# UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

Form 6-K

Report of Foreign Private Issuer Pursuant to Rule 13a-16 or 15d-16 under the Securities Exchange Act of 1934

June 2021

Commission file number: 001-36288

# Akari Therapeutics, Plc

(Translation of registrant's name into English)

75/76 Wimpole Street London W1G 9RT United Kingdom (Address of principal executive offices)

| Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.       |
|--|
| Form 20-F ⊠ Form 40-F □  |
| Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulations S-T Rule 101(b)(1): |
| Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulations S-T Rule 101(b)(7): |

## **CONTENTS**

On June 29, 2021, Akari Therapeutics, Plc (the "Company") issued unaudited interim condensed consolidated financial statements as of March 31, 2021, prepared in accordance with generally accepted accounting principles in the United States, together with the Company's Management Discussion and Analysis of Financial Condition and Results of Operations for the same period. Attached hereto and incorporated by reference herein are the following exhibits:

- 99.1 Unaudited Interim Condensed Consolidated Financial Statements as of March 31, 2021
- 99.2 Management Discussion and Analysis of Financial Condition and Results of Operations as of March 31, 2021

In addition, on June 29, 2021, the Company issued a press release announcing its first quarter 2021 financial results and recent clinical progress highlights. A copy of the press release is attached hereto as Exhibit 99.3, and incorporated herein by reference.

The information contained in Exhibits 99.1 and 99.2 and the statements under "First Quarter 2021 Financial Results", the accompanying financial statements and "Cautionary Note Regarding Forward-Looking Statements" of Exhibit 99.3 are hereby incorporated by reference into all effective registration statements filed by the Company under the Securities Act of 1933.

## Exhibit No.

- 99.1 Unaudited Interim Condensed Consolidated Financial Statements as of March 31, 2021
- 99.2 Management Discussion and Analysis of Financial Condition and Results of Operations as of March 31, 2021
- 99.3 Press release dated June 29, 2021

# **SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Akari Therapeutics, Plc (Registrant)

By: /s/ Clive Richardson

Name: Clive Richardson

Chief Executive Officer and Chief Operating Officer

Date: June 29, 2021

# Quarterly Report For The Period Ended March 31, 2021

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# CONDENSED CONSOLIDATED BALANCE SHEETS

As of March 31, 2021 and December 31, 2020 (in U.S. dollars, except share data)

|  | _  | March 31,<br>2021<br>(Unaudited) | _  | 2020                                    |
|--|----|----------------------------------|----|---|
| Assets   |    |                                  |    |   |
|  |    |                                  |    |   |
| Current Assets:  | ф  | C CC0 225                        | ф  | 14055 555                               |
| Cash   | \$ | 6,668,325                        | \$ | 14,055,777                              |
| Prepaid expenses and other current assets  |    | 1,144,960                        |    | 521,880                                 |
| Total Current Assets   |    | 7,813,285                        |    | 14,577,657                              |
| Patent acquisition costs, net  |    | 26,460                           |    | 27,150                                  |
| Total Assets   | \$ | 7,839,745                        | \$ | 14,604,807                              |
|  | ÷  | ,,,,,,                           | ÷  | ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,, |
| Liabilities and Shareholders' Equity   |    |                                  |    |   |
|  |    |                                  |    |   |
| Current Liabilities:   |    |                                  |    |   |
| Accounts payable   | \$ | 2,831,779                        | \$ | 3,380,782                               |
| Accrued expenses   |    | 1,071,159                        |    | 1,839,706                               |
| Total Liabilities  |    | 3,902,938                        |    | 5,220,488                               |
| Commitments and Contingencies  |    |                                  |    |   |
| Shareholders' Equity:  |    |                                  |    |   |
| Share capital of \$0.0001 par value par value  |    |                                  |    |   |
| Authorized: 10,000,000,000 ordinary shares; issued and outstanding: 3,847,331,923 and 3,847,331,923 at |    |                                  |    |   |
| March 31, 2021 and December 31, 2020, respectively   |    | 384,733                          |    | 384,733                                 |
| Additional paid-in capital   |    | 139,819,543                      |    | 139,734,651                             |
| Capital Redemption Reserve   |    | 52,193,811                       |    | 52,193,811                              |
| Accumulated other comprehensive loss   |    | (341,968)                        |    | (648,065)                               |
| Accumulated deficit  |    | (188,119,312)                    |    | (182,280,811)                           |
| Total Shareholders' Equity   |    | 3,936,807                        |    | 9,384,319                               |
| Total Liabilities and Shareholders' Equity   | \$ | 7,839,745                        | \$ | 14,604,807                              |

# CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS - UNAUDITED For the Three Months Ended March 31, 2021 and 2020 (in U.S. dollars)

|  | Three Months Ended |              |    | Ended         |   |                   |
|--|--------------------|--------------|----|---------------|---|-------------------|
|  | March 31,<br>2021  |              |    |               | ] | March 31,<br>2020 |
| Operating Expenses:  |                    |              |    |               |   |                   |
| Research and development expenses                                | \$                 | 3,529,384    | \$ | 2,732,165     |   |                   |
| General and administrative expenses                              |                    | 2,019,286    |    | 2,194,809     |   |                   |
| Total Operating Expenses   |                    | 5,548,670    |    | 4,926,974     |   |                   |
| Loss from Operations   |                    | (5,548,670)  |    | (4,926,974)   |   |                   |
| Other (Expenses) Income:   |                    |              |    |               |   |                   |
| Interest income  |                    | 3,735        |    | 1,010         |   |                   |
| Changes in fair value of warrant liabilities – gain              |                    | -            |    | 949,456       |   |                   |
| Foreign currency exchange (losses) gains                         |                    | (285,854)    |    | 233,404       |   |                   |
| Other expenses   |                    | (7,712)      |    | (2,303)       |   |                   |
| Total Other (Expenses) Income                                    |                    | (289,831)    | _  | 1,181,567     |   |                   |
|  |                    | •            |    |               |   |                   |
| Net Loss   |                    | (5,838,501)  |    | (3,745,407)   |   |                   |
| Other Comprehensive Income (Loss):                               |                    |              |    |               |   |                   |
| Foreign Currency Translation Adjustment                          |                    | 306,097      |    | (222,725)     |   |                   |
| 1 oreign currency Translation Flaquotinent                       |                    | 300,037      | _  | (222,725)     |   |                   |
| Comprehensive Loss   | \$                 | (5,532,404)  | \$ | (3,968,132)   |   |                   |
|  |                    |              |    |               |   |                   |
| Loss per ordinary share (basic and diluted)                      | \$                 | (0.00)       | \$ | (0.00)        |   |                   |
| Weighted average ordinary shares outstanding (basic and diluted) | 2                  | 047 221 022  |    | 0 E16 200 700 |   |                   |
| meighted average ordinary shares outstanding (basic and diruted) | 3                  | ,847,331,923 |    | 2,516,280,709 |   |                   |

See notes to condensed consolidated financial statements.

# CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN SHAREHOLDERS' EQUITY - UNAUDITED As of and for the Three Months Ended March 31, 2021 and 2020 (in U.S. dollars)

