and Note 9, respectively.

Merger-related expenses, which were comprised primarily of regulatory, financial advisory and legal fees, totaled $3.3 million for the year ended December 31, 2024 and were included in the consolidated statements of operations and comprehensive loss. The Company issued Paulson Investment Company LLC (“Paulson”) an advisory fee in connection with the acquisition equal to 243,000,000 ordinary shares or 121,500 ADS equivalents for a value of $270,945, based on the closing price of the Company's ADS on the Closing Date multiplied by the number of ADS issued.

Peak Bio’s operating results were consolidated with the Company's beginning on November 14, 2024. Therefore, the consolidated results of operations for the year ended December 31, 2024 may not be comparable to the same period in 2023. Peak Bio’s results of operations included in the Company's consolidated results of operations from the acquisition date to December 31, 2024 are presented in the table below (in thousands):

Operating expenses:		
Research and development	$	7,230
General and administrative		104,756
Merger-related expenses		—
Restructuring and other expenses		—
Total operating expenses		111,986
Loss from operations		(111,986)
Other expense, net		(28,007)
Net loss	$	(139,993)

Pro Forma Financial Information (Unaudited)

The following table summarizes certain of the Company's supplemental pro forma financial information for the years ended December 31, 2024 and 2023, as if the acquisition of Peak Bio had occurred as of January 1, 2023. The unaudited pro forma financial information for the years ended December 31, 2024 and 2023 reflect (i) the reversal of a gain recognized on Peak Bio's office lease termination and corresponding impairment of its right to use asset, (ii) the reversal of fair value adjustments recognized on Peak Bio's warrant liabilities and derivative liability, and (iii) the reversal of interest and accretion expense on Peak Bio's debt that was settled on the acquisition date. For the year ended December 31, 2024, transaction costs incurred by the Company and Peak Bio were $3.2 million and $1.5 million, respectively. The unaudited pro forma financial information is for comparative purposes only and is not necessarily indicative of what would have occurred had the acquisition been made at that date or of results which may occur in the future (in thousands).

	Year Ended December 31,			
	2024		2023	
	As Reported	Pro Forma	As Reported	Pro Forma
Net loss.....	$ (19,791)	$ (23,791)	$ (10,008)	$ (19,851)

Note 4. 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, 2024			
(In thousands)	Total	Level 1	Level 2	Level 3
Liabilities				
Warrant liability - November 2022 Peak Warrants.....	$ 95	$ —	$ —	$ 95
Warrant liability - April 2023 Peak Warrants	736	—	—	736
Warrant liability - Series B	181	—	—	181
Total warrant liabilities.....	$ 1,012	$ —	$ —	$ 1,012

	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 warrant liabilities.....	$ 1,253	$ —	$ —	$ 1,253

The Company’s Level 3 liabilities consist of the September 2022 Warrants, the November 2022 Peak Warrants and the April 2023 Peak Warrants, 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, 2024 and 2023.

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

The following table summarizes the activity in the warrant liabilities measured at fair value on a recurring basis using unobservable inputs (Level 3) during the years ended December 31, 2024 and 2023:

	Warrant Liabilities				
(In thousands)	Series A	Series B	November 2022 Warrants	April 2023 Warrants	Total
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
Assumption of Peak Bio warrants	—	—	213	1,631	1,844
Change in the fair value of liability.....	(15)	(1,056)	(119)	(895)	(2,085)
Balance, December 31, 2024.....	$ —	$ 182	$ 94	$ 736	$ 1,012

Assumptions Used in Determining Fair Value of Liability-Classified Warrants

The fair value of the warrant liabilities 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 the Series A Warrants, the Series B Warrants, the November 2022 Peak Warrants and the April 2023 Peak Warrants 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, Series B Warrants, November 2022 Peak Warrants and April 2023 Peak Warrants, as of December 31, 2024 and 2023:

	December 31, 2024			December 31, 2023	
	Series B	November 2022 Warrants	April 2023 Warrants	Series A	Series B
Stock (ADS) price	$ 1.22	$ 1.22	$ 1.22	$ 3.12	$ 3.12
Exercise price	$ 17.00	$ 39.18	$ 2.04	$ 17.00	$ 17.00
Expected term (in years)	4.7	2.8	3.3	0.7	5.7
Expected volatility	85.0%	95.0%	90.0%	85.0%	95.0%
Risk-free interest rate	4.4%	4.3%	4.3%	5.1%	3.9%
Expected dividend yield	—	—	—	—	—

Note 5. Accrued Expenses

Accrued expenses consisted of the following:

(In thousands)	December 31, 2024	December 31, 2023
Employee compensation and benefits	$ 473	$ 187
External research and development expenses	178	635
Professional and consulting fees	1,305	669
Restructuring	450	—
Other	731	75
Total accrued expenses	$ 3,137	$ 1,566

Note 6. Convertible Notes and Notes Payable

September 2024 Note Payable

In November 2024, the Company assumed a promissory note issued by Peak Bio in September 2024 in the amount of $0.3 million (the "September 2024 Note") to its former California landlord. Due to the short-term nature of the September 2024 Note, the Company concluded that its carrying value approximated its fair value as of November 14, 2024. The note bears no interest and is payable over twenty equal monthly installments beginning on November 1, 2024 and expiring on June 1, 2026.

