

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 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)

22 Boston Wharf Road, FL 7

Boston, Massachusetts

(Address of principal executive offices)

98-1034922

(I.R.S. Employer
Identification No.)

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 Depositary 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 Depositary Shares.

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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES NO

The number of shares of Registrant's Ordinary Shares outstanding as of August 9, 2024 was 23,906,899,523.

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GENERAL INFORMATION

Unless otherwise stated or the context requires otherwise, references in this Quarterly Report on Form 10-Q ("Form 10-Q") 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.

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

There are a number of important factors that could cause our actual results to differ materially from those indicated or implied by forward-looking statements. These important factors include those set forth under Part I, “Item 1A. Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2023 (our “Form 10-K”) and Part II “Item 1A. Risk Factors” of this Form 10-Q and in our other disclosures and filings we have made with the SEC. These factors and the other cautionary statements made in this Form 10-Q 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-Q 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-Q 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-Q 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.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

AKARI THERAPEUTICS, PLC

Condensed Consolidated Balance Sheets (Unaudited, in U.S. dollars)

(In thousands, except share and per share amounts)	June 30, 2024	December 31, 2023*
ASSETS		
Current assets:		
Cash	\$ 4,177	\$ 3,845
Prepaid expenses	805	299
Other current assets	94	197
Total current assets	5,076	4,341
Patent acquisition costs, net	—	14
Total assets	\$ 5,076	\$ 4,355
LIABILITIES AND SHAREHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	\$ 4,686	\$ 1,671
Accrued expenses	1,685	1,566
Convertible notes, related party	1,000	—
Warrant liability	755	1,253
Other current liabilities	653	94
Total current liabilities	8,779	4,584
Commitments and contingencies (Note 9)		
Shareholders' deficit:		
Share capital of \$0.0001 par value		
Authorized: 45,122,321,523 ordinary shares at June 30, 2024 and December 31, 2023, respectively; issued and outstanding: 24,289,232,698 and 13,234,315,298 at June 30, 2024 and December 31, 2023, respectively	2,430	1,324
Additional paid-in capital	183,007	174,754
Capital redemption reserve	52,194	52,194
Accumulated other comprehensive loss	(749)	(1,040)
Accumulated deficit	(240,585)	(227,461)
Total shareholders' deficit	(3,703)	(229)
Total liabilities and shareholders' deficit	\$ 5,076	\$ 4,355

* The condensed balance sheet at December 31, 2023 has been derived from the audited consolidated financial statements at that date.

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

AKARI THERAPEUTICS, PLC

**Condensed Consolidated Statements of Operations
and Comprehensive Loss**
(Unaudited, in U.S. dollars)

(In thousands, except share and per share amounts)	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	\$ 3,314	\$ 1,524	\$ 5,593	\$ 3,255
General and administrative	2,241	3,091	4,907	5,954
Merger-related costs	254	—	1,298	—
Restructuring and other costs	1,640	—	1,640	—
Loss from operations	(7,449)	(4,615)	(13,438)	(9,209)
Other income (expense):				
Interest income	2	29	4	59
Interest expense	(51)	—	(51)	—
Change in fair value of warrant liability	(151)	560	498	6,147
Foreign currency exchange gain (loss), net	91	39	(135)	28
Other expense, net	—	(13)	(2)	(24)
Total other income (expense), net	(109)	615	314	6,210
Net loss	<u>\$ (7,558)</u>	<u>\$ (4,000)</u>	<u>\$ (13,124)</u>	<u>\$ (2,999)</u>
Net loss per share — basic and diluted	<u>\$ (0.00)</u>	<u>\$ (0.00)</u>	<u>\$ (0.00)</u>	<u>\$ (0.00)</u>
Weighted-average number of ordinary shares used in computing net loss per share — basic and diluted	<u>18,836,478,977</u>	<u>10,115,005,727</u>	<u>16,144,813,478</u>	<u>8,787,337,361</u>
Comprehensive loss:				
Net loss	\$ (7,558)	\$ (4,000)	\$ (13,124)	\$ (2,999)
Other comprehensive income, net of tax:				
Foreign currency translation adjustment	12	(57)	291	(55)
Total other comprehensive income, net of tax	12	(57)	291	(55)
Total comprehensive loss	<u>\$ (7,546)</u>	<u>\$ (4,057)</u>	<u>\$ (12,833)</u>	<u>\$ (3,054)</u>

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

AKARI THERAPEUTICS, PLC

Condensed Consolidated Statements of Changes in Shareholders' Equity (Deficit)
(Unaudited, in U.S. dollars)

Six Months Ended June 30, 2024

(In thousands, except share amounts)	Share Capital \$0.0001 par value		Additional Paid-in- Capital	Capital Redemption Reserve	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Shareholders' Deficit
	Shares	Amount					
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	2,641,228,000	264	1,400	—	—	—	1,664
Vesting of restricted shares	97,578,000	10	(7)	—	—	—	3
Share-based compensation	—	—	296	—	—	—	296
Foreign currency translation	—	—	—	—	279	—	279
Net loss	—	—	—	—	—	(5,566)	(5,566)
Balance, March 31, 2024	15,973,121,298	\$ 1,598	\$ 176,443	\$ 52,194	\$ (761)	\$ (233,027)	\$ (3,553)
Issuance of share capital related to financing, net of issuance costs	8,059,508,000	806	6,145	—	—	—	6,951
Issuance of share capital for services	91,396,000	9	(9)	—	—	—	—
Vesting of restricted shares	285,697,400	29	(29)	—	—	—	—
Shares withheld for payroll taxes	(120,490,000)	(12)	12	—	—	—	—
Share-based compensation	—	—	445	—	—	—	445
Foreign currency translation	—	—	—	—	12	—	12
Net loss	—	—	—	—	—	(7,558)	(7,558)
Balance, June 30, 2024	24,289,232,698	\$ 2,430	\$ 183,007	\$ 52,194	\$ (749)	\$ (240,585)	\$ (3,703)

Six Months Ended June 30, 2023

(In thousands, except share amounts)	Share Capital \$0.0001 par value		Additional Paid-in- Capital	Capital Redemption Reserve	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount					
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	2,666,666,700	267	3,235	—	—	—	3,502
Share-based compensation	—	—	265	—	—	—	265
Foreign currency translation	—	—	—	—	2	—	2
Net income	—	—	—	—	—	1,001	1,001
Balance, March 31, 2023	10,111,583,823	\$ 1,012	\$ 170,576	\$ 52,194	\$ (769)	\$ (216,452)	\$ 6,561
Vesting of restricted shares	10,737,700	1	—	—	—	—	1
Share-based compensation	—	—	276	—	—	—	276
Foreign currency translation	—	—	—	—	(57)	—	(57)
Net loss	—	—	—	—	—	(4,000)	(4,000)
Balance, June 30, 2023	10,122,321,523	\$ 1,013	\$ 170,852	\$ 52,194	\$ (826)	\$ (220,452)	\$ 2,781

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

AKARI THERAPEUTICS, PLC

Condensed Consolidated Statements of Cash Flows
(Unaudited, in U.S. dollars)

(In thousands)	Six Months Ended	
	June 30,	
	2024	2023
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (13,124)	\$ (2,999)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	13	2
Share-based compensation	741	541
Change in fair value of warrant liability	(498)	(6,147)
Foreign currency exchange losses (gains)	280	(34)
Change in assets and liabilities:		
Prepaid expenses and other current assets	702	(269)
Accounts payable and accrued expenses	2,948	(668)
Net cash used in operating activities	(8,938)	(9,574)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of shares, net of issuance costs	8,820	3,502
Proceeds from issuance of convertible notes	1,000	—
Proceeds from employee vesting of restricted shares	3	1
Payments on short-term financing arrangement	(546)	—
Net cash provided by financing activities	9,277	3,503
Effect of exchange rates on cash	(7)	2
Net increase (decrease) in cash	332	(6,069)
Cash at beginning of period	3,845	13,250
Cash at end of period	\$ 4,177	\$ 7,181
SUPPLEMENTAL DISCLOSURES OF NONCASH ACTIVITIES:		
Financing costs in accrued expenses	\$ 205	\$ —
Non-cash seller-financed purchases	\$ 1,105	\$ —
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFO:		
Cash paid during the period for interest	\$ 51	\$ —

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

AKARI THERAPEUTICS, PLC

Notes to the Condensed Consolidated Financial Statements (Unaudited)

Note 1. Description of Business

Business Overview

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

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

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

Agreement and Plan of Merger

As further described in Note 3, in March 2024, the Company entered into an Agreement and Plan of Merger with Peak Bio, Inc. (“Peak Bio”). However, the Merger has not yet closed. The Company expects to close the merger in the fourth quarter of 2024.

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 \$240.6 million as of June 30, 2024. The Company’s cash balance of \$4.2 million as of June 30, 2024 is not sufficient to fund its operations for the one-year period after the date these condensed consolidated financial statements are issued. These factors raise substantial doubt about the Company’s ability to continue as a going concern. The accompanying condensed 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 condensed consolidated financial statements do not include any adjustments related to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

The Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales of its product candidates currently in development. The Company is subject to a number of risks and uncertainties similar to those of other companies of the same size within the biotechnology industry, such as uncertainty of clinical trial outcomes, uncertainty of additional funding, and history of operating losses. Substantial additional financing will be needed by the Company to fund its operations and to commercially develop its product candidates. Management is currently evaluating different strategies to obtain the required funding for future operations. These

strategies may include, but are not limited to: product development financing, private placements and/or public offerings of equity and/or debt securities, and strategic research and development collaborations and/or similar arrangements. There can be no assurance that these future funding efforts will be successful.

Nasdaq Continued Listing Rules

On April 5, 2024, the Company received a letter (“Letter”) from the Listing Qualifications Staff (the “Staff”) of The Nasdaq Capital Market (“Nasdaq”) notifying the Company that the Company’s shareholders’ equity as reported in its Form 10-K is no longer in compliance with the minimum shareholders’ equity requirement for continued listing on Nasdaq under Nasdaq Listing Rule 5550(b)(1), which requires listed companies to maintain shareholders’ equity of at least \$2.5 million (the “Shareholders’ Equity Requirement”). As reported on the Form 10-K, the Company’s shareholders’ deficit as of December 31, 2023 was approximately \$0.2 million. The Letter has no immediate impact on the listing of the Company’s American Depositary Shares (“ADSs”) on Nasdaq. As of June 30, 2024, the Company had a shareholders’ deficit of \$3.7 million and therefore is still not in compliance with the Shareholders’ Equity Requirement.

In accordance with the Nasdaq Listing Rules, on May 20, 2024, the Company submitted a plan to regain compliance with the Stockholders’ Equity Requirement (the “Compliance Plan”) for the Staff’s consideration. On August 5, 2024, the Company was notified by the Staff that it has been granted an extension until September 30, 2024 to comply with the Compliance Plan and evidence compliance with the Minimum Equity Requirement.

There can be no assurance that the Company will be able to evidence compliance with the Shareholders’ Equity Requirement during the extension period granted by the Staff. In the event the Company does not satisfy the terms of the Nasdaq Notice and evidence compliance with the Shareholders’ Equity Requirement, the Staff will provide written notification that the Company’s securities will be delisted. The Company would, at that time, be entitled to request a hearing before a Nasdaq Hearings Panel to present its Compliance Plan to regain compliance and to request a further extension period to regain compliance with the Shareholders’ Equity Requirement. The request for a hearing would stay any delisting action by the Staff.

Note 2. Summary of Significant Accounting Policies

Basis of presentation – The accompanying unaudited interim condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (“U.S. GAAP”) for interim financial information and the rules and regulations of the SEC and assumes that the Company will continue to operate as a going concern. Accordingly, they do not include all the information and footnotes required by U.S. GAAP for complete financial statements. These condensed consolidated financial statements have been prepared on the same basis as the Company’s annual consolidated financial statements and, in the opinion of management, reflect all adjustments, including normal and recurring adjustments, which the Company considers necessary for the fair statement of financial information. The results of operations and comprehensive loss for the three and six months ended June 30, 2024 are not necessarily indicative of expected results for the fiscal year ended December 31, 2024 or any other future period. These interim condensed consolidated financial statements should be read in conjunction with the Company’s audited consolidated financial statements as of December 31, 2023 and notes thereto included in its Form 10-K, as filed with the SEC on March 29, 2024.

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

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

The reporting currency of the Company is U.S. dollars. The financial statements of certain of the Company’s foreign subsidiaries are measured using their local currency as the functional currency. The Company translates its non-U.S. operations’ assets and liabilities denominated in foreign currencies into U.S. dollars at current rates of exchange as

of the balance sheet date and income and expense items at the average exchange rate for the reporting period. Translation adjustments resulting from exchange rate fluctuations are recorded as foreign currency translation adjustments, a component of accumulated other comprehensive loss. Gains or losses from foreign currency transactions are included in foreign currency exchange gains/(losses).

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

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.

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 June 30, 2024 or December 31, 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 June 30, 2024 and December 31, 2023 were principally comprised of Value Added Tax (“VAT”) receivables.

Patent acquisition costs – Patent acquisition costs and related capitalized legal fees are amortized on a straight-line basis over the shorter of the legal or economic life. The estimated useful life is 22 years. The Company expenses costs associated with maintaining and defending patents after their issuance in the period incurred. Amortization expense for each of the three and six months ended June 30, 2024 and 2023 was less than \$0.1 million.

Accrued expenses – As part of the process of preparing the condensed 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 condensed 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 – On May 10, 2024, the Company entered into unsecured convertible promissory notes (the “May 2024 Notes”) with existing investors: the Company’s Chairman, Dr. Ray Prudo, and Interim President and Chief Executive Officer and director of the Company, 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 Merger, 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.