| Shareholders' Equity, December 31, 2020<br>Stock-based compensation             | Share (<br>Shares<br>3,847,331,923 | Capital                 | Additional Paid-in Capital \$ 139,734,651 84,892 | Capital<br>Redemption<br>Reserve<br>\$ 52,193,811 | Accumulated Other Comprehensive Loss \$ (648,065) | Accumulated Deficit \$ (182,280,811) | Total<br>\$ 9,384,319<br>84,892 |
|---|------------------------------------|-------------------------|--|---|---|--------------------------------------|---------------------------------|
| Comprehensive income (loss)   | -                                  | -                       | 04,032   | -   | 306,097   | (5,838,501)                          | (5,532,404)                     |
| Shareholders' Equity, March 31, 2021  | 3,847,331,923                      | \$ 384,733              | \$ 139,819,543                                   | \$ 52,193,811                                     | \$ (341,968)                                      | \$ (188,119,312)                     | \$ 3,936,807                    |
|   |                                    |                         |  |   |   |                                      |                                 |
|   | Share (                            | Capital                 | Additional<br>Paid-in                            | Capital<br>Redemption                             | Accumulated<br>Other<br>Comprehensive             | Accumulated                          |                                 |
|   | Share (                            | Capital<br>Amount       |  | •   | Other   | Accumulated Deficit                  | Total                           |
| Shareholders' Equity, December 31, 2019   |                                    |                         | Paid-in  | Redemption  | Other<br>Comprehensive                            |                                      | Total \$ 7,598                  |
| Stock-based compensation  | Shares                             | Amount                  | Paid-in<br>Capital                               | Redemption  | Other<br>Comprehensive<br>Loss                    | Deficit                              |                                 |
|   | Shares                             | Amount                  | Paid-in Capital \$ 133,568,636                   | Redemption  | Other<br>Comprehensive<br>Loss                    | Deficit                              | \$ 7,598                        |
| Stock-based compensation Issuance of share capital related to financing, net of | Shares<br>2,245,865,913            | ** Amount ** 31,987,016 | Paid-in Capital \$ 133,568,636 100,504           | Redemption  | Other<br>Comprehensive<br>Loss                    | Deficit                              | \$ 7,598<br>100,504             |

See notes to condensed consolidated financial statements.

# CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS - UNAUDITED For the Three Months Ended March 31, 2021 and 2020 (in U.S. dollars)

|   | Three Months Ended |             |                   | Ended       |
|---|--------------------|-------------|-------------------|-------------|
|   | March 31,<br>2021  |             | March 31,<br>2020 |             |
| Cash Flows from Operating Activities:                                       |                    |             |                   |             |
| Net loss  | \$                 | (5,838,501) | \$                | (3,745,407) |
| Adjustments to reconcile net loss to net cash used in operating activities: |                    |             |                   |             |
| Depreciation and amortization   |                    | 1,034       |                   | 3,877       |
| Stock-based compensation  |                    | 84,892      |                   | 100,504     |
| Changes in fair value of warrant liabilities - gain                         |                    | -           |                   | (949,456)   |
| Foreign currency exchange losses (gains)                                    |                    | 265,484     |                   | (171,806)   |
| Changes in operating assets and liabilities:                                |                    |             |                   |             |
| Prepaid expenses and other current assets                                   |                    | (623,629)   |                   | (1,115,329) |
| Accounts payable and accrued expenses                                       |                    | (1,307,452) |                   | (1,862,039) |
| Total adjustments   |                    | (1,579,671) |                   | (3,994,249) |
| Net Cash Used in Operating Activities                                       |                    | (7,418,172) |                   | (7,739,656) |
|   |                    |             |                   |             |
| Cash Flows from Financing Activities:                                       |                    |             |                   |             |
| Net proceeds from issuance of shares and warrants                           |                    | _           |                   | 9,877,988   |
| Net Cash Provided by Financing Activities                                   |                    | -           |                   | 9,877,988   |
|   |                    |             |                   |             |
| Effect of Exchange Rates on Cash  |                    | 30,720      |                   | (47,843)    |
|   |                    |             |                   |             |
| Net (Decrease) Increase in Cash   |                    | (7,387,452) |                   | 2,090,489   |
| Cash, beginning of period   | _                  | 14,055,777  |                   | 5,731,691   |
| Cash, end of period   | \$                 | 6,668,325   | \$                | 7,822,180   |

See notes to condensed consolidated financial statements.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS - UNAUDITED March 31, 2021 (in U.S. dollars)

## **NOTE 1 – Nature of Business**

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

As of March 31, 2021, the Company has an accumulated deficit of \$188,119,312 and cash of \$6,668,325 and negative cash flows from operating activities in the amount of \$7,418,172. On June 30, 2020, the Company entered into a securities purchase agreement (the "2020 Purchase Agreement") with Aspire Capital Fund, LLC, an Illinois limited liability company ("Aspire Capital") which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of \$30.0 million of the Company's ADSs over the 30-month term of the Purchase Agreement (See Note 3). As of March 31, 2021, \$24,000,000 remains available under the facility.