The Company began making payments subsequent to the acquisition of Peak Bio. As of December 31, 2024, the outstanding balance on the September 2024 Note was $0.3 million. The installment due on December 1, 2024 was made in February 2025.

November 2023 Note Payable

In November 2024, the Company assumed a promissory note issued by Peak Bio in November 2023 in the amount of $0.4 million (the "November 2023 Note") bearing interest at 6% per annum with a maturity date of December 31, 2024. Due to the short-term nature of the November 2023 Note, the Company concluded that its carrying value approximated its fair value as of November 14, 2024. The Company recognized interest expense of less than $0.1 million subsequent to the acquisition date, through December 31, 2024. As of December 31, 2024, accrued interest on the November 2023 Note of less than $0.1 million is presented within "Accrued expenses" in the Company's consolidated balance sheets.

As of December 31, 2024, the principal balance of $0.4 million plus accrued interest of less than $0.1 million was due for payment in order to settle the November 2023 Note obligation. On February 28, 2025 (Note 13), the Company signed a Settlement Agreement and Release for full satisfaction of the outstanding principal and accrued interest owed on the November 2023 Notes in the amount of $325,000.

April 2023 Convertible Notes

In November 2024, the Company assumed convertible promissory notes issued by Peak Bio in April 2023 in the principal amount of $0.7 million (the "April 2023 Convertible Notes"). Due to the short-term nature of the April 2023 Convertible Notes, the Company concluded that its carrying value approximated its fair value as of November 14, 2024. The April 2023 Convertible Notes bear interest at a default rate of 10% per annum and were originally due in October 2023. The April 2023 Convertible Notes permitted the holder to convert the outstanding principal and accrued interest at any time at a price of $0.001 per ordinary share of the Company, after giving effect to the Exchange Ratio. As of December 31, 2024, the outstanding balance of $0.7 million was in default.

The Company evaluated the embedded conversion and other features within the April 2023 Convertible Notes to determine whether any of the embedded features should be bifurcated from the host instrument and accounted for as a derivative at fair value. Based on management's evaluation, the Company determined that the April 2023 Convertible Notes were not issued at a substantial premium and none of the embedded features were required to be bifurcated and accounted for separately. The April 2023 Convertible Notes are in default and the Company concluded their fair value approximates their carrying value. Accordingly, the April 2023 Convertible Notes are accounted for at carrying value as of December 31, 2024.

The Company recognized interest expense of less than $0.1 million subsequent to the acquisition date, through December 31, 2024. As of December 31, 2024, accrued interest on the April 2023 Notes of less than $0.1 million is presented within "Accrued expenses" in the Company's consolidated balance sheets.

Refer to Note 9 for notes payable, related party and convertible notes, related party.

Note 7. Shareholders' Equity (Deficit)

Ordinary Shares

On November 7, 2024, the Company's shareholders approved an increase to the number of authorized ordinary shares the Company can issue by 199,913,470,000 ordinary shares in addition to the number of shares outstanding on December 31, 2023. Accordingly, following November 7, 2024 and as of December 31, 2024, the Company was authorized to issue up to 245,035,791,523 ordinary shares. As of December 31, 2023, the Company was authorized to issue up to 45,122,321,523 ordinary shares.

Currently, each ADS represents 2,000 ordinary shares (the "ADS Ratio"). All ADS and per ADS amounts in the accompanying consolidated financial statements reflect the ADS Ratio.

Merger with Peak Bio, Inc.

On November 14, 2024, the Company completed its previously announced strategic combination with Peak Bio (Note 3). In connection with the acquisition, the Company issued 25,227,884,000 ordinary shares and assumed (i) November 2022 Peak Warrants to purchase an aggregate of 1,577,566 ADSs at $39.18 per ADS, and (ii) April 2023 Peak Warrants to purchase an aggregate of 1,187,013 ADSs at $2.04 per ADS.

The Company determined that the November 2022 Peak Warrants and the April 2023 Peak Warrants are not indexed to the Company's own stock in the manner contemplated by the relevant accounting standard (Note 2). Accordingly, on the Closing of the acquisition, the Company classified these warrants as derivative liabilities in its consolidated balance sheets.

November 2024 Private Placement

In November 2024, the Company entered into a definitive purchase agreement with certain investors, Dr. Prudo and Dr. Patel, pursuant to which the Company sold and issued in a private placement an aggregate of 3,426,804,000 ordinary shares (1,713,402 ADSs), and Series D Warrants (the "Series D Warrants") to purchase up to 1,713,402 ADSs, at a per unit price of $2.26 for aggregate gross proceeds of $3.2 million (the "November 2024 Private Placement"). The Series D Warrants have 3-year terms ranging from December 2, 2027 to June 2, 2028 and have cashless exercise provisions in limited circumstances.