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 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 three and six months ended June 30, 2024. As of June 30, 2024, accrued interest on the May 2024 Notes of less than \$0.1 million is included within “Accrued expenses” in the Company’s balance sheets.

Warrant Liability – The Company accounts for ordinary share or ADS warrants as either equity instruments, liabilities or derivative liabilities in accordance with ASC Topic 480, *Distinguishing Liabilities from Equity* (“ASC 480”) and/or ASC Topic 815, *Derivatives and Hedging* (“ASC 815”), depending on the specific terms of the warrant agreement. Liability-classified warrants are recorded at their estimated fair values at issuance 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 liability” in the Company’s condensed consolidated statements of operations and comprehensive loss. Equity-classified warrants are recorded within “additional paid-in capital” in the Company’s condensed consolidated statements of shareholders’ (deficit) equity at the time of issuance and 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 derivative liabilities in its consolidated balance sheets.

Other Current Liabilities – In February 2024, the Company entered into a short-term financing arrangement with a third-party vendor to finance insurance premiums. The aggregate amount financed under this agreement was \$1.1 million bearing interest at an annual rate of 7.49%. As of June 30, 2024, the balance of \$0.6 million, which is included in “Other current liabilities” in the Company’s balance sheets, is scheduled to be paid in monthly installments through November 2024.

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 condensed consolidated statements of operations and comprehensive loss.

Merger-Related Costs – Merger-related costs include direct expenses incurred in connection with the proposed Merger, as more fully described in Note 3, and are comprised primarily of legal and professional fees and other incremental costs directly associated to the Merger. For the three and six months ended June 30, 2024 merger-related costs totaled \$0.3 million and \$1.3 million, respectively.

Restructuring and Other Costs – In May 2024, the Company began to implement 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 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 substantially completed by June 30, 2024. The purpose of the restructuring plan, including the reduction-in-force, is to reduce HSCT-TMA related operating costs, while supporting the execution of the Company’s long-term strategic plan. During the three and six months ended June 30, 2024, the Company has incurred restructuring-related charges of \$1.6 million related to the May 2024 Plan, including \$1.3 million related to severance and other settlement payments to terminated executives and employees, and \$0.3 million of non-cash expenses related to accelerated vesting of equity awards. The Company does not expect to incur additional restructuring-related expenses related to the May 2024 Plan.

As of June 30, 2024, of the \$1.6 million total restructuring-related charges incurred, \$0.5 million was unpaid and included in accrued expenses in the accompanying condensed consolidated balance sheet. See Note 5. The Company expects these costs to be payable through the fourth quarter of 2024.

Share-based compensation expense – The Company measures all share-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 share-based compensation expense in its condensed 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 7. The Company estimates stock price volatility based on the Company’s historical stock price performance over a period of time that matches the expected term of the stock 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 condensed consolidated balance sheet and are recognized on a straight-line basis over the lease term. As of June 30, 2024 and December 31, 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 condensed consolidated balance sheets as of June 30, 2024 or December 31, 2023.

Income taxes – In accordance with ASC 270, *Interim Reporting*, and ASC 740, *Income Taxes*, the Company is required at the end of each interim period to determine the best estimate of its annual effective tax rate and then apply that rate in providing for income taxes on a current year-to-date (interim period) basis. For the three and six months ended June 30, 2024 and 2023, the Company recorded no tax expense or benefit due to the expected current year loss and its historical losses. The Company has not recorded its net deferred tax asset as of either June 30, 2024 or December 31, 2023 because it maintained a full valuation allowance against all deferred tax assets as of these dates as management has determined that it is not more likely than not that the Company will realize these future tax benefits. As of June 30, 2024 and December 31, 2023, the Company had no uncertain tax positions.

Net loss per share – Basic net loss per ordinary share is computed by dividing net 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 loss per ordinary share includes the effect, if any, from the potential exercise or conversion of securities, such as stock options, unvested restricted stock units, and warrants, which would result in the issuance of incremental ordinary shares, unless their effect would be anti-dilutive. For each of the three and six months ended June 30, 2024 and 2023, diluted net loss per ordinary share is the same as basic net loss per ordinary share as the effects of the Company’s potentially dilutive securities were anti-dilutive.

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 June 30,	
	2024	2023
Stock options	351,934,688	680,112,400
Restricted stock units	251,823,915	418,580,700
Warrants	13,191,074,600	4,155,347,500
Convertible notes	1,257,860,000	—
Total	15,052,693,203	5,254,040,600

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

Recently Issued (Not Yet Adopted) Accounting Pronouncements

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

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

Note 3. Agreement and Plan of Merger

Agreement and Plan of Merger

On March 4, 2024, the Company entered into an Agreement and Plan of Merger (the “Merger Agreement”) with Peak Bio and Pegasus Merger Sub, Inc., a Delaware corporation and a wholly-owned subsidiary of Akari (“Pegasus Merger Sub”), pursuant to which, upon the terms and subject to the conditions thereof, Pegasus Merger Sub will be merged with and into Peak Bio (the “Merger”), with Peak Bio surviving the Merger as a wholly-owned subsidiary of Akari.

Pursuant to the Merger Agreement, and upon the terms and subject to the conditions thereof, at the effective time of the Merger (the “Effective Time”), each issued and outstanding share of Peak Bio common stock, par value \$0.0001 per share (the “Peak Common Stock”) (other than (x) shares of Peak Common Stock held by Peak Bio as treasury stock, or shares of Peak Common Stock owned by Akari, Pegasus Merger Sub or any direct or indirect wholly-owned subsidiaries of Akari and (y) Dissenting Shares (as defined in the Merger Agreement), will be converted into the right to receive the Company’s ADSs representing a number of Akari ordinary shares, par value \$0.0001 per share (the “Akari Ordinary Shares”) equal to an exchange ratio calculated in accordance with the Merger Agreement (the “Exchange Ratio”), each such share duly and validly issued against the deposit of the requisite number of Akari Ordinary Shares in accordance with the Deposit Agreement (as defined in the Merger Agreement). The Exchange

Ratio will be calculated such that the total number of shares of Akari ADSs to be issued as merger consideration for the Peak Common Stock will be expected to be, upon issuance, approximately 50% of the outstanding shares of Akari ADSs (provided, certain adjustments to this ratio will be made in respect of the net cash, as determined in accordance with the Merger Agreement, of each of Akari and Peak Bio at the close of business one business day prior to the anticipated consummation of the Merger). The Merger Agreement provides that, under certain circumstances, additional Akari ADSs may be issued to the holders of shares of Peak Common Stock following the consummation of the Merger equal to an exchange ratio calculated in accordance with the Merger Agreement (the “Additional Exchange Ratio”).

The board of directors of each of Akari and Peak has unanimously approved the Merger Agreement and the transactions contemplated thereby. Consummation of the Merger is subject to various conditions, including, among others, (i) approval of the Merger Agreement and Merger by Peak Bio stockholders, (ii) Akari’s shareholders authorizing Akari’s board of directors to allot all Akari ordinary shares to be issued in connection with the Merger (to be represented by Akari ADSs), (iii) the absence of any law or order prohibiting consummation of the Merger, (iv) Akari’s Registration Statement on Form S-4 (to be issued in connection with the Merger) having been declared effective, (v) the Akari ADSs issuable to Peak Bio stockholders having been authorized for listing on Nasdaq, (vi) accuracy of the other party’s representations and warranties (subject to certain materiality standards set forth in the Merger Agreement), (vii) compliance by the other party in all material respects with such other party’s obligations under the Merger Agreement; (viii) the absence of a material adverse effect on the other party, (ix) the other party’s net cash being greater than negative \$13.5 million and (x) the PIPE Investment (as defined in the Merger Agreement) shall have been consummated simultaneously with, and conditioned only upon, the occurrence of the closing, and shall result in net proceeds to Akari of at least \$10 million.

Either Akari or Peak Bio may terminate the Merger Agreement under certain circumstances, including if (i) the Merger is not completed by December 2, 2024, (ii) the other party’s board of directors withdraws, modifies or qualifies its recommendation in favor of the transactions contemplated by the Merger Agreement or approves or recommends an alternative transaction or (iii) Akari’s or Peak Bio’s board of directors, as applicable, resolves to enter into a definitive agreement with respect to a superior proposal prior to obtaining approval of the Akari ADS issuance or Merger, as applicable, from Akari’s shareholders or Peak Bio’s stockholders, as applicable. The Merger Agreement also provides that under certain specified circumstances of termination described in the Merger Agreement, Akari or Peak Bio, as applicable, will be required to pay a termination fee equal to \$300,000 and reimburse the other party for expenses related to the transaction up to \$1.5 million.

Concurrently with the Merger Agreement, Akari and Peak Bio entered into voting and support agreements (the “Voting Agreements”) with certain shareholders of Akari (the “Akari Shareholders”), and certain stockholders of Peak Bio (the “Peak Stockholders” and, together with the Akari Shareholders, the “Supporting Holders”). The Supporting Holders have agreed to, among other things, vote their shares in favor of the Merger Agreement and the Merger or the issuance of Akari Ordinary Shares in connection therewith, as applicable, in accordance with the recommendation of the respective boards of directors of Akari and Peak Bio.

The Voting Agreements will terminate at the earliest to occur of (a) the Effective Time, (b) receipt of approval of the Supporting Holders, as applicable, and (c) such date and time as the Merger Agreement is validly terminated.

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:

(In thousands)	June 30, 2024			
	Total	Level 1	Level 2	Level 3
Liabilities				
Warrant liability - Series A	\$ —	\$ —	\$ —	\$ —
Warrant liability - Series B	755	—	—	755
Total liabilities	<u>\$ 755</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 755</u>

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

The Company's Level 3 liabilities consist of the September 2022 Warrants, which were determined to be liability-classified instruments. There were no transfers between Level 1, Level 2, and Level 3 during the six months ended June 30, 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 liability measured at fair value on a recurring basis using unobservable inputs (Level 3) during the six months ended June 30, 2024:

(In thousands)	Warrant Liability		
	Series A	Series B	Total
Balance, December 31, 2023	\$ 15	\$ 1,238	\$ 1,253
Change in the fair value of liability	(15)	(483)	(498)
Balance, June 30, 2024	<u>\$ —</u>	<u>\$ 755</u>	<u>\$ 755</u>

Assumptions Used in Determining Fair Value of Liability-Classified Warrants

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

Below are the assumptions used for the fair value calculations of the Series A Warrants and Series B Warrants (each defined below), as of June 30, 2024 and December 31, 2023:

	June 30, 2024		December 31, 2023	
	Series A	Series B	Series A	Series B
Stock (ADS) price	\$ 2.70	\$ 2.70	\$ 3.12	\$ 3.12
Exercise price	\$ 17.00	\$ 17.00	\$ 17.00	\$ 17.00
Expected term (in years)	0.2	5.2	0.7	5.7
Expected volatility	135.0%	85.0%	85.0%	95.0%
Risk-free interest rate	5.5%	4.3%	5.1%	3.9%
Expected dividend yield	—	—	—	—

Note 5. Accrued Expenses

Accrued expenses consisted of the following as of June 30, 2024 and December 31, 2023:

(\$ in thousands)	June 30, 2024	December 31, 2023
Employee compensation and benefits	\$ 377	\$ 187
External research and development expenses	446	635
Professional and consulting fees	363	669
Restructuring	458	—
Other	41	75
Total accrued expenses	<u>\$ 1,685</u>	<u>\$ 1,566</u>

Accrued restructuring expenses of \$0.5 million as of June 30, 2024 relate to one-time termination benefits payable to former employees, including an executive, which are payable through the fourth quarter of 2024. See Note 2.

Note 6. Shareholders' (Deficit) Equity

Ordinary Shares

On June 30, 2023, the Company's shareholders approved an increase to the number of authorized ordinary shares, par value \$0.0001 (the "Ordinary Shares"), the Company can issue by 35,000,000,000 ordinary shares in addition to the number of shares outstanding on June 30, 2023. Accordingly, as of June 30, 2024 and 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 condensed consolidated financial statements reflect the ADS Ratio.

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 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 Investment Company, LLC ("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 were 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 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 were 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 Registered Direct Offering”) providing for the issuance of an aggregate of 1,333,333 ADSs in a registered direct offering at \$3.00 per ADS, resulting in gross proceeds of approximately \$4.0 million. Net proceeds from the March Registered Direct Offering 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 accounting policies related to the Company's warrants.

The following table summarizes the Company's outstanding warrants as of June 30, 2024 and December 31, 2023:

	Number of Warrant ADSs		Weighted-Average Exercise Price	Expiration Date
	June 30, 2024	December 31, 2023		
Equity-classified Warrants				
2019 Investor Warrants	59,211	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	—
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
	<u>5,133,924</u>	<u>658,610</u>		
Liability-classified Warrants				
September 2022 Series A Investor Warrants	755,000	755,000	\$ 17.00	9/14/2024
September 2022 Series B Investor Warrants	755,000	755,000	\$ 17.00	9/14/2029
	<u>1,510,000</u>	<u>1,510,000</u>		
Total outstanding	<u><u>6,643,924</u></u>	<u><u>2,168,610</u></u>		

The following table summarizes the Company's warrants activity for the six months ended June 30, 2024:

(\$ in thousands, except per share data)	Number of Warrants	Weighted-Average Exercise Price
Outstanding at December 31, 2023	2,168,610	\$ 21.97
Issued	4,484,195	1.78
Exercised	—	—
Expired	(8,881)	57.00
Outstanding at June 30, 2024	6,643,924	\$ 8.30

Capital Redemption Reserve

In December 2020, for the purpose of changing the nominal value of the Company's ordinary shares from £0.01 to \$0.0001 the Company issued 3,847,331,913 deferred shares (the "Deferred Shares") of \$0.01315. The Deferred Shares were created for technical reasons of company law and did not increase the aggregate value of share capital. Also in December 2020, the Deferred Shares were purchased by the Company in accordance with their terms of issue for aggregate consideration of \$0.01 and immediately cancelled. The aggregate nominal value at cancellation was \$50.6 million.