The Company believes its current capital resources are sufficient to support its operations into September 2021 without giving effect to the sale of additional shares to Aspire Capital under the Purchase Agreement. To fund its capital needs, the Company plans to raise additional funds through equity or debt financings or other sources, such as strategic partnerships and alliance and licensing arrangements, and in the long term, proceeds from sales of commercial product.

The Company is subject to a number of risks similar to those of clinical stage companies, including dependence on key individuals, uncertainty of product development and generation of revenues, dependence on outside sources of capital, risks associated with the outbreak of coronavirus, risks associated with clinical trials of products, dependence on third-party collaborators for research operations, need for regulatory approval of products, risks associated with protection of intellectual property, and competition with larger, better-capitalized companies. In addition, the Company is subject to risks related to the COVID-19 outbreak.

For the three months ended March 31, 2021, the Company reported a net loss of \$5,838,501 and expects to continue to incur substantial losses over the next several years during its development phase. 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. To fund its capital needs, the Company plans to raise funds through equity or debt financings or other sources, such as strategic partnerships and alliance and licensing arrangements, and in the long term, from the proceeds from sales of commercial products. Additional funds may not be available when the Company needs them, on terms that are acceptable to it, or at all. These matters raise substantial doubt about the Company's ability to continue as a going concern. The financial statements do not include any adjustments to the carrying amounts and classifications of assets and liabilities that would result if the Company was unable to continue as a going concern.

The global outbreak of COVID-19, also known as coronavirus and public health epidemics can adversely impact the Company's business as a result of disruptions, such as travel bans, quarantines, 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. Moreover, as a result of COVID-19, there is a general unease of conducting unnecessary activities in medical centers. As a consequence, the Company's ongoing trials have been halted or disrupted. It is too early to assess the full impact of the COVID-19 outbreak on trials for nomacopan, but COVID-19 may affect the Company's ability to complete recruitment in the original timeframe. For example, during 2020, the Phase I/II clinical trial in patients with AKC study was halted and recruitment in the Phase III clinical trial in pediatric patients with HSCT-TMA was delayed until the end of 2020 althought it is now open for enrollment of patients. The extent to which COVID-19 impacts operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration and continued severity of the outbreak, and the actions that may be required to contain the coronavirus or treat its impact. In particular, the continued spread of COVID-19 globally could adversely impact the Company's operations and workforce, including research and clinical trials and the ability to raise capital, could affect the operations of key governmental agencies, such as the FDA, which may delay the development of the Company's product candidates, and could result in the inability of suppliers to deliver components or raw materials on a timely basis or at all, each of which in turn could have an adverse impact on the Company's business, financial condition and results of operation.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS - UNAUDITED March 31, 2021 (in U.S. dollars)

## **NOTE 2 – Summary of Significant Accounting Policies**

Basis of Presentation – The accompanying unaudited Condensed Consolidated Financial Statements have been prepared in accordance with 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 of the information and footnotes required by U.S. GAAP for complete financial statements. These financial statements have been prepared on the same basis as the Company's annual financial statements and, in the opinion of management, reflect all adjustments, including normal and recurring adjustments, which the Company considers necessary for the fair presentation of financial information. The results of operations and comprehensive loss for the three months ended March 31, 2021 and March 31, 2020, are not necessarily indicative of expected results for the full fiscal year or any other period. These interim condensed consolidated financial statements should be read in conjunction with the Company's audited financial statements as of December 31, 2020 and notes thereto included in the Form 20-F for the year ended December 31, 2020 ("2020 Annual Report").