At close of the November 2024 Private Placement, the Company incurred $204,000 in placement agent fees with Paulson Investment Company, LLC ("Paulson"). Net proceeds from the November 2024 Private Placement were approximately $2.8 million after deducting placement agent fees and other expenses. In April 2025, the Company issued 408,000,000 ordinary shares (204,000 ADSs) to Paulson in lieu of $204,000 in cash payment.

The Company determined that the Series D Warrants met all of the criteria for equity classification. Accordingly, upon closing of the November 2024 Private Placement, each of the Series D Warrants was recorded as a component of additional paid-in capital.

May 2024 Private Placement

In May 2024, the Company entered into a definitive purchase agreement with certain investors, Dr. Prudo and Dr. Patel, pursuant to which the Company sold and issued in a private placement an aggregate of 8,059,508,000 ordinary shares (4,029,754 ADSs), and Series C Warrants (the "Series C Warrants") to purchase up to 4,029,754 ADS, at a per unit price of $1.885 per ADS and Series C Warrant for aggregate gross proceeds of approximately $7.6 million (the "May 2024 Private Placement"). The Series C Warrants have 3-year terms ranging from May 31, 2027 to June 21, 2027 and have cashless exercise provisions in limited circumstances. The Series C Warrants (other than those issued to Dr. Prudo and Dr. Patel) have an exercise price of $1.76 per ADS. The Series C Warrants issued to Dr. Prudo and Dr. Patel have an exercise price of $1.79 per ADS. Net proceeds from the May 2024 Private Placement were approximately $7.0 million after deducting placement agent fees and other expenses.

At close of the May 2024 Private Placement, the Company issued to Paulson, as placement agent for the May 2024 Private Placement, warrants to purchase 332,380 ADSs at an exercise price of $1.885 per ADS and a term expiring on May 31, 2029 (the "May 2024 Placement Agent Warrants"). The estimated fair value of the May 2024 Placement Agent Warrants on the issuance date was approximately $0.4 million.

The Company determined that the Series C Warrants and May 2024 Placement Agent Warrants met all of the criteria for equity classification. Accordingly, upon closing of the May 2024 Private Placement, each of the Series C Warrants and May 2024 Placement Agent Warrants was recorded as a component of additional paid-in capital.

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 2,641,228,000 ordinary shares (1,320,614 ADSs) at $1.48 per ADS, for aggregate gross proceeds of approximately $2.0 million (the "March 2024 Private Placement"). Net proceeds from the March 2024 Private Placement were approximately $1.7 million after deducting placement agent fees and other expenses.

At close of the March 2024 Private Placement, the Company issued to Paulson, as placement agent for the March 2024 Private Placement, warrants to purchase 132,061 ADSs at an exercise price of $1.85 per ADS (representing 125% of the purchase price per ADS sold in the March 2024 Private Placement) and a term expiring on March 27, 2029 (the "March 2024 Placement Agent Warrants"). The estimated fair value of the March 2024 Placement Agent Warrants on the issuance date was approximately $0.2 million.

The Company determined that the March 2024 Placement Agent Warrants met all of the criteria for equity classification. Accordingly, upon closing of the March 2024 Private Placement, each of the March 2024 Placement Agent Warrants was recorded as a component of additional paid-in capital.

December 2023 Private Placement

In December 2023, the Company entered into purchase agreements to sell, in a private placement, to existing investors, Dr. Ray Prudo and Dr. Patel, (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 were 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 and directors, including Dr. Prudo and Ms. Rachelle Jacques, the Company's then President and Chief Executive Officer (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, 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 purchase price per ADS sold 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. Prudo (the "March 2023 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 2023 Registered Direct Offering were approximately $3.5 million after deducting placement agent fees and expenses.

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 the accounting policy related to the Company's warrants.

The following table summarizes the Company's outstanding warrants as of December 31, 2024 and 2023:

	Number of Warrant ADSs			
	December 31, 2024	December 31, 2023	Weighted-Average Exercise Price	Expiration Date
Equity-classified Warrants				
2019 Investor Warrants	—	59,211	$ 60.00	7/1/2024
2019 Placement Warrants	—	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	48,387	$ 0.20	None
October 2023 Placement Agent Warrants	42,550	42,550	$ 4.13	10/6/2028
March 2024 Placement Agent Warrants	132,061	—	$ 1.85	3/27/2029
May 2024 Investor Warrants	4,029,754	—	$ 1.77	May-Jun 2027
May 2024 Placement Agent Warrants	322,380	—	$ 1.89	5/31/2029
November 2024 Investor Warrants	1,713,402	—	$ 2.26	Dec 2027-Jun 2028
	6,788,115	658,610		
Liability-classified Warrants				
September 2022 Series A Investor Warrants	—	755,000	$ 17.00	9/14/2024
September 2022 Series B Investor Warrants	755,000	755,000	$ 17.00	9/14/2029
November 2022 Peak Bio Warrants	1,577,556	—	$ 39.18	11/1/2027
April 2023 Peak Bio Warrants	1,187,013	—	$ 2.04	4/28/2028
	3,519,569	1,510,000		
Total outstanding	10,307,684	2,168,610		