Amounts transferred from share capital on the redemption of the Deferred Shares of \$50.6 million, along with the resulting foreign currency effect of the redenomination of Company ordinary shares of \$1.6 million, are classified as "capital redemption reserve" within the Company's condensed consolidated balance sheets and condensed statements of shareholders' (deficit) equity.

Note 7. Share-Based Compensation

2023 Equity Incentive Plan

On June 30, 2023, the Company's shareholders approved the 2023 Equity Incentive Plan (the "2023 Plan"), which provides for the grant of stock options, both incentive stock options and nonqualified stock options, stock, with and without vesting restrictions, restricted stock units ("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 June 30, 2024, the Company had 318,823,915 ordinary shares underlying outstanding equity awards under the 2023 Plan, consisting of stock options and RSUs, and 724,581,522 ordinary shares remained available for future grants 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, RSUs and other awards, to employees, members of the board of directors and consultants. Upon effectiveness of the 2023 Plan no further awards were available to be issued under the 2014 Plan. As of June 30, 2024, the Company had 284,934,688 ordinary shares underlying outstanding equity awards under the 2014 Plan, consisting of stock options.

Stock Options

The following is a summary of the Company's stock option activity under the 2014 Plan and the 2023 Plan for the six months ended June 30, 2024:

(\$ in thousands, except share and per share data)	Stock Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2023	651,237,400	\$ 0.01	8.5	\$ —
Granted	25,000,000	—		
Exercised	—	—		
Forfeited	(299,802,712)	0.01		
Expired	(24,500,000)	0.02		
Outstanding at June 30, 2024 (1)	<u>351,934,688</u>	<u>\$ 0.01</u>	<u>4.6</u>	<u>\$ —</u>
Exercisable at June 30, 2024	<u>263,101,355</u>	<u>\$ 0.01</u>	<u>3.2</u>	<u>\$ —</u>

- (1) Includes both vested stock options as well as unvested stock options for which the requisite service period has not been rendered but that are expected to vest based on achievement of a service condition.

The aggregate intrinsic value of options is calculated as the difference between the exercise price of the options and the fair value of the Company's ordinary shares 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 six months ended June 30, 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	98.0 %	99.3 %
Risk-free interest rate	4.3 %	3.8 %
Expected dividend yield	—	—
Expected term (in years)	5.5	6.0

Restricted Stock Units

The 2014 Plan provided, and the 2023 Plan provides, for the award of 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 RSUs, which is derived from the closing price of the Company's ADSs on the date of grant.

The following table summarizes the Company's RSU activity for the six months ended June 30, 2024:

(\$ in thousands, except per share data)	Time-based Awards	
	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	(383,275,400)	0.00
Nonvested shares at June 30, 2024	251,823,915	\$ 0.00

The fair value of time-based RSUs that vested during the six months ended June 30, 2024 and 2023 was approximately \$0.5 million and \$0.1 million, respectively.

As of June 30, 2024, 290,937,175 ordinary shares underlying vested time-based RSUs, which have been included in the condensed consolidated statement of shareholders' (deficit) equity, were pending issuance.

Share-Based Compensation Expense

The Company classifies share-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 share-based compensation expense attributable to share-based payments made to employees, consultants and directors included in operating expenses in the Company's condensed consolidated statements of operations and comprehensive loss for the three and six months ended June 30, 2024 and 2023, was as follows:

(\$ in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Research and development	\$ 13	\$ 32	\$ 56	\$ 63
General and administrative	147	244	400	478
Restructuring and other costs	285	—	285	—
Total share-based compensation expense	\$ 445	\$ 276	\$ 741	\$ 541

During the three and six months ended June 30, 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 June 30, 2024, total unrecognized compensation cost related to unvested stock options and time-based RSUs was \$0.2 million and \$0.2 million, respectively. The Company expects total unrecognized compensation costs related to unvested stock options and RSUs to be recognized over a weighted average period of 1.8 and 1.7 years, respectively.

Note 8. Related Party Transactions

The Doctors Laboratory

The Company leases office space for its U.K. headquarters in London from The Doctors Laboratory (“TDL”) and has incurred expenses of less than \$0.1 million plus VAT during each of the three and six months ended June 30, 2024 and 2023. David Byrne, a former non-employee director of the Company, is the Chief Executive Officer of TDL and Dr. Prudo 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 less than \$0.1 million during each of the three and six months ended June 30, 2024 and 2023.

The Company recorded payable balances owed to TDL of less than \$0.1 million as of June 30, 2024 and December 31, 2023.

Interim CEO Agreement

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 serves as the Company’s Interim President and Chief Executive Officer as an independent contractor on an at-will basis. The Interim CEO Agreement can be terminated by the Company immediately for any reason. As the sole compensation for services provided under the Interim CEO Agreement, Dr. Patel is paid \$50,000 per month in the form of fully vested ordinary shares.

During the three and six months ended June 30, 2024, the Company granted 91,396,000 fully vested ordinary shares to Dr. Patel and recognized approximately \$0.1 million in compensation costs pursuant to the Interim CEO Agreement. As of June 30, 2024, the 91,396,000 ordinary shares granted to Dr. Patel, which have been included in the condensed consolidated statement of shareholders’ (deficit) equity, were pending issuance.

Note 9. Commitments and Contingencies

Leases

The Company **is currently party to a short-term lease for its U.S headquarters, which currently expires in November 2024, and a short-term lease with TDL for its London offices, which currently expires in July 2025.** The Company is not party to any material lease agreements.

For each of the three months ended June 30, 2024 and 2023, the Company incurred lease costs of less than \$0.1 million. For the six months ended June 30, 2024 and 2023, the Company incurred leases costs of approximately \$0.2 million and \$0.1 million, respectively.

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 the annual eligible compensation contributed by each employee, subject to Internal Revenue Code limitations.

The Company also adopted a defined contribution pension scheme which allows for U.K. employees to make contributions and provides U.K. employees with a Company contribution of 10% of compensation, subject to U.K. law.

During each of the three and six months ended June 30, 2024 and 2023, the Company charged less than \$0.1 million to operating expenses related to the Company's contributions to employee benefit plans.

Note 10. Subsequent Events

The Company considers events or transactions that occur after the balance sheet date but prior to the issuance of the financial statements to provide additional evidence relative to certain estimates or to identify matters that require additional disclosure or retroactive adjustment to information reported at the balance sheet date.

Item 2. 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 in conjunction with:

- our unaudited condensed consolidated financial statements and accompanying notes included in Part I, Item 1 of this Form 10-Q; and
- our audited consolidated financial statements and accompanying notes included in the Form 10-K, as well as the information contained under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our Form 10-K.

In addition to historical information, this discussion and analysis contains forward-looking statements that are subject to risks and uncertainties, including those discussed in the section titled “Risk Factors,” set forth in Item 1A of our Form 10-K and this Form 10-Q, that could cause actual results to differ materially from historical results or anticipated results.

Overview

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

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

Up until May 2024, we were conducting a clinical trial of subcutaneous nomacopan for the treatment of hematopoietic stem cell transplant-related thrombotic microangiopathy (“HSCT-TMA”) in pediatrics. Following completion of a portfolio prioritization review, we announced that our HSCT-TMA program will be suspended, as more fully described below. We are currently investigating long-acting PASylated-nomacopan (“PAS-nomacopan”) for treatment of Geographic Atrophy (“GA”) secondary to dry age-related macular degeneration (“dry AMD”) in preclinical studies and expect to file an Investigational New Drug (“IND”) application in 2025.

Recent Developments

Pipeline Prioritization

In May 2024, we announced the completion of a joint portfolio prioritization review pursuant to which the anticipated combined entity, following completion of the previously announced Merger (as defined below), will focus on Peak Bio’s antibody drug conjugate (“ADC”) platform technology and our PAS-nomacopan GA program. As a result, our HSCT-TMA program was suspended, with enrollment in its pediatric clinical study discontinued due to cost and timeline. Following closing of the Merger, we plan to work closely with the U.S. Food and Drug Administration to define the best path for this technology and consider the opportunity for partnership and licensing, specifically as it relates to the potential eligibility for a priority review voucher in connection with future marketing applications for nomacopan, including as a treatment for pediatric HSCT-TMA.

Restructuring and Reduction-in-Force

In May 2024, we began to implement 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 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 substantially completed by the end of the second quarter. The purpose of the restructuring plan, including the reduction-in-force, is to reduce HSCT-TMA related operating costs, while supporting the execution of our long-term strategic plan. For additional information, refer to the below discussion under the heading “Restructuring and Other Costs” and Note 2 to the notes to unaudited condensed consolidated financial statements included elsewhere in this Form 10-Q.

Merger Agreement

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

The merger is expected to close in the fourth quarter of 2024, subject to certain conditions, including, among others, (i) approval of the Merger Agreement and Merger by Peak Bio stockholders, (ii) our shareholders authorizing our board of directors to allot ordinary shares to be issued in connection with the Merger (to be represented by ADSs), (iii) our Registration Statement on Form S-4 having been declared effective, (iv) the ADSs issuable to Peak Bio stockholders having been authorized for listing on the Nasdaq Stock Market, and (v) private placement financings shall have been consummated simultaneously with, and conditioned only upon, the occurrence of the closing, and shall result in net proceeds to us of at least \$10 million.

For additional information on the Merger, refer to Note 3 to the notes to unaudited condensed consolidated financial statements included elsewhere in this Form 10-Q.

Results of Operations

Three and Six Months Ended June 30, 2024 and 2023

Overview

During the three months ended June 30, 2024, our loss from operations totaled \$7.4 million, a 61% increase, compared to a loss from operations of \$4.6 million for the three months ended June 30, 2023. During the six months ended June 30, 2024, our loss from operations totaled \$13.4 million, a 46% increase, compared to a loss from operations of \$9.2 million for the six months ended June 30, 2023. Our total operating expenses are set forth by category in the table below:

(\$ in thousands)	Three Months Ended June 30,			Six Months Ended June 30,		
	2024	2023	\$ Change	2024	2023	\$ Change
Operating expenses:						
Research and development	\$ 3,314	\$ 1,524	\$ 1,790	\$ 5,593	\$ 3,255	\$ 2,338
General and administrative	2,241	3,091	(850)	4,907	5,954	(1,047)
Merger-related costs	254	—	254	1,298	—	1,298
Restructuring and other costs	1,640	—	1,640	1,640	—	1,640
Total operating expenses	\$ 7,449	\$ 4,615	\$ 2,834	13,438	9,209	4,229
Loss from operations	\$ (7,449)	\$ (4,615)	\$ (2,834)	\$ (13,438)	\$ (9,209)	\$ (4,229)

Research and development expenses

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

During the three months ended June 30, 2024, total research and development expenses increased by approximately \$1.8 million, or 117%, as compared to the three months ended June 30, 2023. During the six months ended June 30, 2024, total research and development expenses increased by approximately \$2.3 million, or 72%, as compared to the six months ended June 30, 2023. The following sets forth research and development expenses for the three and six months ended June 30, 2024 and 2023 by category:

(\$ in thousands)	Three Months Ended June 30,			Six Months Ended June 30,		
	2024	2023	\$ Change	2024	2023	\$ Change
Clinical Trials:						
HSCT-TMA clinical development (AK901)	\$ 450	\$ 534	\$ (84)	\$ 1,083	\$ 724	\$ 359
BP clinical development (AK802)	—	(1,063)	1,063	—	(1,063)	1,063
Chemistry, manufacturing and control	2,231	565	1,666	2,942	844	2,098
Other external development expenses	290	495	(205)	595	1,065	(470)
Personnel costs	343	993	(650)	973	1,685	(712)
Total research and development expenses	\$ 3,314	\$ 1,524	\$ 1,790	\$ 5,593	\$ 3,255	\$ 2,338

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. Expenses incurred during the three months ended June 30, 2024 were consistent with the three months ended June 30, 2023. The \$0.1 million, or 16%, decrease in expenses incurred during the three months ended June 30, 2024, as compared to 2023, is primarily due to suspension of our HSCT-TMA program in May 2024, as further described below. The \$0.4 million, or 50%, increase in expenses incurred during the six months ended June 30, 2024, as compared to 2023, is primarily due to increases in patient enrollment and related clinical trial costs incurred during the first quarter of 2024, prior to suspension of the program. In May 2024, following the completion of a pipeline prioritization review, we determined to suspend our HSCT-TMA program. Accordingly, we expect future HSCT-TMA costs to decrease reflecting the winddown and closeout of the clinical trial.

BP clinical development (AK802)

These expenses include external expenses that we incurred in connection with the development of nomacopan for the treatment of bullous pemphigoid (“BP”) and primarily consist of payments to CROs and other vendors. In 2022 we discontinued our BP clinical program and in connection with the final reconciliation of clinical trial close-out costs, we recorded a \$1.1 million credit in 2023 and do not expect to incur material additional costs related to this program.