**Principles of Consolidation** – The unaudited Condensed Consolidated Financial Statements include the accounts of the Company, 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 primary economic environment in which the Company operates as well as the currency in which it has been financed.

The reporting currency of the Company is U.S. dollars. The Company translated 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 financial statements in conformity with U.S. GAAP requires management to make estimates and judgments that may affect the reported amounts of assets, liabilities, equity, revenue, expenses and related disclosure of contingent assets and liabilities. Management's estimates and judgments include assumptions used in the evaluation of impairment and useful lives of intangible assets (patents), accrued liabilities, deferred income taxes, liabilities related to warrants, stock-based compensation and various other assumptions that are believed to be reasonable under the circumstances. Actual results may differ from those estimates under different assumptions or conditions.

**Fair Value Measurements** – The carrying amounts of financial instruments, including cash, prepaid expenses and other current assets, accounts payable and accrued expenses approximate fair value due to their short-term maturities.

The Company accounted for unregistered warrants issued to investors and a placement agent in connection with its 2019 registered direct offering and its 2020 private placements as a warrant liability on the consolidated balance sheets and measured at their grant date fair values and subsequently re-measured at each reporting period, with changes being recorded as a component of Comprehensive Income/ (Loss) and included in changes in fair value of warrant liabilities – gain/ (loss). On December 8, 2020, the Company changed the nominal currency of its ordinary shares from pounds sterling to U.S. dollars and reclassified its warrants from liabilities to shareholders' equity (See Note 3).

# NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS - UNAUDITED March 31, 2021 (in U.S. dollars)

## **NOTE 2 – Summary of Significant Accounting Policies (cont.)**

Computers, peripheral, and scientific equipment

Office furniture and equipment

Property and equipment, net

**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 March 31, 2021 and December 31, 2020.

Prepaid Expenses and Other Current Assets – Prepaid expenses and other current assets consist principally of prepaid expenses and VAT receivables.

**Property and Equipment, net** – Property and equipment are stated at cost, net of accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets at the following annual rates:

Years

3

3

| Property and equipment, consists of the following: |                   |                      |
|--|-------------------|----------------------|
|  | March 31,<br>2021 | December 31,<br>2020 |
| Computers, peripheral, and scientific equipment    | \$ 85,489         | \$ 85,489            |
| Office furniture and equipment                     | 79,449            | 79,449               |
| Total property and equipment                       | 164,938           | 164,938              |
| Less: Accumulated depreciation                     | (164,938)         | (164,938)            |

Depreciation expense for the three months ended March 31, 2021 and 2020 was \$0 and \$2,917, respectively, and was recorded in both research and development expenses and general and administrative expenses in the unaudited Condensed Consolidated Statements of Comprehensive Loss.

**Long-Lived Assets** — The Company reviews all long-lived assets for impairment whenever events or circumstances indicate the carrying amount of such assets may not be recoverable. Recoverability of assets to be held or used is measured by comparison of the carrying value of the asset to the future undiscounted net cash flows expected to be generated by the asset. If such asset is considered to be impaired, the impairment recognized is measured by the amount by which the carrying value of the asset exceeds the discounted future cash flows expected to be generated by the asset.

**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 subsequent to their issuance in the period incurred. Amortization of patent acquisition costs for the three months ended March 31, 2021 and 2020 was \$1,034 and \$960, respectively.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS - UNAUDITED March 31, 2020 (in U.S. dollars)

## **NOTE 2 – Summary of Significant Accounting Policies (cont.)**

Accrued Expenses — As part of the process of preparing the unaudited 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 unaudited 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. In the event that 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.

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 (CROs) 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 payment 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.

Research and development expenses for the three months ended March 31, 2021 and 2020 were \$3,529,384 and \$2,732,165, respectively. The Company accounts for research and development tax credits at the time its realization becomes probable as a credit to research and development expenses in the Consolidated Statements of Comprehensive Loss.