The following table summarizes the Company's warrants activity for the year ended December 31, 2024:

	Number of Warrant ADSs	Weighted-Average Exercise Price
Outstanding at December 31, 2023	2,168,610	$ 21.97
Issued	6,197,597	1.91
Assumed	2,764,569	23.23
Expired	(823,092)	20.52
Outstanding at December 31, 2024	10,307,684	$ 4.37

Note 8. Stock-Based Compensation

2023 Equity Incentive Plan

On November 7, 2024, the Company's shareholders approved an increase in the number of shares available for the grant of awards under the 2023 Plan by 7,800,000,000 Ordinary Shares to an aggregate of 8,780,000,000 Ordinary Shares, plus such additional number of ordinary shares subject to awards granted under the 2014 Plan, to the extent such awards are forfeited, cancelled, or expire unexercised. 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 9,635,637,300 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.

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 ("RSUs") and stock appreciation rights, to be granted to employees, directors and consultants. The Company is permitted to issue up to 980,000,000 ordinary shares under the 2023 Plan, plus such additional number of ordinary shares (up to 855,637,300 ordinary shares) subject to awards granted under the 2014 Equity Incentive Plan (the "2014 Plan"), to the extent such awards are forfeited, cancelled, or expire unexercised.

As of December 31, 2024, the Company had 474,368,000 ordinary shares underlying outstanding equity awards under the 2023 Plan and 8,148,713,522 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 are available to be issued under the 2014 Plan. As of December 31, 2023, the Company had 253,434,688 ordinary shares underlying outstanding equity awards under the 2014 Plan, consisting of stock option awards.

Stock Options

The following is a summary of the Company's stock option activity under the 2023 Plan and the 2014 Plan for the year ended December 31, 2024:

	Stock Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2023	651,237,400	$ 0.01	8.5	$ —
Granted	447,368,000	0.00		
Assumed	3,236,162,000	0.00		
Exercised	—	—		
Forfeited	(319,302,712)	0.01		
Expired	(51,500,000)	0.01		
Outstanding at December 31, 2024 (1)	3,963,964,688	$ 0.01	7.5	$ —
Exercisable at December 31, 2024	1,473,081,355	$ 0.01	3.9	$ —

(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.

Pursuant to the Merger Agreement with Peak Bio, the Company assumed the outstanding options of Peak Bio. Based on the Exchange Ratio, the Company assumed options to purchase 1,618,081 ADSs or 3,236,162,000 ordinary shares of the Company. The exercise price ranges from $27.43 per ADS to $2.73 per ADS. The assumed options, vested and unvested, will continue to be governed by the terms of the Peak Bio 2022 Long Term Incentive Plan, which was assumed by the Company in connection with the closing of the acquisition.

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 ADSs for those options that had exercise prices lower than the fair value of the Company's ordinary shares.

The weighted-average grant-date fair value per share of options granted during each of the years ended December 31, 2024 and 2023 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:

	2024	2023
Expected volatility	83.0%	99.2%
Risk-free interest rate	3.9%	3.8%
Expected dividend yield	—	—
Expected term (in years)	5.0	6.0

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, 2024:

	Time-based Awards	
($ in thousands, except per share data)	**Number of Shares**	**Weighted-Average Grant Date Fair Value**
Nonvested shares at December 31, 2023	385,954,925	$ 0.00
Granted	731,393,807	0.00
Forfeited	(482,249,417)	0.00
Vested	(635,099,315)	0.00
Nonvested shares at December 31, 2024	—	$ —

The fair value of time-based RSUs that vested during the years ended December 31, 2024 and 2023 was approximately $0.5 million and $0.2 million, respectively.

During the year ended December 31, 2024, 276,000,000 ordinary shares underlying unvested time-based RSUs held by a former executive upon termination of employment were accelerated, resulting in additional stock-based compensation expense of $0.3 million.

As of December 31, 2024, there were no ordinary shares underlying vested time-based RSUs. 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 (deficit), 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, 2024 and 2023, was as follows:

	Year Ended December 31,	
($ in thousands)	**2024**	**2023**
Research and development	$ 577	$ 153
General and administrative	1,383	997
Restructuring and other costs	285	—
Total stock-based compensation expense	$ 2,245	$ 1,150

As of December 31, 2024, total unrecognized compensation cost related to unvested stock options and time-based RSUs was $1.1 million, which is expected to be recognized over a weighted average period of 1.1 years.

Note 9. Related Party Transactions

Interim CEO Agreement

On December 12, 2024, the Company's board of directors approved the appointment of Dr. Patel to Chief Executive Officer and principal executive officer, effective December 16, 2024. There were no changes to Dr. Patel's revised compensation as provided for under the September 16, 2024 Interim CEO Amendment Agreement, described below, following Dr. Patel's appointment as President and Chief Executive Officer on December 16, 2024.