Chemistry, manufacturing and control

These expenses include external expenses incurred related to the development and manufacturing of nomacopan for use in clinical trials and preclinical development of PAS-nomacopan. Such expenses primarily consist of payments to CMOs and other vendors for manufacturing of drug substances (including raw materials), drug product, supplies, and validation, quality assurance and manufacturing development activities. The \$1.7 million, or 295%, increase in expenses incurred during the three months ended June 30, 2024 and \$2.1 million, or 249%, increase in expenses incurred during the six months ended June 30, 2024, each as compared to the corresponding periods in 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, as well as completion of PAS-nomacopan good manufacturing practice (“GMP”) drug substance manufacturing during the second quarter of 2024.

Other external development expenses

These expenses include external expenses, such as payments to contract vendors, which may be related to preclinical development activities and other unallocated expenses. The \$0.2 million, or 41%, decrease in expenses incurred during the three months ended June 30, 2024 and \$0.5 million, or 44%, decrease in expenses incurred during the six months ended June 30, 2024, each as compared to the corresponding periods in 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 \$0.7 million, or 65%, decrease in expenses incurred during the three months ended June 30, 2024 and \$0.7 million, or 42%, decrease in expenses incurred during the six months ended June 30, 2024, each as compared to the corresponding periods in 2023, is primarily due to the impact of the RIF which was announced in May 2024, along with lower costs incurred with independent consultants. Separation benefits paid to impacted employees are classified separately under “Restructuring and other costs” as discussed below.

The extent of our future research and development expenditures will be determined based on future funding and closing of the Merger.

General and administrative expenses

During the three months ended June 30, 2024, total general and administrative costs decreased by approximately \$0.9 million, or 27% , as compared to the three months ended June 30, 2023. During the six months ended June 30, 2024, total general and administrative costs decreased by approximately \$1.0 million, or 18%, as compared to the six months ended June 30, 2023. The decreases during both periods were primarily due to decreases in personnel costs resulting from the impact of the RIF which was announced in May 2024, along with lower costs incurred with consultants. Separation benefits paid to impacted employees are classified separately under “Restructuring and other costs” as discussed below.

Merger-related Costs

Merger-related costs consist of direct expenses incurred in connection with the proposed Merger and are comprised primarily of legal and professional fees.

Merger-related costs for the three and six months ended June 30, 2024 were \$0.3 million and \$1.3 million, respectively. No such costs were incurred during the corresponding 2023 periods.

Restructuring and Other Costs

Restructuring costs consist primarily of severance and related benefit costs related to workforce reductions incurred in connection with the RIF, which the Company began to implement in May 2024.

Restructuring and other costs for each of the three and six months ended June 30, 2024 were \$1.6 million, including \$0.3 million of non-cash share-based compensation expense. No such costs were incurred during the corresponding 2023 periods.

Interest income

Interest income consists primarily of interest income received on deposits.

During the three and six months ended June 30, 2024 and 2023, interest income was less than \$0.1 million. Interest income 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 Notes and in connection with the financing of director and officer insurance premiums.

During the three and six months ended June 30, 2024, interest expense was less than \$0.1 million. 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 three and six months ended June 30, 2023.

Change in fair value of warrant liability

Change in fair value of warrant liability represents non-cash warrant revaluation gains or losses related to the remeasurement of our liability-classified September 2022 Warrants, as more fully described in Note 2 and Note 4 of the notes to the condensed consolidated financial statements appearing elsewhere in this Form 10-Q. Due to the nature of and inputs in the model used to assess the fair value of our outstanding September 2022 Warrants, it is not abnormal to experience significant fluctuations during each remeasurement period. These fluctuations may be due to a variety of factors, including changes in our stock price and changes in estimated stock price volatility over the remaining life of the warrants.

During the three months ended June 30, 2024, we recorded a change in the fair value of warrant liability, representing a non-cash warrant revaluation loss of approximately \$0.2 million, as compared to a non-cash warrant

revaluation gain of approximately \$0.6 million for the three months ended June 30, 2023. Changes in the fair value of the warrant liability and resulting warrant revaluation loss for the three months ended June 30, 2024 was driven primarily by the increase in our stock price during the reporting period. Changes in the fair value of the warrant liability and resulting warrant revaluation gain for the three months ended June 30, 2023 was driven primarily by the decrease in expected volatility assumptions.

During the six months ended June 30, 2024 and 2023, we recorded a change in the fair value of warrant liability, representing a non-cash warrant revaluation gain, of approximately \$0.5 million and \$6.1 million, respectively. Changes in the fair value of the warrant liability and resulting warrant revaluation gains for the six months ended June 30, 2024 and 2023 was driven primarily by the decrease in our stock price during the reporting periods.

Foreign currency exchange gain (loss), net

During the three months ended June 30, 2024, we recorded a net foreign currency exchange gain of \$0.1 million, as compared to a net foreign currency exchange loss for the three months ended June 30, 2023. During each of the six months ended June 30, 2024 and 2023, we recorded a net foreign currency exchange gain of 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 three and six months ended June 30, 2024 and 2023, net other expense was less than \$0.1 million and not material. Such expenses are not expected to be material to our future results of operations.

Net Loss Applicable to Ordinary Shareholders

As a result of the factors discussed above, net loss applicable to ordinary shareholders for the three months ended June 30, 2024 and 2023 was \$7.6 million and \$4.0 million, respectively. Net loss applicable to ordinary shareholders for the six months ended June 30, 2024 and 2023 was \$13.1 million and \$3.0 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 June 30, 2024, we had \$4.2 million in cash and an accumulated deficit of \$240.6 million. To date, we have not generated any revenue.

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

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

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

with collaborators or others that may require us to relinquish rights to certain potential products that we might otherwise seek to develop or commercialize independently.

May 2024 Private Placement

As discussed in Note 6 to our notes to unaudited condensed consolidated financial statements included elsewhere in this Form 10-Q, in May 2024, we entered into a purchase agreement with certain investors, pursuant to which we sold and issued in a private placement an aggregate of 4,029,754 ADSs, and warrants to purchase up to 4,029,754 ADS, at a per unit (each unit consists of one ADS and one warrant) purchase price of \$1.885, for aggregate gross proceeds of approximately \$7.6 million. 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

As discussed in Note 2 to our notes to unaudited condensed consolidated financial statements included elsewhere in this Form 10-Q, in May 2024, we entered into convertible promissory notes with existing investors and directors, Dr. Prudo and Dr. Patel, for an aggregate of \$1.0 million (the “May 2024 Notes”).

March 2024 Private Placement

As discussed in Note 6 to our notes to unaudited condensed consolidated financial statements included elsewhere in this Form 10-Q, 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. Net proceeds from the March 2024 Private Placement were approximately \$1.7 million after deducting placement agent fees and other expenses.

Funding Requirements

As of the date of this report, we expect our existing cash to be sufficient to fund our operations into the fourth quarter of 2024. Further, closing of the Merger is contingent on the PIPE Investment (as defined in the Merger Agreement) which shall have been consummated simultaneously with, and conditioned only upon, the occurrence of the closing, and shall result in net proceeds to us of at least \$10 million. If we are unable to raise additional capital when needed, we will not be able to continue as a going concern. We do not currently have any products approved for sale and do not generate any revenue from product sales. We are currently seeking and expect to continue to seek additional funding through financings of equity and/or debt securities. We may also engage in strategic research and development collaborations, clinical funding arrangements, the sale or license of technology assets, and/or other strategic alternatives.

Financing may not be available to us when we need it, or on favorable or acceptable terms, or at all. We could be required to seek funds through means that may require us to relinquish rights to some of our technologies, drug candidates or drugs that we would otherwise pursue on our own. In addition, if we raise additional funds by issuing equity securities, our then existing shareholders may experience dilution. The terms of any financing may adversely affect the holdings or the rights of existing shareholders. An equity financing that involves existing shareholders may cause a concentration of ownership. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, and are likely to include rights that are senior to the holders of our ordinary shares. Any additional debt or equity financing may contain terms which are not favorable to us or to our shareholders, such as liquidation and other preferences, or liens or other restrictions on our assets. As discussed in Note 9 to the consolidated financial statements included in the 2023 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;
- delay, or terminate the Merger, of which closing is contingent on the PIPE Investment (as defined in the Merger Agreement), altogether;
- pursue the sale of our company to a third party at a price that may result in a loss on investment for our shareholders; or
- file for bankruptcy or cease operations altogether.

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

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

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

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

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

Cash Flows

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

(In thousands)	Six Months Ended	
	June 30,	
	2024	2023
Net cash (used in) provided by:		
Net cash used in operating activities	\$ (8,938)	\$ (9,574)
Net cash provided by financing activities	9,277	3,503
Effect of exchange rates on cash	(7)	2
Net increase (decrease) in cash	\$ 332	\$ (6,069)

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 six months ended June 30, 2024, as compared to the 2023 period, was primarily due to the net impact of deferrals of payables in order to preserve cash until additional capital is raised for working capital purposes, partially offset by an increase in operating expenses.

Investment Activities. There were no investing activities during the six months ended June 30, 2024 and 2023.

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

- For the six months ended June 30, 2024, an aggregate of \$9.3 million in net proceeds received from debt and equity financings, 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 Notes, and (iii) \$7.1 million in net proceeds from the May 2024 Private Placement, partially offset by \$0.5 million in payments related to our short-term insurance premium financing arrangement; and
- For the six months ended June 30, 2023, an aggregate of \$3.5 million in net proceeds received from the March 2023 Registered Direct Offering.

Material Cash Requirements

During the six months ended June 30, 2024, there were no material changes outside the ordinary course of our business to our contractual obligations and cash requirements, as disclosed in our Form 10-K.

Critical Accounting Estimates

This management's discussion and analysis of financial condition and results of operations is based on our condensed 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) share-based compensation, (ii) fair value of warrants classified as liabilities, (iii) research and development prepayments, accruals and related expenses, and (iv) the valuation allowance for deferred income taxes. Management bases its estimates and judgments on historical experience and on various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

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

- the nature of the estimate or assumption is material due to the level of subjectivity and judgment necessary to account for highly uncertain matters or the susceptibility of such matters to change; and
- the impact of the estimates and assumptions on financial condition or operating performance is material.

There have been no material changes to our critical accounting policies and estimates since December 31, 2023. See "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations — Critical Accounting Estimates" of our Form 10-K, for a discussion of significant estimates and assumptions made by our management as part of the preparation of this management's discussion and analysis of financial condition and results of operations and accompanying condensed consolidated financial statements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are a smaller reporting company, as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, and are not required to provide the information required under this item.

Item 4. Controls and Procedures.

Disclosure Controls and Procedures

a) Evaluation of 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 June 30, 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 as of June 30, 2024, our disclosure controls and procedures were (1) designed to ensure that material information relating to us is made known to our principal executive officer and principal financial officer by others, particularly during the period in which this report was prepared, and (2) effective, in that they provide reasonable assurance that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

b) Changes in Internal Control over Financial Reporting.

During the fiscal quarter ended June 30, 2024, the Company implemented a new general ledger and accounting system to support its accounting activities and enhance business information. As a result, the Company revised certain processes and procedures related to the recording of financial transactions. The Company completed testing of the implemented system prior to its launch, continues to monitor impacted financial and business processes and believes that an effective control environment has been maintained post-implementation.

There were no other changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the fiscal quarter ended June 30, 2024 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may become involved in various legal proceedings that arise in the ordinary course of our business. We are not currently a party to any material legal proceedings, and are not aware of any pending or threatened legal proceeding against us that we believe could have an adverse effect on our business, operating results or financial condition.

Item 1A. Risk Factors.

Risk Factors Summary

Our business is subject to a number of risks and uncertainties, including those risks discussed at length below. These risks include, among others, the following principal risk factors that make an investment in our company speculative or risky. You are encouraged to carefully review our full discussion of the material risk factors relevant to an investment in our business, which follows the brief bulleted list of our principal risk factors set forth below:

- We have a history of operating losses and cannot give assurance of future revenues or operating profits; investors may lose their entire investment.
- Our auditor's report on our consolidated financial statements states that our recurring operating losses, negative cash flows and dependence on additional financial support raises substantial doubt about our ability to continue as a going concern, which may have a detrimental effect on our ability to obtain additional funding.
- There is no guarantee that our merger with Peak Bio will increase shareholder value or that Peak Bio will be successfully integrated into our operations or achieve its desired benefits.
- Recent adjustments to our operating plans, including our pipeline prioritization and reduction-in-force may not be successful.
- We will require additional capital to fund our operations, and if we are unable to obtain such capital, we will be unable to successfully develop and commercialize any product candidates.
- Our business depends on the success of PAS-nomacopan, which is still under development. If we are unable to obtain marketing authorization for or successfully commercialize PAS-nomacopan, our business could be materially harmed.
- If we encounter difficulties enrolling patients in our future clinical trials, our clinical development activities could be delayed or otherwise adversely affected.
- If clinical trials or marketing authorization processes for PAS-nomacopan or any future product candidates are prolonged, delayed or suspended, we may be unable to commercialize PAS-nomacopan or any future product candidates on a timely basis.
- The efficacy of PAS-nomacopan or any future product candidates may not be known until advanced stages of testing, after we have incurred significant product development costs which may not be recoverable.
- Results of earlier preclinical studies or clinical trials may not be predictive of advancement to the next phase of development.
- Long-term animal toxicity and long-term human safety studies of PAS-nomacopan could demonstrate that the administration of PAS-nomacopan results in serious adverse events.
- Chronic dosing of patients with PAS-nomacopan could lead to an immune response that causes adverse reactions or impairs the activity of the drug.

- Because PAS-nomacopan has not yet received marketing authorization, it is difficult to predict the time and cost of development and our ability to successfully complete clinical development and obtain the necessary marketing authorizations for commercialization.
- We have obtained orphan drug designation for nomacopan in the United States for the use in bullous pemphigoid (“BP”), paroxysmal nocturnal hemoglobinuria (“PNH”), Guillain-Barré syndrome (“GBS”), hematopoietic stem cell transplantation-associated thrombotic microangiopathy (“HSCT-TMA”) and in the EU for GBS, PNH and BP but we may be unable to maintain the benefits associated with orphan drug designation or obtain orphan drug exclusivity upon potential approval of nomacopan in one or more of these orphan indications.
- We have obtained fast track designation from the FDA for the treatment of HSCT-TMA, and may seek such designation in other indications. Such designation or a similar designation from other national or international regulatory agencies, may not lead to a faster development or regulatory review or approval process, and may not result in nomacopan or any other product candidates receiving marketing approval.
- Even if we obtain FDA approval of PAS-nomacopan or any other future product candidates, we or our partners may never obtain approval or commercialize our product candidates outside of the United States and, conversely, even if we obtain marketing authorization of PAS-nomacopan or any other future product candidates in the EU, we or our partners may never obtain approval or commercialize our product candidates outside the EU.
- If we or our partners market products in a manner that violates fraud and abuse and other healthcare laws, or if we or they violate government price reporting laws, we or our partners may be subject to administrative civil and/or criminal penalties.
- Our success depends in part on our ability to protect our intellectual property and our proprietary technologies.
- We currently have no marketing, sales or distribution infrastructure with respect to PAS-nomacopan or other product candidates we may pursue following the Merger. If we are unable to develop our sales, marketing and distribution capability on our own or through collaborations with partners, we may not be successful in commercializing any approved drugs.
- If physicians and patients do not adopt our products, if approved, or if the market size for indications for which any product candidate is approved is smaller than expected, we may be unable to achieve forecasted revenues, if any.
- If product liability lawsuits are successfully brought against us or any of our collaborative partners, we may incur substantial liabilities and may be required to limit commercialization of our products.
- If we fail to develop and commercialize other product candidates, we may be unable to generate revenues.
- We seek to partner with third-party collaborators with respect to aspects of the development and commercialization of our product candidates and we may not succeed in establishing and maintaining collaborative relationships, which may significantly limit our ability to develop and commercialize our product candidates successfully, if at all.
- 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.
- Ownership of our ADSs and/or ordinary shares involves a high degree of risk.
- The rights of our shareholders may differ from the rights typically offered to shareholders of a U.S. corporation.

Risks Relating to Our Financial Position and Our Business

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

We do not expect to generate revenue or profitability that is necessary to finance our operations in the short term. We incurred net losses of \$10.0 million and \$17.7 million for the years ended December 31, 2023 and 2022, respectively, and \$13.1 million and \$3.0 million for the six months ended June 30, 2024 and 2023, respectively. As of June 30, 2024, we have not yet generated revenues and had an accumulated deficit of \$240.6 million. Losses have principally resulted from costs incurred for manufacturing, preclinical studies and clinical trial activities and general and administrative expenses. We have funded our operations primarily through the private placement and public offering of equity securities.

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

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

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

The report of our U.S. independent registered public accounting firm on our consolidated financial statements for the period ended December 31, 2023, includes an explanatory paragraph raising substantial doubt about our ability to continue as a going concern as a result of our recurring losses from operations and net capital deficiency. Our future is dependent upon our ability to obtain financing in the future. This opinion could materially limit our ability to raise funds. As of the date of this report, we expect our existing cash to be sufficient to fund our operations into the fourth quarter of 2024. If we fail to raise sufficient capital when needed, we will not be able to complete our business plan. As a result, we may have to liquidate our business and investors may lose their investment in our ADSs.

If the conditions to closing are not met, we may not be able to consummate our planned merger with Peak Bio.

In March 2024, we entered into an Agreement and Plan of Merger (the "Merger Agreement") with Peak Bio, Inc. ("Peak Bio") and Pegasus Merger Sub, Inc. ("Merger Sub"), pursuant to which, upon the terms and subject to the conditions thereof, Merger Sub will be merged with and into Peak Bio (the "Merger"), with Peak Bio surviving the Merger as our wholly-owned subsidiary. Consummation of the Merger is subject to various conditions, including, among others, (i) approval of the Merger Agreement and Merger by Peak Bio stockholders, (ii) Akari's shareholders authorizing Akari's board of directors to allot all Akari ordinary shares to be issued in connection with the Merger (to be represented by Akari ADSs), (iii) the absence of any law or order prohibiting consummation of the Merger, (iv) Akari's Registration Statement on Form S-4 having been declared effective, (v) the Akari ADSs issuable to Peak Bio stockholders having been authorized for listing on the Nasdaq Stock Market, and (vi) private placement financings shall have been consummated simultaneously with, and conditioned only upon, the occurrence of the closing, and shall result in net proceeds to Akari of at least \$10 million. We cannot guarantee that all of the closing conditions to the Merger will be satisfied or waived. If the closing conditions are not satisfied or waived, the Merger may not occur, or may be delayed and such delay may cause us to lose some or all of the intended benefits of the Merger.

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

The process of integrating our operations with Peak Bio could encounter unexpected costs and delays, which include:

- failure to implement our business plans for the combined businesses;
- unexpected losses of key employees, manufacturers or suppliers;
- diversion of management’s attention from other business concerns;
- adverse effects on our or Peak Bio’s existing business relationships;
- unanticipated expenses and liabilities.

If we are unable to timely and effectively integrate our operations with Peak Bio, the anticipated cost savings, growth opportunities and other synergies of the Merger may not be realized fully or at all, or may take longer to realize than expected, which would adversely affect our business. Further, even if the integration is timely and effective, we cannot guarantee our integration efforts as a result of the Merger and the related transactions will not impair shareholder value or otherwise adversely affect our results of operation and business prospects.

Recent adjustments to our operating plans, including our pipeline prioritization and reduction-in-force may not be successful.

In connection with the Merger, in May 2024, we announced the completion of a joint pipeline prioritization review pursuant to which the anticipated combined entity, following completion of the Merger, will focus on Peak Bio’s antibody drug conjugate (“ADC”) platform technology and our PASylated-nomacopan (“PAS-nomacopan”) for treatment of geographic atrophy (“GA”) secondary to dry age-related macular degeneration (“dry AMD”). As a result, our HSCT-TMA program was suspended, with enrollment in our pediatric clinical study discontinued due to cost and timeline. Following closing of the Merger, we plan to work closely with the U.S. Food and Drug Administration (“FDA”) to define the best path for this technology and consider the opportunity for partnership and licensing, specifically as it relates to the potential eligibility for a priority review voucher in connection with future marketing applications for nomacopan, including as a treatment for pediatric HSCT-TMA.

Following the announcement of our pipeline prioritization, we implemented a reduction-in-force (“RIF”) of approximately 67% of our total workforce, including members of senior management, as part of an operational restructuring plan to reduce HSCT-TMA related operating costs, while also supporting the execution of our long-term strategic plan. The RIF may result in unintended consequences and costs, such as the loss of institutional knowledge and expertise, attrition beyond the intended number of employees, decreased morale among our remaining employees, and the risk that we may not achieve the anticipated benefits of the RIF. In addition, while we have key talent necessary to run our operations, we may be unsuccessful in distributing the duties and obligations of departed employees among our remaining employees. The RIF could also make it difficult for us to pursue, or prevent us from pursuing, new opportunities and initiatives due to insufficient personnel, or require us to incur additional and unanticipated costs to hire new personnel to pursue such opportunities or initiatives. If we are unable to realize the anticipated benefits from the RIF, or if we experience significant adverse consequences from the RIF, our business, financial condition, and results of operations may be materially adversely affected.

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

As of June 30, 2024, we had cash of approximately \$4.2 million. We believe we do not have sufficient funds to fund our operations for the next twelve months as of the filing of this Quarterly Report on Form 10-Q. We will require additional capital in order to develop and commercialize our current product candidates or any product candidates that we acquire, if any. There is no assurance that additional funds will be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available on a timely basis, we may be required to terminate or delay development for one or more of our product candidates, which raises substantial doubt about our ability to continue as a going concern. The report from our U.S. independent registered public accounting firm

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

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

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

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

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

We may not be able to complete a divestiture or strategic partnership for nomacopan.

We have discontinued clinical development of nomacopan in HSCT-TMA and are evaluating strategic partnering options for the product candidate, including divestiture. We cannot predict if any such arrangement would be available at all or whether they would be available on commercially reasonable terms. If we are unable to enter into any such arrangement on acceptable terms or at all, we may not be able to generate much, if any, value from this asset.

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

We will need to raise additional capital, including the PIPE Investment (as defined in the Merger Agreement) resulting in net proceeds to the Company of at least \$10 million which is required as a condition to close the Merger. In any financing transaction, we may sell ordinary shares or ADSs, convertible securities or other equity securities. To the extent that we raised additional funds by issuing equity securities, our shareholders may experience significant dilution. To the extent that we raise additional capital through the sale of equity or convertible debt securities by any other means, existing ownership interests will be diluted. The sale of a substantial number of ADSs, or anticipation of such sales, could cause the trading price of our ADSs to decline or make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise desire.

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

Our business is dependent on our ability to advance our current and future product candidates through preclinical studies and clinical trials, obtain marketing approval, and ultimately commercialize them.

Although we previously conducted clinical trials for nomacopan, all of our current product candidates are in preclinical development. We expect to file an Investigational New Drug (“IND”) application for our lead product candidate, PAS-nomacopan for the treatment of GA, in 2025. Additionally, we are actively engaged in a number of earlier stage discovery programs that may never advance to clinical-stage development. Our ability to generate product revenue, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our product candidates, which may never occur. We currently generate no revenue from product sales and we may never be able to develop or commercialize a marketable product.

Each of our product candidates will require additional preclinical and/or clinical development, regulatory approval in multiple jurisdictions, obtaining manufacturing supply, capacity and expertise, building a commercial organization, or successfully outsourcing commercialization, substantial investment, and significant marketing efforts before we generate any revenue from product sales. Our product candidates must be authorized for marketing by the FDA, or certain other foreign regulatory agencies before we may commercialize our product candidates.

The clinical and commercial success of PAS-nomacopan is subject to a number of risks, including the following:

- we may not have sufficient financial and other resources to complete the necessary preclinical studies and clinical trials for PAS-nomacopan and other future product candidates;
- we may be unable to submit an IND application for PAS-nomacopan on our expected timelines, or such IND may not be cleared by the FDA without additional preclinical studies or at all;
- we may not be able to obtain adequate evidence of efficacy and safety for PAS-nomacopan;
- we do not know the degree to which PAS-nomacopan will be adopted by the market, even if approved;
- in our clinical programs, we may experience difficulty in enrollment, adjustments to clinical trial protocols or the need for additional clinical trial sites, which could delay our clinical trial progress;
- our reliance on a sole manufacturer to supply drug substance and a sole manufacturer to provide drug product formulation of PAS-nomacopan that is being used in our preclinical studies or future clinical trials may negatively impact the availability of our drug product;
- we may encounter disruptions in the supply chain of PAS-nomacopan which could negatively impact our ability to supply our drug product to clinical trial sites, delaying future clinical studies;
- the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA, MHRA, EMA or comparable foreign regulatory bodies for marketing approval;

- patients in our clinical trials may die or suffer other adverse effects for reasons that may or may not be related to PAS-nomacopan, which could delay or prevent further clinical development;
- the standards implemented by clinical or regulatory agencies may change at any time;
- the FDA, MHRA, EMA or comparable foreign regulatory agencies may require efficacy endpoints for a clinical trial that differ from the endpoints of our current or future trials, which may require us to conduct additional clinical trials;
- the mechanism of action of PAS-nomacopan is complex and we do not know the degree to which it will translate into a medical benefit in certain indications; and
- we may not be able to obtain, maintain or enforce our patents and other intellectual property rights.

Of the large number of drugs in development in the pharmaceutical industry, only a small percentage results in the submission of a new drug application (“NDA”), or biologics license application (“BLA”) to the FDA, or a marketing authorization application (“MAA”) to the EMA and even fewer are approved for commercialization. Furthermore, even if we do receive marketing authorization to market PAS-nomacopan, any such approval may be subject to limitations on the indicated uses or patient populations for which we may market the product. Accordingly, even if we are able to obtain the requisite financing to continue to fund our development programs, we cannot assure that PAS-nomacopan will be successfully developed or commercialized. If we or any of our future development partners are unable to develop, or obtain marketing authorization for, or, if approved, successfully commercialize PAS-nomacopan, we may not be able to achieve forecasted revenues.

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

We may not be able to initiate clinical trials required by the FDA, MHRA, EMA or other foreign regulatory agencies for PAS-nomacopan or other future product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these clinical trials. We will be required to identify and enroll a sufficient number of patients for our clinical trials of PAS-nomacopan and other future product candidates. To date, 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.

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 specialist physicians that treat patients with these diseases;
- ability to identify and enroll such patients with a stage of disease appropriate for our ongoing or future clinical trials;

- the costs of finding and diagnosing patients;
- patient referral practices of physicians; and •our ability to monitor patients adequately during and after treatment.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

PAS-nomacopan has not yet received marketing authorization for the treatment of any indications, and unexpected problems may arise that could cause us to delay, suspend or terminate our development efforts. To date, we have not yet begun clinical trials for PAS-nomacopan, which will be required to obtain marketing authorization and the long-term safety consequences of PAS-nomacopan is not known. Marketing authorization of product candidates such as PAS-nomacopan can be more expensive and take longer than approval of previously approved products.