On May 31, 2024, the Company and Dr. Patel entered into an Interim Chief Executive Officer Agreement, effective as of May 1, 2024 (the "Interim CEO Agreement"). Pursuant to the Interim CEO Agreement, Dr. Patel served as the Company's Interim President and Chief Executive Officer as an independent contractor on an at-will basis. The Interim CEO Agreement could be terminated by the Company immediately for any reason. As the sole compensation for services provided under the Interim CEO Agreement, Dr. Patel was paid $50,000 per month in the form of fully vested ordinary shares. On September 16, 2024, the Company entered into an amendment to the Interim CEO Agreement (the "Amendment"), effective July 1, 2024, to revise Dr. Patel's compensation in connection with the services as Interim President and Chief Executive Officer. Pursuant to the Amendment, in lieu of receiving the stated monthly compensation of $50,000 in the form of fully vested ordinary shares, Dr. Patel is paid in the form of fully vested non-qualified stock options to purchase ordinary shares ("NQSO"), with the number of ADSs underlying each such monthly NQSOs grant to be equal to two times the number determined by dividing (i) $50,000 by (ii) the closing price of the Company's ADSs on the Nasdaq Capital Market on the last day of each month (or partial month) Dr. Patel serves as the Company's Interim President and Chief Executive Officer.

During the year ended December 31, 2024, the Company recognized approximately $0.3 million in non-cash stock-based compensation costs pursuant to the Interim CEO Agreement, as amended, pertaining to (i) NQSOs granted to Dr. Patel to purchase 422,368,000 ordinary shares at an exercise price of less than $0.01 per ordinary share with a grant date fair value of approximately $0.3 million, and (ii) 91,396,000 fully vested ordinary shares granted to Dr. Patel.

Notes Payable, Related Party

Pursuant to the acquisition of Peak Bio (Note 3), which closed on November 14, 2024, the Company assumed three notes payable due to Dr. Huh, the Company's Chairman of the Board.

January 2024 Note

As a result of the business combination, the Company assumed a note in the amount of $0.75 million owed to Dr. Huh, which was entered into in January 2024 (the "January 2024 Note"). Prior to the March 2025 Private Placement, the January 2024 Note had a maturity date of January 23, 2025, and carries an interest rate of 15% per annum. In connection with the closing of the acquisition, Dr. Huh released Peak Bio of its rights to any security interest in all of the assets of Peak Bio and its subsidiaries.

As of the closing date, and as of December 31, 2024, the outstanding balance of the January 2024 Note was $0.75 million. The Company recognized interest expense of less than $0.1 million subsequent to the acquisition date, through December 31, 2024. As of December 31, 2024, accrued interest of $0.1 million is presented within accrued expenses in the consolidated balance sheets.

2021 Notes

As a result of the business combination, the Company assumed a note in the amount of $0.9 million owed to Dr. Huh, which was entered into at various dates in 2021 (the "2021 Notes"). The 2021 Notes, which matured at various dates in 2022, carried an interest rate of 1.0% per annum.

As of the closing date, and as of December 31, 2024, the outstanding balance of the 2021 Notes was $0.9 million. The Company recognized interest expense of less than $0.1 million subsequent to the acquisition date, through December 31, 2024. As of December 31, 2024, accrued interest of $0.1 million is presented within accrued expenses in the consolidated balance sheets.

In connection with the March 2025 Private Placement (Note 13), Dr. Huh's 2021 Notes and a portion of his January 2024 Note aggregating to $1.0 million were cancelled, extinguished and paid in full for an equal amount of ordinary shares and warrants. On March 17, 2025, Dr. Huh's January 2024 Note was amended to extend the maturity date to December 31, 2025 (Note 13).

Convertible Notes, Related Party

On May 10, 2024, the Company entered into unsecured convertible promissory notes (the "May 2024 Notes") with Dr. Ray Prudo, the Company's Chairman at the time, and its then Interim President and Chief Executive Officer and director, Dr. Samir Patel, for an aggregate of $1.0 million in gross proceeds. The May 2024 Notes bear interest at 15% per annum, which may be increased to 17% upon the occurrence of certain events of default as described therein, and the principal and all accrued but unpaid interest is due on the date that is the earlier of (a) ten (10) business days following the Company's receipt of a U.K. research and development tax credit from HM Revenue and Customs, and (b) November 10, 2024. Provided, however, at any time or times from the date of the note and until the tenth business day prior to closing of the acquisition, the note holders are entitled to convert any portion of the outstanding and unpaid amount, including principal and accrued interest, into Company ADSs at a fixed conversion price equal to $1.59, representing the Nasdaq official closing price of the Company's ADSs on the issuance date, subject to certain restrictions. In October 2024, Drs. Prudo and Patel each elected to convert $125,000 of principal and accrued interest into the Company's ADSs at a conversion price of $1.59 per ADS. These ordinary shares remain unissued as of December 31, 2024 and are expected to be issued during the second quarter of 2025. The remaining unconverted aggregate principal balance of the May 2024 Notes, or $750,000, was repaid in cash with proceeds from the Company's U.K. research and development tax credit from HM Revenue and Customs.

The Company recognized interest expense of less than $0.1 million during the year ended December 31, 2024. As of December 31, 2024, accrued interest on the May 2024 Notes of less than $0.1 million is presented within "Accrued expenses" in the Company's consolidated balance sheets.