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

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

If a product that has orphan drug designation subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan product

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

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

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

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

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

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

In order to market any products in a country, we must establish and comply with numerous and varying regulatory requirements regarding clinical trial design, safety and efficacy. Clinical trials conducted in one country

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

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

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

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

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

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

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

We are also exposed to the risk of employees, independent contractors, principal investigators, consultants, commercial partners or vendors engaging in fraud or other misconduct. Misconduct by employees, independent contractors, principal investigators, consultants, commercial partners and vendors could include intentional failures to comply with United Kingdom (“UK”) or European Union (“EU”) regulations, to provide accurate information to the UK, EMA or EU Member States authorities or to comply with manufacturing or quality standards we have or will have established. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices such as promotion of products by medical practitioners. Of general application are the European Anti-Fraud Office Regulation 883/2013, and the UK Bribery Act 2010. Under the latter, a commercial organization can be guilty of the offence if the bribery is carried out by an employee, agent, subsidiary, or another third-party, and the location of the third-party is irrelevant to the prosecution. The advertising of medicinal products in the EU is

regulated by Title VIII of European Directive 2001/83/EC. The corresponding UK legislation is Part 14 of the Human Medicines Regulations 2012 (S.I. 2012/1916 as amended). Such laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct could also involve the improper use of information obtained in the course of clinical studies, which could result in regulatory sanctions and serious and irreparable harm to our reputation.

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

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

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

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

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

Risks Related to our Intellectual Property

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

Our commercial success depends in part on our ability to obtain and maintain patent protection and trade secret protection in the U.S. and other countries for our product candidates, proprietary technologies, and their uses as well as our ability to operate without infringing upon the proprietary rights of others. We can provide no assurance that our patent applications or those of our licensors will result in additional patents being issued or that issued patents will afford sufficient protection against competitors with similar technologies, nor can there be any assurance that the patents issued will not be infringed, designed around or invalidated by third parties. Even issued patents may later be found unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. The degree of future protection for our proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep competitive advantage. We have issued method-of-use patents in the United States and other countries for methods of treatment of various specific indications using PAS-nomacopan, but we cannot be certain that the claims in our issued patents will not be found invalid or unenforceable if challenged. We cannot be certain that the claims in any patent applications covering 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 patents will not be found invalid or unenforceable if challenged. 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. 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.

Our issued patents for methods of using PAS-nomacopan are expected to expire at various dates from 5th September 2026 to 20th April 2038 (excluding any patent term adjustment or potential patent term extension). Our pending patent applications for methods of using PAS-nomacopan, if issued, are expected to expire at various dates from 10th September 2027 up to 4th March 2040 (excluding any potential patent term adjustment or extension).

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

- the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case;
- patent applications may not result in any patents being issued;

- patents that may be issued or in-licensed may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;
- patents have a finite term and thus may expire before the technologies they protect are approved or marketed and thus may not provide any competitive advantage. For example, issued method-of-use patents for the PAS-nomacopan product candidate will expire at various dates from 5th September 2026 to 20th April 2038 (excluding any patent term adjustment or extension);
- our competitors, many of whom have substantially greater resources and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use, and sell our potential product candidates;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns;
- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates; and
- some countries in Europe and China have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we, or any of our licensors, are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired and our business, financial condition and results of operations may be adversely affected.

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

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

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

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

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and exploiting patents in the biopharmaceutical industry involve both technological and legal complexity. Therefore, obtaining and exploiting biopharmaceutical patents is costly, time-consuming and inherently uncertain. For example, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. These rulings have created uncertainty with respect to the validity and enforceability of patents, even once obtained. Depending on future actions and decisions by the U.S. Congress, the federal courts, and the U.S. Patent and Trademark Office, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we may obtain in the future.

Risks Related to our Business Operations

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

We currently have no marketing, sales or distribution capabilities. If PAS-nomacopan or other product candidates we may pursue in the future are approved, we intend either to establish a sales and marketing organization with technical expertise and supporting distribution capabilities to commercialize such products, or to outsource this function to a third party. Either of these options could be expensive and time-consuming. Some of these costs may be incurred in advance of any approval of PAS-nomacopan or other product candidates. 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 PAS-nomacopan and/or other future product candidates, if and when approved by the FDA.

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

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

As of August 9, 2024, we had 7 employees, 6 of which are full-time. Our limited financial resources have led us to focus on the development of nomacopan and to manage and operate our business in a highly efficient manner. We cannot make assurances that we will be able to hire and/or retain adequate staffing levels to develop PAS-nomacopan or other product candidates we may pursue following the Merger or run our operations and/or to accomplish all of the objectives that we otherwise would seek to accomplish.

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

We are engaged in a rapidly evolving field. Competition from other pharmaceutical companies, biotechnology companies and research and academic institutions is intense and likely to increase. Many of those companies and institutions have substantially greater financial, technical and human resources than us. Those companies and institutions also have substantially greater experience in developing products, conducting clinical trials, obtaining marketing authorization and in manufacturing and marketing biologic products. Our competitors may succeed in obtaining marketing authorization for their products more rapidly than we do. Competitors have developed or are in the process of developing technologies that are, or in the future may be, the basis for competitive

products. Our competitors may succeed in developing products that are more effective than those we are developing, or that would render our product candidates less competitive or even obsolete. In addition, one or more of our competitors may achieve product commercialization or patent protection, which could materially adversely affect our business.

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

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

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

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

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

Healthcare providers, physicians and others will play a primary role in the recommendation and prescription of our product candidates, if approved. Our future arrangements with third-party payors will expose us broadly to applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our product candidates, if we obtain marketing approval. In addition, we may be subject to patient privacy regulation by both the federal government and the states or other countries in which we conduct our business. For more information, see the section of our Annual Report on Form 10-K titled “*Business - U.S. Healthcare Reform and Other Healthcare Laws.*”

Ensuring that our future business arrangements with third parties comply with applicable healthcare laws and regulations could be costly. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations, including anticipated activities to be conducted by our sales team, were found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines and exclusion from government funded healthcare programs, such as Medicare and Medicaid, any of which could substantially disrupt our operations and would materially adversely affect our business, financial condition and results of operations. If any of the physicians or other providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs, which could have a material adverse effect on our business, results of operations, financial condition and prospects.

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

The commercial potential for our product candidates, if any, could be affected by changes in healthcare spending and policy in the United States and abroad. We operate in a highly regulated industry. New laws, regulations or judicial decisions or new interpretations of existing laws, regulations or decisions, related to healthcare availability, the method of delivery or payment for healthcare products and services could adversely affect our business, operations and financial condition. The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that may affect our ability to profitably sell our product and product candidates, if approved. The United States government, state legislatures and foreign governments also have shown significant interest in implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. The pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. Previously, in March 2010, the PPACA was enacted, which was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Healthcare reform initiatives recently culminated in the enactment of the IRA, which, among other things, allows HHS to directly negotiate the ceiling price of a statutorily specified number of drugs and biologic each year that receive reimbursement under Medicare Part B and Part D, requires the payment of rebates on Medicare Part B and Part D drugs whose prices have increased at a rate faster than the rate of inflation, and redesign the Medicare Part D cost sharing structure, including revising manufacturer financial liability for covered products. For more information, see the section of our Annual Report on Form 10-K titled “Business - U.S. Healthcare Reform and Other Healthcare Laws.”

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

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

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

The United States and several foreign jurisdictions are considering, or have already enacted, a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell future products profitably. There is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access to healthcare. In the United States, the pharmaceutical industry has been a particular focus of these efforts. We may experience pricing pressures in connection with the sale of any products that we develop due to the trend toward managed healthcare, increasing influence of health maintenance organizations and additional legislative proposals. See the section of our Annual Report on Form 10-K titled, “Business - Pharmaceutical Pricing & Reimbursement.”

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

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

- decreased demand for any of our future approved products;
- injury to our reputation;
- withdrawal of clinical trial participants;
- termination of clinical trial sites or entire trial programs;
- significant litigation costs;
- substantial monetary awards to or costly settlements with patients or other claimants;
- product recalls or a change in the indications for which they may be used;
- loss of revenue;
- diversion of management and scientific resources from our business operations; and
- the inability to commercialize any approved drugs.

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

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

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

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

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

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

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

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

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

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

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

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

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

Our growth and success also depend on our ability to attract and retain additional highly qualified scientific, clinical, technical, sales, managerial and finance personnel. We are currently conducting a search for a permanent Chief Executive Officer. We experience intense competition for qualified personnel, and the existence of non-competition agreements between prospective employees and their former employers may prevent us from hiring those individuals or subject us to suit from their former employers. In addition, if we elect to independently commercialize any approved drug, we will need to expand our marketing and sales capabilities. While we attempt to provide competitive compensation packages to attract and retain key personnel, many of our competitors are likely to have greater resources and more experience than we have, making it difficult for us to compete successfully for key personnel. If we cannot attract and retain sufficiently qualified technical employees on acceptable terms, we may not be able to develop and commercialize products. Further, any failure to effectively integrate new personnel could prevent us from successfully growing our company.

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

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

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

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

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

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

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

Risks Related to Our Reliance on Third Parties

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

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

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

- may shift its priorities and resources away from our product candidates due to a change in business strategies, or a merger, acquisition, sale or downsizing;
- may seek to renegotiate or terminate their relationships with us due to unsatisfactory clinical results, manufacturing issues, a change in business strategy, a change of control or other reasons;
- may cease development in therapeutic areas which are the subject of our strategic collaboration;
- may not devote sufficient capital or resources towards our product candidates;
- may change the success criteria for a drug candidate thereby delaying or ceasing development of such candidate;
- experiences significant delays in initiating certain development activities, which will also delay payment of milestones tied to such activities, thereby impacting our ability to fund our own activities;
- develops a product that competes, either directly or indirectly, with our drug candidate;
- may not commit sufficient financial or human resources to the marketing, distribution or sale of our product;
- may encounter regulatory, resource or quality issues and be unable to meet demand requirements;
- may exercise a contractual right to terminate a strategic alliance;

- has a dispute arise concerning the research, development or commercialization of a drug candidate resulting in a delay in milestones, royalty payments or termination of an alliance and possibly resulting in costly litigation or arbitration which may divert management attention and resources; and
- may use our products or technology in such a way as to invite litigation from a third party.

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

If the third parties on which we rely for our future 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 will heavily rely on third-party contract research organizations to conduct and/or oversee the clinical trials of our product candidates. Nonetheless, we will be responsible for confirming that each of our clinical trials is conducted in accordance with the FDA's, MHRA's and/or EMA's requirements and its general investigational plan and protocol.

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

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

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

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

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

- reliance on third-parties for manufacturing process development, regulatory compliance and quality assurance, which may result in delays or inadequate supply of product;
- limitations on supply availability resulting from capacity and scheduling constraints of third-parties;
- limitation on supply availability due to difficulties in sourcing raw materials;
- the possible breach of manufacturing agreements by third-parties because of factors beyond our control;
- the possible termination or non-renewal of the manufacturing agreements by the third-party, at a time that is costly or inconvenient to us; and
- delays associated with the lack of availability of staff at third-party manufacturers.

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

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

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

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

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

Manufacturing methods and formulation are sometimes altered through the development of drug candidates from clinical trials to approval, and further to commercialization, in an effort to optimize manufacturing processes and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause the drug candidates to perform differently and affect the results of future clinical trials conducted with the altered materials. This could delay the commercialization of any approved drugs and require bridging studies or

the repetition of one or more clinical trials, which may result in increases in clinical trial costs, delays in drug approvals and may jeopardize our ability to commence product sales and generate revenue.

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

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

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

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

Risks Related to our Ordinary Shares and ADSs

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

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

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

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

On April 5, 2024, we received a letter (“Letter”) from the Listing Qualifications Staff (the “Staff”) of The Nasdaq Capital Market (“Nasdaq”) notifying us that our shareholders’ equity as reported in our Annual Report on Form 10-K for the year ended December 31, 2023 was not in compliance with the Minimum Equity Requirement. Our shareholders’ deficit as of December 31, 2023 was approximately \$0.2 million. The Letter does not have an immediate impact on the listing of our ADSs on Nasdaq. As of June 30, 2024, we had a shareholders’ deficit of \$3.7

million and therefore is still not in compliance with the Minimum Equity Requirement. In accordance with the Nasdaq Listing Rules, on May 20, 2024, we submitted a plan to regain compliance with the Minimum Equity Requirement (the “Compliance Plan”) for the Staff’s consideration. On August 5, 2024, we were notified by the Staff that we have been granted an extension until September 30, 2024 to comply with the Compliance Plan and evidence compliance with the Minimum Equity Requirement.

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

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

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

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

More recently, the closures of SVB and Signature Bank and their placement into receivership with the FDIC created bank-specific and broader financial institution liquidity risk and concerns. Although the Department of the Treasury, the Federal Reserve and the FDIC jointly released a statement that depositors at SVB and Signature Bank would have access to their funds, even those in excess of the standard FDIC insurance limits, under a systemic risk exception, future adverse developments with respect to specific financial institutions or the broader financial services industry may lead to market-wide liquidity shortages, impair the ability of companies to access near-term working capital needs, and create additional market and economic uncertainty. There can be no assurance that future credit and financial market instability and a deterioration in confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, liquidity shortages, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, or if adverse developments are experienced by financial institutions, it may cause short-term liquidity risk and also make any necessary debt or equity financing more difficult, more costly, more onerous with respect to financial and operating covenants and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to alter our operating plans. In addition, there is a risk that one or more of our service providers, financial institutions, manufacturers, suppliers and other partners may be adversely affected by the foregoing risks, which could directly affect our ability to attain our operating goals on schedule and on budget.

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

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

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

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

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

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

- sales or potential sales of substantial amounts of our ordinary shares or ADSs;
- delay or failure in initiating, enrolling, or completing clinical trials or unsatisfactory results of these trials or events reported in any of our current or future clinical trials;
- announcements about us or about our competitors, including clinical trial results, marketing authorizations or new product introductions;
- a serious adverse event in a clinical trial and/or a long-term safety issue;
- developments concerning our licensors or product manufacturers;

- litigation and other developments relating to our patents or other proprietary rights or those of our competitors;
- conditions in the pharmaceutical or biotechnology industries;
- variations in our anticipated or actual operating results;
- governmental regulation and legislation, actual or anticipated;
- change in securities analysts' estimates of our performance, or our failure to meet analysts' expectations;
- whether, to what extent and under what conditions the FDA, MHRA or EMA will permit us to continue developing our product candidates, if at all, and if development is continued, any reports of safety issues or other adverse events observed in any potential future studies of these product candidates;
- adverse publicity;
- our ability to enter into new collaborative arrangements with respect to our product candidates;
- the terms and timing of any future collaborative, licensing or other arrangements that we may establish;
- our ability to raise additional capital to carry through with our clinical development plans and current and future operations and the terms of any related financing arrangements;
- the timing of achievement of, or failure to achieve, our and any potential future collaborators' clinical, regulatory and other milestones, such as the commencement of clinical development, the completion of a clinical trial or the receipt of marketing authorization;
- announcement of FDA, MHRA or EMA approval or non-approval of our product candidates or delays in or adverse events during the FDA, MHRA or EMA review process;
- actions taken by regulatory agencies with respect to our product candidates or products, our preclinical studies or 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;
- unanticipated problems in the supply of the raw materials used to produce our product candidates;
- the commercial success of any product approved by the FDA, MHRA, EMA or any other foreign counterpart;
- introductions or announcements of technological innovations or new products by us, our potential future collaborators, or our competitors, and the timing of these introductions or announcements;
- market conditions for equity investments in general, or the biotechnology or pharmaceutical industries in particular;
- we may have limited or very low trading volume that may increase the volatility of the market price of our ADSs;
- regulatory developments in the United States and foreign countries;
- changes in the structure or reimbursement policies of health care payment systems;
- any intellectual property infringement lawsuit involving us;
- actual or anticipated fluctuations in our results of operations;
- changes in financial estimates or recommendations by securities analysts;
- hedging activity that may develop regarding our ADSs;
- regional or worldwide recession;
- sales of our ordinary shares or ADSs by our executive officers, directors and significant shareholders;

- managerial costs and expenses;
- changes in accounting principles or practices;
- the loss of any of our key scientific or management personnel; and
- natural disasters and political and economic instability, including wars, terrorism, political unrest, results of certain elections and votes, emergence of a pandemic, or other widespread health emergencies (or concerns over the possibility of such an emergency, including for example, a resurgence of COVID-19), boycotts, adoption or expansion of government trade restrictions, and other business restrictions.

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

In the past, class action litigation has often been instituted against companies whose securities have experienced periods of volatility in market price. Any such litigation brought against us, could result in substantial costs, which could hurt our financial condition and results of operations and divert management's attention and resources, which could result in delays of our preclinical studies, 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 August 9, 2024, our directors and executive officers, together with their affiliates and related persons, beneficially own, in the aggregate, approximately 33.3% of our outstanding ordinary shares. Our Chairman, Dr. Ray Prudo, and director, Dr. Samir Patel, each beneficially own approximately 18.6% and 14.5% of our outstanding ordinary shares, respectively. Accordingly, these shareholders, if acting together, or Dr. Prudo or Dr. Patel, each individually, may have the ability to impact the outcome of matters submitted to our shareholders for approval, including the election and removal of directors and any merger, consolidation, or sale of all or substantially all of our assets. In addition, these persons may have the ability to influence the management and affairs of our Company. Accordingly, this concentration of ownership may harm the market price of our ADSs by:

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

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

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

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

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

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

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

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

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

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

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

As of January 1, 2024, we were no longer a foreign private issuer, and we are required to comply with all of the provisions applicable to a U.S. domestic issuer under the Exchange Act, including filing an annual report on Form 10-K, quarterly periodic reports and current reports for certain events, complying with the sections of the

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

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

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

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

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

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

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

We are incorporated under English law. The rights of holders of ordinary shares and, therefore, certain of the rights of holders of ADSs, are governed by English law, including the provisions of the Companies Act, and by

our Articles of Association. These rights differ in certain respects from the rights of shareholders in typical U.S. corporations.

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

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

If at the time of a takeover offer the Takeover Panel determines that we have our place of central management and control in the United Kingdom, we will be subject to a number of rules and restrictions, including but not limited to the following: (1) our ability to enter into deal protection arrangements with a bidder will be extremely limited; (2) we may not, without the approval of our shareholders, be able to perform certain actions that could have the effect of frustrating an offer, such as issuing shares or carrying out acquisitions or disposals; and (3) we will be obliged to provide equality of information to all bona fide competing bidders.

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

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

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

are not voted as they requested. In addition, in the capacity as an ADS holder, they will not be able to call a shareholders' meeting.

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

ADSs are transferable on the books of the depository. However, the depository 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 depository may refuse to deliver, transfer or register transfers of ADSs generally when our books or the books of the depository are closed, or at any time if we or the depository 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 depository 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 depository 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 depository may, at its discretion, decide that it is inequitable or impractical to make a distribution available to any holders of ADSs. For example, the depository 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 depository may decide not to distribute such property and holders of our ADSs will not receive any such distribution.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

During the three months ended June 30, 2024, we did not have any sales of unregistered securities, other than as previously disclosed in a Quarterly Report on Form 10-Q filed with the SEC on May 15, 2024 and a Current Report on Form 8-K filed with the SEC on June 4, 2024.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

None.

Item 5. Other Information.

None of our directors or “officers,” as defined in Rule 16a-1(f) under the Securities Exchange Act of 1934, adopted or terminated a Rule 10b5-1 trading plan or arrangement or a non-Rule 10b5-1 trading plan or arrangement, as defined in Item 408(c) of Regulation S-K, during the fiscal quarter covered by this report.

Side Letter Agreement to Merger Agreement

On August 15, 2024, the parties to the Merger Agreement entered into a Side Letter Agreement (the “Amendment”) pursuant to which the parties agreed to extend the date by which if the Merger is not consummated, either we or Peak Bio may terminate the Merger Agreement, from September 4, 2024 to December 2, 2024.

The foregoing description of the Amendment is not complete and is subject to and qualified in its entirety by reference to the Amendment, a copy of which is filed with this Quarterly Report on Form 10-Q as Exhibit 10.5 and the terms of which are incorporated herein by reference.

Item 6. Exhibits.

<u>Exhibit Number</u>	<u>Description</u>
4.1	Form of Series C Warrant (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).
4.2	Form of Placement Agent Warrant (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).
10.1	Form of Securities Purchase Agreement, dated May 29, 2024, by and among Akari Therapeutics, Plc and the purchasers party thereto (incorporated by reference to Exhibit 10.1 to Registrant's Current Report on Form 8-K, as filed with the SEC on June 4, 2024).
10.2†	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).
10.3*	Form of Convertible Promissory Note, dated May 10, 2024, by and between Akari Therapeutics, Plc and the purchasers party thereto.
10.4†	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).
10.5*	Side Letter Agreement, dated August 15, 2024, by and among Akari Therapeutics, Plc, Pegasus Merger Sub, Inc. and Peak Bio, Inc.
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.
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	Inline 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.

** This certification is not deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to the liability of that section. Such certification will may not be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934, except to the extent that the Registrant specifically incorporates it by reference.

† 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

Date: August 19, 2024

By:

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

Samir R. Patel, M.D.

Interim President, Chief Executive Officer and Director

Date: August 19, 2024

By:

/s/ Wendy DiCicco

Wendy DiCicco

Interim Chief Financial Officer

THIS NOTE AND THE SECURITIES ISSUABLE UPON THE CONVERSION HEREOF HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED. THEY MAY NOT BE SOLD, OFFERED FOR SALE, PLEDGED, HYPOTHECATED, OR OTHERWISE TRANSFERRED EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR AN OPINION OF COUNSEL SATISFACTORY TO MAKER THAT REGISTRATION IS NOT REQUIRED UNDER SUCH ACT OR UNLESS SOLD PURSUANT TO RULE 144 UNDER SUCH ACT.

PROMISSORY NOTE

\$500,000

May 10, 2024

For value received, Akari Therapeutics, plc, a company incorporated in England and Wales with registered number 05252842 (“Maker”), hereby promises to pay to [], an individual with his principal address at [] and his heirs, successors or assigns as indicated in the Register (as defined below) (“Payee”), the aggregate principal sum of Five Hundred Thousand and 00/100 Dollars (\$500,000.00), plus any interest accrued thereon from time to time in accordance with Section 2(a) hereof, in the amounts and on the dates set forth in this Promissory Note (this “Note”).

1. Payment of Principal. Maker shall pay the principal balance of this Note to Payee on the first to occur of (a) the date falling ten (10) Business Days after Maker receives payment in respect of a research and development tax credit from HM Revenue and Customs, and (b) the date that is six (6) months following the date of this Note (the “Maturity Date”).

2. Interest Rate; Payment of Interest.

(a) The principal amount outstanding under this Note shall accrue interest at a fixed rate equal to fifteen percent (15.0%) per annum; provided that upon the occurrence and during the continuance of an Event of Default under Section 5(a)(i) of this Note, the principal amount outstanding under this Note shall, if Payee so notifies Maker in writing, accrue interest at a fixed rate equal to seventeen percent (17.0%) per annum. Interest shall accrue on the outstanding principal of this Note until all outstanding principal of and other amounts under this Note have been paid in full. Interest shall be computed on the basis of a 365-day year for the actual number of days elapsed including the date of this Note and excluding the date of repayment.

(b) Any repayment or prepayment under this Note (including any repayment of the Note on the Maturity Date) shall be made with accrued and unpaid interest on the then-outstanding principal amount of this Note.

3. Voluntary Prepayment. Maker may prepay, in whole or in part, the outstanding principal balance of this Note, without premium or penalty, provided that Maker shall provide Payee at least two (2) business days’ prior written notice. In this Note, “business day” means a means any day other than Saturday or Sunday or public holiday under the laws of the State of New York or other day on which banking institutions are authorized or obligated to close in New York, New York.

4. Optional Conversion.

(a) Subject to the terms and conditions hereof, Payee, at its sole option, may deliver to Maker a notice, in the form attached hereto as Exhibit A (a “Conversion Notice”), at any time and from time to time after the date hereof and prior to the payment of the principal amount and all accrued interest

thereon (but in any event not later than ten (10) Business Days prior to the closing of the transactions contemplated by that certain Agreement and Plan of Merger, dated as of March 4, 2024, by and between Maker, Pegasus Merger Sub, Inc., and Peak Bio, Inc. (the “Merger Agreement”), to convert all or any portion of the outstanding principal balance of this Note, together with any unpaid accrued interest thereunder (the “Conversion Amount”), into Maker’s American Depository Shares representing two thousand (2,000) Parent Ordinary Shares (the “Conversion Shares”) at a conversion price (“Conversion Price”) equal to \$1.59 (which Conversion Price is not less than the “Minimum Price” as specified by Nasdaq Rule 5635(d) as of the execution date of this Note) (the “Conversion”). The number of Conversion Shares issued to Payee on the Conversion shall be equal to the quotient obtained by dividing the Conversion Amount by the Conversion Price. Notwithstanding the foregoing, Payee may not convert an outstanding principal amount of this Note or accrued and unpaid interest thereon to the extent such conversion would require Maker to issue ordinary shares in excess of Maker’s then sufficient authorized and unissued allotment of ordinary shares.

(b) Not later than three (3) trading days after the Conversion Date; provided that a conversion notice on any such date is received prior to 12 p.m. EST and for notices received after 12 p.m. EST, then on the fourth Trading Day (the “Delivery Date”), Maker will deliver to Payee a certificate or certificates or evidence of book-entry notation representing the number of Conversion Shares being acquired upon the Conversion (subject to the limitations set forth in Section 3 hereof). Payee agrees to execute and become party to all agreements that Maker reasonably requests in connection with the Conversion that all other holders of the Conversion Shares are or have been required to execute and become party.

(c) On Conversion, Payee shall surrender this Note to Maker (if in Payee’s possession or control). Maker shall not be required to issue or deliver any Conversion Shares until Payee has surrendered this Note (if in Payee’s possession or control) and delivered it to Maker. If Conversion would result in the issuance of any fractional shares, Maker shall, in lieu of issuance of any fractional shares, pay Payee a sum in cash equal to the product of the then current fair market value of one Conversion Share by such fraction.