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, 2024 and 2023, respectively. Dr. Ray Prudo, the Company's Director, 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, 2024 and 2023.

The Company recorded payable balances owed to TDL of less than $0.1 million as of December 31, 2024 and 2023.

Other

In November 2024, the Company assumed an amount due to an entity in which the Company's Chairman, Dr. Hoyoung Huh, is a director. As of December 31, 2024, the amounts due totaled less than $0.1 million and are included in accounts payable in the consolidated balance sheets.

Note 10. Commitments and Contingencies

Leases

The Company currently leases 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 July 2025, unless terminated earlier with not less than three months notice. We lease our U.S. headquarters virtual office, located in Boston, Massachusetts, on a month-to-month basis. The Company also leases laboratory space, located in San Francisco, California, which expires in September 2025 and is cancellable anytime with 60 days notice. We are not party to any material lease agreements.

For each of the years ended December 31, 2024 and 2023, 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 the years ended December 31, 2024 and 2023, the Company charged less than $0.1 million and approximately $0.2 million to operating expenses, respectively, which related to the Company's contributions to employee benefit plans.

Bayer Acquisition Agreement

In November 2024, the Company assumed an assignment, license, development and commercialization agreement dated March 17, 2017 with Bayer (the "Bayer Acquisition Agreement"), to acquire from Bayer all right, title and interest in and to PHP-303, including each and every invention and any priority rights relating to its patents.

Under the Bayer Acquisition Agreement, the Company is committed to pay certain development and regulatory milestones up to an aggregate amount of $23,500,000 and high single digit royalties based on the sale of products developed based on the licensed compound. Royalties will be payable on a licensed product-by-licensed product and country-by-country basis until the later of ten years after the first commercial sale of such licensed product in such country and expiration of the last patent covering such licensed product in such country that would be sufficient to prevent generic entry.

Either party may terminate the Bayer Acquisition Agreement upon prior written notice for the other party's material breach that remains uncured for a specified period of time or insolvency. Bayer agreed not to assert any Bayer intellectual property rights that were included in the scope of the Bayer Acquisition Agreement against the Company.

The Company incurred zero expenses under this agreement as no milestones have been achieved since inception, and no products were sold from inception through December 31, 2024.

Legal Proceedings

In December 2024, the Company received demand letters from two individuals formerly serving the Company as consultants outlining claims relating to wrongful termination. The wrongful termination claims included claims for unpaid wages, wages owed due to improper termination notice, unpaid bonuses, severance, and the accelerated vesting of outstanding restricted stock unit awards as of the termination date. In March 2025, the Company entered into a settlement agreement with one of the former consultants (Note 13). The events took place prior to December 31, 2024, and for this reason the Company treated the March 2025 litigation settlement as a recognized subsequent event. As of December 31, 2024, the Company accrued $0.5 million in aggregate representing the settlement amount and an estimate for the second individual's claims. In addition, the Company recognized stock-based compensation expense of $0.2 million related to the continued vesting of restricted stock units as allowed under the settlement agreement.

On November 21, 2024, "Sabby" Volatility Warrant Master Fund Ltd. ("Sabby") filed a lawsuit against the Company in New York state court for alleged breach of contract. Sabby alleges that it validly exercised a warrant issued to Sabby in September 2022 and alleges that the Company breached the warrant by not honoring Sabby's exercise request. The Company filed a motion to dismiss on February 3, 2025, which the court denied on March 25, 2025. The case is currently in discovery. The Company denies Sabby's claim and intends to vigorously defend itself against the lawsuit. As of December 31, 2024, the Company accrued its best estimate of potential losses relating to Sabby's lawsuit.

Note 11. Income Taxes

The components of net loss before income tax are as follows:

	Year Ended December 31,	
(In thousands)	**2024**	**2023**
Domestic (UK)	$ (19,424)	$ (10,267)
Foreign	(367)	259
Net loss before income tax	$ (19,791)	$ (10,008)

The components of income tax expense are as follows:

	Year Ended December 31,	
	2024	2023
Current income taxes		
Domestic (UK)	$ —	$ —
U.S.	—	—
Foreign	—	—
Deferred income taxes		
Domestic (UK)	—	—
U.S.	—	—
Foreign	—	—
Income tax expense	$ —	$ —

Deferred tax assets and liabilities reflect the net tax effects of temporary differences between the carrying amount of assets and liabilities for financial reporting and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets and liabilities were as follows:

	December 31,	
(In thousands)	2024	2023
Deferred tax assets:		
Net operating loss carryforwards	$ 56,704	$ 42,978
Accrued expenses	700	445
Capitalized research and development	1,023	440
Stock-based compensation	809	480
Intangibles	863	780
Tax credits	331	—
Other	6	18
Total gross deferred tax assets	60,436	45,141
Valuation allowance	(60,340)	(42,242)
Deferred tax assets, net of valuation allowance	$ 96	$ 2,899
Deferred tax liabilities:		
In-process research and development	$ (8,040)	$ —
Revaluation of warrant liabilities	—	(2,895)
Other	(96)	(4)
Total deferred tax liabilities	(8,136)	(2,899)
Net deferred tax liabilities	$ (8,040)	$ —

During the years ended December 31, 2024 and 2023, the Company's valuation allowance increased by $18.1 million and $7.6 million, respectively, primarily as a result of its U.S. operating loss, increases in accrued expenses and capitalized research and development costs.

In connection with the Company's acquired IPR&D assets, it recognized a deferred tax liability of $8.0 million because the Company does not have sufficient indefinite-lived deferred tax assets to fully offset the indefinite-lived deferred tax liability. 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 maintains a full valuation allowance against its net deferred tax assets as of December 31, 2024 and 2023.

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, 2024, 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 (2024: 25.0%, 2023: 23.5% (pro-rated)) compared to the Company’s income tax expense as reported in its consolidated statements of operations and comprehensive loss:

(In thousands)	Year Ended December 31, 2024	2023
Net loss before income tax	$ (19,791)	$ (10,008)
Statutory income tax rate	25.00%	23.50%
Expected income tax benefit	(4,948)	(2,352)
Impact on income tax expense/(benefit)		
Change in valuation allowance	7,434	7,617
Permanent differences	1	4
U.S. state income taxes, net of FBOS	949	1,394
Tax rate difference in foreign jurisdictions	(1,295)	(974)
Change in stock-based compensation	685	123
Change in operating losses	—	(94)
Change of tax rate from prior year	—	(6,635)
Sec. 382 limitation	1,035	—
Deferred tax adjustments	(4,158)	760
Non-deductible transaction costs	818	157
Revaluation of warrant liabilities	(521)	—
Income tax expense	$ —	$ —

As of December 31, 2024 and 2023, 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.

As of December 31, 2024, the Company had cumulative U.K., U.S. federal, various U.S. state, Switzerland, and South Korea net operating loss carryforwards ("NOLs") of approximately $145.7 million, $38.1 million, $71.8 million, less than $0.3 million, and $87.0 million, respectively, available to reduce U.K., U.S. federal, U.S. state, Switzerland, and South Korea taxable income, respectively. The U.K. NOLs do not expire. Of the $38.1 million of U.S. federal NOLs, $37.1 million have an unlimited carryforward and the remaining NOLs are subject to expiration through 2037. Of the $71.8 million of U.S. state NOLs, less than $0.3 million have an unlimited carryforward and the remaining NOLs are subject to expiration through 2044. The South Korea NOLs are subject to expiration through 2039.

In general, an ownership change, as defined by Section 382 of the Internal Revenue Code ("Section 382"), 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. Since inception, the Company has raised capital through the issuance of capital stock on multiple occasions. These financings could result in a change of control as defined by Section 382. In the fourth quarter of 2024, the Company conducted a study to assess whether a change of control 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 limited under Section 382. The Company determined that the limitation would result in approximately $4.9 million of net operating loss carryforwards to expire unused, which is reflected in the Company's consolidated financial statements. In addition, the merger of the Company with Peak Bio also resulted in approximately $6.4 million of Peak Bio net operating loss carryforwards to expire unused.

Research and development credits

The Company conducts extensive research and development activities and may benefit from the U.K. research and development tax relief regime, whereby the Company can receive an enhanced U.K. 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. When the Company is loss-making for a 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, 2024 available at a rate of 14.5%. The credit therefore gives a cash flow advantage to the 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 2024 tax year as of December 31, 2024.

Note 12. Segment Information

The Company manages its operations as a single operating segment for the purpose of assessing performance, making operating decisions and allocating resources, resulting in a single reportable segment. The Company has determined that its CODM is its Chief Executive Officer. The Company's CODM reviews the Company's financial information on a consolidated basis for the purpose of allocating resources and assessing financial performance.

The Company has assembled a portfolio of preclinical product candidates that aim to develop next-generation precision bi-functional ADCs for the treatment of cancer. The Company has not generated any revenue since its inception and does not expect to generate any revenue from the sale of products in the near future. The Company primarily incurs expenses in connection with the research and development of its product candidates as well as general and administrative costs consisting of salaries and related costs for personnel in executive, finance and administrative functions, as well as consulting, restructuring and merger-related expenses.

The key measure of segment profit or loss that the CODM uses to allocate resources and assess performance is the Company's consolidated net loss, as reported on the consolidated statements of operations and comprehensive loss. In addition, the CODM is regularly provided the following significant segment expense categories which are reviewed against budgeted expectations to assist in resource allocation decision-making:

	Year Ended December 31,	
(In thousands)	**2024**	**2023**
HSCT-TMA (AK901) program expense	$ (1,896)	$ (1,802)
BP (AK802) program expense	—	1,073
ADC preclinical development	(47)	—
Chemistry, manufacturing and control	(3,497)	(2,684)
Other external development expense	(837)	(1,498)
Internal and other research and development expense	(129)	(386)
General and administrative expense	(8,281)	(10,359)
Merger-related expense	(3,273)	—
Restructuring and other expense	(1,438)	—
Stock-based compensation expense	(2,245)	(1,150)
Other segment items *(1)*	1,852	6,798
Net loss	$ (19,791)	$ (10,008)

(1) Other segment items include interest income, interest expense, change in fair value of warrant liabilities, net foreign currency exchange gains (losses) and other expense, net as reported on the consolidated statements of operations and comprehensive loss.