5. Defaults. Each of the following conditions, events or circumstances is an “Event of Default”: (a) Maker fails to pay (i) any principal required to be paid hereunder within three business days of its due date, or (ii) any interest required to be paid hereunder within seven business days of its due date; (b) an involuntary case against Maker under any applicable bankruptcy or insolvency law seeking to have an order for relief entered with respect to it, or seeking to adjudicate it as bankrupt or insolvent, or seeking reorganization, arrangement, adjustment, winding-up, liquidation, dissolution, composition or other relief with respect to it or its debts commences and is not dismissed, discharged or bonded on or before the date that is sixty (60) days after its commencement; (c) a court with proper jurisdiction enters a decree or order for relief against Maker in an involuntary case under any applicable bankruptcy or insolvency law of a nature referred to in clause (b) above; (d) a court with proper jurisdiction appoints a receiver, liquidator, custodian or trustee for Maker or for any substantial part of Maker’s property with respect to the winding up or liquidation of Maker’s affairs; or (e) Maker commences a voluntary case under any applicable bankruptcy or insolvency law seeking to have an order for relief entered with respect to it, or seeking to adjudicate it as bankrupt or insolvent, or seeking reorganization, arrangement, adjustment, winding-up, liquidation, dissolution, composition or other relief with respect to it or its debts, makes a general assignment for the benefit of Maker’s creditors, consents to the appointment of a receiver, liquidator, custodian or trustee for Maker or for a substantial part of Maker’s property, or consents to the entry of an order for relief against Maker in an involuntary case under any applicable bankruptcy or insolvency law.

6. Consequence of Event of Default. Upon the occurrence and during the continuance of an Event of Default, the entire outstanding principal balance of this Note, together with all accrued and unpaid interest and all other sums payable hereunder shall, at the option of Payee (or automatically with respect to Section 5(b) through (e) of this Note), become immediately due and payable, without any action or election by Payee.

7. Payments. The accounts or records maintained by Payee shall be *prima facie* evidence, absent manifest error, of the amount of outstanding principal under this Note and interest and the interest and payments thereon. Any failure to so record, or any error in doing so, shall not, however, limit the obligation of Maker hereunder to pay any amount owing with respect to this Note. Principal and interest due and payable under this Note shall be paid to Payee in lawful money of the United States of America in immediately available funds at such address as may be specified in a written notice to Maker by Payee or if no address is specified, at Payee's principal place of business. If any payment on this Note is due on a day which is not a business day, such payment shall be made on the next succeeding business day.

8. Interest Rate. If the interest payable under this Note is in excess of the maximum permitted by law, the interest chargeable hereunder shall be reduced to the maximum amount permitted by law.

9. Representations, Warranties and Covenants of Maker. Maker hereby represents and warrants to Payee as follows:

(a) Organization; Subsistence and Qualification. Maker is a corporation duly formed, validly existing and in good standing under the laws of England and Wales. Maker has the requisite power to own and operate its material properties and assets and to carry on its business as now conducted and as presently proposed to be conducted in all material respects. Maker is duly qualified and is authorized to do business and is in good standing as a foreign corporation in all jurisdictions in which the nature of its activities and of its properties makes such qualification necessary, except for those jurisdictions in which failure to do so would not have a material adverse effect with respect to Maker and its consolidated business, operations or assets, taken as a whole (a "Material Adverse Effect").

(b) Corporate Power. Maker has all requisite corporate power to execute and deliver this Note and to carry out and perform its obligations under the terms of this Note.

(c) Authorization. All action on the part of Maker necessary for the authorization of this Note and the execution, delivery and performance of all obligations of Maker under this Note, including the issuance and delivery of this Note pursuant hereto, has been taken or will be taken prior to the issuance of this Note. This Note, when executed and delivered by Maker, shall constitute valid and binding obligations of Maker enforceable in accordance with its terms, subject to laws of general application relating to equitable principles, bankruptcy, insolvency, the relief of debtors and, with respect to rights to indemnity, subject to federal and state securities laws. This Note has been issued in compliance with all applicable federal and state securities laws, and free of any liens or encumbrances.

(d) Litigation. To the knowledge of Maker, there is no action, suit, proceeding, claim, order or investigation pending or threatened in writing against Maker before any court or administrative agency that, if adversely determined, would reasonably be expected to have a Material Adverse Effect. There is no judgment, decree or order against Maker, that would reasonably be expected to prevent, enjoin, or materially alter or delay any of the transactions contemplated by this Note, or that would reasonably be expected to have a Material Adverse Effect.

(e) Governmental Consents. There is no consent or approval required from any federal or state governmental authority on the part of Maker required in connection with the execution, delivery and performance of this Note and the completion of the transactions contemplated by this Note.

(f) Compliance with Other Instruments. Maker is not in violation of any term of its certificate of incorporation or bylaws, or of any provision of any mortgage, indenture or contract to which it is a party and by which it is bound or of any judgment, decree, order or writ, other than such violation(s) that would not have a Material Adverse Effect. The execution, delivery and performance of this Note will not result in any such violation or be in conflict with, or constitute, with or without the passage of time and giving of notice, either a default under any such provision, instrument, judgment, decree, order or writ or an event that results in the creation of any lien, charge or encumbrance upon any assets of Maker or the suspension, revocation, impairment, forfeiture, or nonrenewal of any material permit, license, authorization

or approval applicable to Maker, in each case to an extent that would reasonably be expected to have a Material Adverse Effect. Without limiting the foregoing, Maker has obtained all waivers reasonably necessary with respect to any preemptive rights, rights of first refusal or similar rights, including any notice or offering periods provided for as part of any such rights, in order for Maker to consummate the transactions contemplated hereunder without any third party obtaining any rights to cause Maker to offer or issue any securities of Maker as a result of the consummation of the transactions contemplated hereunder.

(g) No breach of other obligations. Maker is not in violation of any term of, or in default under, any contract, agreement or instrument relating to any indebtedness for borrowed money that would reasonably be expected to result in a Material Adverse Effect.

10. Waivers by Maker. Maker hereby waives: (a) any right to require Payee, as a condition of payment or performance by Maker, to (i) proceed against any guarantor of the Obligations or any other person, entity or group, (ii) proceed against or exhaust any security held from any guarantor or any other person, entity or group, or (iii) pursue any other remedy in the power of Payee whatsoever; (b) any defense arising by reason of the incapacity, lack of authority or any disability or other defense of Maker or any guarantor including any defense based on or arising out of the lack of validity or the unenforceability of the Obligations or any agreement or instrument relating thereto or by reason of the cessation of the liability of Maker or any guarantor from any cause other than payment in full of the Obligations; (c) any defense based upon any statute or rule of law which provides that the obligation of a surety must be neither larger in amount nor in other respects more burdensome than that of the principal; (d) any defense based upon Payee's errors or omissions in the administration of the Obligations, except behavior which amounts to bad faith; (e) (i) any principles or provisions of law, statutory or otherwise, which are in conflict with the terms hereof and any legal or equitable discharge of Maker's obligations hereunder, (ii) any rights to set-offs, recoupments and counterclaims, and (iii) promptness or diligence; (f) notices, demands, presentments, protests, notices of protest, notices of dishonor and notices of any action or inaction, including acceptance hereof, notices of default hereunder or any agreement or instrument related hereto, notices of any renewal, extension or modification of the Obligations, notices of any extension of credit to Maker and notices of any of other matters and any right to consent hereunder to any thereof; and (g) any defenses or benefits derived from or afforded by law which limit the liability of or exonerate guarantors or sureties, or which may conflict with the terms hereof.

11. Exercise of Remedies. No delay or omission on the part of Payee in the exercise of any right or remedy under this Note shall operate as a waiver thereof, and no partial exercise of any right or remedy, acceptance of a past due installment or other indulgences granted from time to time shall be construed as a novation of this Note or precludes other or further exercise thereof or the exercise of any other rights or remedy.

12. Collection Costs. If Maker fails to pay any amounts due hereunder when due, Maker shall pay to Payee, in addition to such amounts due, on demand, all reasonable documented out of pocket costs and expenses of collection, including reasonable documented out of pocket attorneys' fees.

13. Governing Law. This Note shall be governed and construed in accordance with the laws of the State of New York.

14. Counterparts. This Note may be executed in any number of counterparts or counterpart signature pages (by DocuSign or other electronic transmission or otherwise), each of which, when so executed, shall be deemed an original, but all such counterparts shall constitute but one and the same instrument.

15. Fees and Expenses. Each party will pay all costs and expenses that it incurs with respect to the negotiation, execution, delivery, and performance of this Note.

16. Assignment; Registered Note.

(a) This Note shall be binding upon and inure to the benefit of the successors, heirs and assigns of Maker and Payee. Maker shall not be entitled to assign any of its rights or obligations hereunder. Payee shall be entitled to assign its rights under this Note, with the consent of Maker, and on any such assignment Payee will provide to Maker the corresponding assignment agreement, and surrender this Note to Maker for re-issuance to the transferee (who shall be treated as Payee for purposes of this Note). Any prohibited assignment of this Note is absolutely void *ab initio*. This Note may be pledged by Payee to any of its lenders or creditors as collateral with the consent of Maker. Maker shall maintain at one of its offices a copy of any such assignment agreement delivered to it and a register for the recordation of the names and addresses of each Payee (the "Register"). The entries in the Register shall be conclusive (absent manifest error), and Maker shall treat each person or entity whose name is recorded in the Register pursuant to the terms hereof as a Payee hereunder for all purposes of this Note, notwithstanding notice to the contrary.

(b) This Note is registered as to principal and interest with Maker. Notwithstanding any provision of this Note to the contrary, this Note may be transferred only in accordance with the terms of Section 16(a) of this Note. The foregoing provisions are intended to cause this Note to be in registered form (within the meaning of Treasury Regulations Section 5f.103-1(c)) and shall be interpreted consistently therewith. If Payee is other than a United States person, Payee agrees to provide Maker with a properly executed IRS Form W-8BEN (or other applicable IRS Form W-8) establishing Payee's status as other than a United States person, and if Payee is a United States person, Payee agrees to provide Maker with a properly executed IRS Form W-9.

The remainder of this page is intentionally left blank.

IN WITNESS WHEREOF, the parties hereto have executed this Note as of the date first set forth above.

AKARI THERAPEUTICS, PLC

Name:
Title:

ACCEPTED AND AGREED TO:

By:

August 15, 2024

Side Letter Agreement

Akari Therapeutics, Plc
22 Boston Wharf Road FL 7
Boston, MA 02210
Attention: Samir R. Patel, M.D.

Pegasus Merger Sub, Inc.
22 Boston Wharf Road FL 7
Boston, MA 02210
Attention: Samir R. Patel, M.D.

Peak Bio, Inc.
4900 Hopyard Road, Suite100
Pleasanton, CA 94588
Attention: Hoyoung Huh

Re : Extension of Merger Agreement Termination Date

Ladies and Gentlemen:

Reference is made to that certain Agreement and Plan of Merger (the “**Merger Agreement**”) dated as of March 4, 2024, by and among Akari Therapeutics, Plc, a public company limited by shares incorporated in England and Wales (“**Parent**”), Pegasus Merger Sub, Inc., a Delaware corporation and a wholly owned subsidiary of Parent (“**Merger Sub**”) and Peak Bio, Inc., a Delaware corporation (the “**Company**”).

Pursuant to Section 8.5 of the Merger Agreement, Parent, Merger Sub and the Company hereby agree to amend and restate Section 8.1(d)(i) in the Merger Agreement in its entirety as set forth below:

“if (A) a Restraint prohibiting the Merger shall be in effect and have become final and non-appealable or (B) the Effective Time has not occurred by 5:00 p.m. Eastern time on December 2, 2024 (the “Termination Date”), unless extended by mutual written agreement of Parent and the Company; provided, however, that the right to terminate this Agreement under this Section 8.1(d) shall not be available to any party if the failure by such party to perform any of its obligations under this Agreement has been the principal cause of the failure of any condition set forth in this Section 8.1(d) to be satisfied;”

Except as otherwise expressly set forth herein, all other terms of the Merger Agreement remain unchanged and in full force and effect.

[Signature Page Follows]

IN WITNESS WHEREOF the parties have executed this agreement as of the date first written above.

PARENT:

AKARI THERAPEUTICS, PLC

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

Name: Samir R. Patel, M.D.

Title: Interim President and Chief Executive Officer

MERGER SUB:

PEGASUS MERGER SUB, INC.

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

Name: Samir R. Patel, M.D.

Title: Interim President and Chief Executive Officer

[Signature Page to Side Letter Agreement]

IN WITNESS WHEREOF the parties have executed this agreement as of the date first written above.

COMPANY:

PEAK BIO, INC.

By: /s/ Hoyoung Huh

Name: Hoyoung Huh

Title: Authorized Signatory

[Signature Page to Side Letter Agreement]

**CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER UNDER
SECTION 302 OF THE SARBANES-OXLEY ACT**

I, Samir R. Patel, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Akari Therapeutics, Plc;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
 - (c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the company's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and
5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: August 19, 2024

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

Samir R. Patel, M.D.

*Interim President and Chief Executive Officer, and Director
(Principal Executive Officer)*

**CERTIFICATION OF THE PRINCIPAL FINANCIAL OFFICER UNDER
SECTION 302 OF THE SARBANES-OXLEY ACT**

I, Wendy DiCicco, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Akari Therapeutics, Plc;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
 - (c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the company's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and
5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: August 19, 2024

/s/ Wendy DiCicco

Wendy DiCicco

Interim Chief Financial Officer

(Principal Financial Officer)

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Akari Therapeutics, Plc (the "Company") on Form 10-Q for the quarter ended June 30, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to such officer's knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m or 78o(d)); and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 19, 2024

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

Samir R. Patel, M.D.

*Interim President and Chief Executive Officer, and Director
(Principal Executive Officer)*

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Akari Therapeutics, Plc (the "Company") on Form 10-Q for the quarter ended June 30, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to such officer's knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m or 78o(d)); and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 19, 2024

/s/ Wendy DiCicco

Wendy DiCicco

Interim Chief Financial Officer

(Principal Financial Officer)