Assets regularly provided to the CODM are consistent with those reported on the consolidated balance sheets with particular emphasis on the Company's available liquidity, including its cash and restricted cash. All of the Company's tangible assets are held in the United States.

Note 13. 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.

Settlement of the November 2023 Note Payable

On February 28, 2025, the Company signed a Settlement Agreement and Release for full satisfaction of the outstanding principal and accrued interest owed on the November 2023 Note (Note 6) in the amount of $325,000. Payment was made in March 2025.

March 2025 Private Placement

On March 2, 2025, the Company entered into a securities purchase agreement (the "March 2025 Purchase Agreement") with certain investors, including the Company's Chairman, Dr. Hoyoung Huh, director, President and Chief Executive Officer, Dr. Samir R. Patel, and all other members of the Company's board, pursuant to which the Company agreed to sell and issue in a private placement (the "March 2025 Offering") an aggregate of 6,637,626 unregistered ADSs, each representing 2,000 of the Company's ordinary shares (the "Shares"), or prefunded warrants in lieu thereof ("Pre-Funded Warrants"), and, in each case, Series A warrants to purchase ADSs ("Series A Warrants") and Series B warrants to purchase ADSs ("Series B Warrants"), together with the Pre-Funded Warrants and Series A Warrants, the "Warrants," and together with the ADSs or Pre-Funded Warrants, the "Units")). The Units consist of (i) for investors committing less than $1.0 million in the March 2025 Offering ("Tier 1 Investors") one ADS or Pre-Funded Warrant plus a Series A Warrant to purchase one ADS and a Series B Warrant to purchase one ADS, (ii) for investors committing at least $1.0 million but less than $3.0 million in the March 2025 Offering ("Tier 2 Investors") one ADS or Pre-Funded Warrant plus a Series A Warrant to purchase 1.25 ADSs and a Series B Warrant to purchase one ADS, and (iii) for investors committing $3.0 million or more in the March 2025 Offering ("Tier 3 Investors"), one ADS or Pre-Funded Warrant plus a Series A Warrant to purchase 1.5 ADSs and a Series B Warrant to purchase one ADS. The purchase price per Unit for investors purchasing ADSs is equal to $0.87 plus (a) $0.25 for Tier 1 Investors, (b) $0.28125 for Tier 2 Investors, or (c) $0.3125 for Tier 3 Investors (the "ADS Unit Purchase Price"). The purchase price per Pre-Funded Warrant and accompanying Series A Warrant and Series B Warrant is equal to $0.67 (which represents the ADS purchase price minus the $0.20 exercise price for such Pre-Funded Warrant) plus (a) $0.25 for Tier 1 Investors, (b) $0.28125 for Tier 2 Investors, or (c) $0.3125 for Tier 3 Investors (the "Pre-Funded Unit Purchase Price").

As part of the March 2025 Offering, Dr. Huh agreed to purchase $1 million of Units, with the purchase price thereof to be satisfied through his agreement to cancel and extinguish $1.0 million of notes previously issued to him by the Company (the "Note Termination") for an equal amount of ordinary shares and warrants.

The gross proceeds from the March 2025 Offering are expected to be approximately $6.6 million, net of the $1.0 million from the Note Termination, before deducting placement agent fees and other offering expenses payable by the Company.

The placement agent will be paid three percent (3%) of the total number of ADSs issued in the March 2025 Offering, including any of the ADSs issuable upon exercise of the Pre-Funded Warrants (excluding the ADSs issued to Dr. Huh in respect to the Note Termination).

Legal Settlement

On March 3, 2025, the Company signed a Settlement Agreement and Mutual Release with a former consultant to settle the demand letter claims received in December 2024 (Note 10). The agreement requires the Company to make a payment in the amount of $0.3 million in nine equal monthly installments beginning in March 2025. In addition, the agreement allows for the terms of the restricted stock unit award to continue to govern, including the continued vesting of the restricted stock units through the first anniversary of the grant (May 1, 2025).

Appointment of New President and Chief Executive Officer

On March 14, 2025, the Company entered into an Executive Offer of Employment Agreement (as amended by a subsequent Chief Executive Officer Letter Agreement, dated March 18, 2025, the "Employment Agreement") with Mr. Abizer Gaslightwala pursuant to which Mr. Gaslightwala will serve as the President and Chief Executive Officer of the Company, effective on or around April 21, 2025. Mr. Gaslightwala will earn a base salary, which includes an annual cash bonus target, and receive share-based payment compensation based on time service and the achievement of specific performance criteria.

Note Payable, Related Party

On March 17, 2025, Dr. Huh's January 2024 Note (Note 9) was amended to extend the maturity date to December 31, 2025.

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