Stock-Based Compensation Expense – Stock-based compensation expense is recorded using the fair-value based method for all awards granted. Compensation costs for stock options and awards is recorded in earnings (loss) over the requisite service period based on the fair value of those options and awards. For employees, fair value is estimated at the grant date, and for non-employees, fair value is re-measured at each reporting date as required by Accounting Standards Codification (ASC) 718, "Compensation-Stock Compensation" and Accounting Standards Updates (ASU) 2018-07, "Compensation - Stock Compensation". Stock options for non-employee directors for their services as directors acting in their role as members of a board of directors are treated as employees if those directors were elected by the employer's shareholders or appointed to a board position that will be filled by shareholder election when the existing term expires. Awards granted to those individuals for other services shall be accounted for as awards to non-employees. Fair values of awards granted under the share option plans are estimated using a Black-Scholes option pricing model. The determination of fair value for stock-based awards on the date of grant using an option pricing model requires management to make certain assumptions regarding a number of complex and subjective variables. The Company classifies its stock-based payments which are settled in ordinary shares as equity-classified awards. The Company accounts for awards of equity instruments issued to employees, non-employees and directors under the fair value method of accounting and recognizes such amounts, upon vesting, in general administrative or research and development expenses within its unaudited Condensed Consolidated Statements of Comprehensive Loss.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS - UNAUDITED March 31, 2021 (in U.S. dollars)

## **NOTE 2 – Summary of Significant Accounting Policies (cont.)**

Leases – The Company accounts for its leases in accordance with Accounting Standards Updates (ASU) No. 2016-02, Leases ("ASU 2016-2). ASU 2016-02 establishes a right-of-use (ROU) model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. The Company determines if an arrangement is a lease at inception. This determination generally depends on whether the arrangement conveys to the Company the right to control the use of an explicitly or implicitly identified fixed asset for a period of time in exchange for consideration. Control of an underlying asset is conveyed to the Company if the Company obtains the rights to direct the use of and to obtain substantially all of the economic benefits from using the underlying asset. Operating leases are classified as right of use ("ROU") assets, short term lease liabilities, and long-term lease liabilities. Operating lease ROU assets and lease liabilities are recognized at the commencement date based on the present value of lease payments over the lease term. ROU assets are amortized and lease liabilities accrete to yield straight-line expense over the term of the lease. Lease payments included in the measurement of the lease liability are comprised of fixed payments. Leases with an initial term of twelve months or less are not recorded on the consolidated balance sheet and the Company recognizes lease expense for these leases on a straight-line basis over the lease term. The Company applies this policy to all underlying asset categories. Leasehold improvements are capitalized and depreciated over the lesser of useful life or lease term. As of March 31, 2020, the Company did not have a lease with a term longer than twelve months.

**Concentration of Credit Risk** – Financial instruments that subject the Company to credit risk consist of cash. The Company maintains cash with well-capitalized financial institutions. At times, those amounts may exceed insured limits. The Company has no other significant concentrations of credit risk.

**Income Taxes** – On March 27, 2020, the United States enacted the Coronavirus Aid, Relief, and Economic Security Act, referred to herein as the CARES Act, as a response to the economic uncertainty resulting from COVID-19. The CARES Act includes modifications for net operating loss carryovers and carrybacks, limitations of business interest expense for tax, immediate refund of alternative minimum tax (AMT) credit carryovers. Tax provisions of the Act also include the deferral of certain payroll taxes, relief for retaining employees, and other provisions. The Company determined that these provisions did not have a material impact on the consolidated financial statements.

The Company accounts for income taxes in accordance with the accounting rules that require an asset and liability approach to accounting for income taxes based upon the future expected values of the related assets and liabilities. Deferred income tax assets and liabilities are determined based on the differences between the financial reporting and tax bases of assets and liabilities and for tax loss and credit carry forwards and are measured using the expected tax rates estimated to be in effect when such basis differences reverse. Valuation allowances are established, if necessary, to reduce the deferred tax asset to the amount that will, more likely than not, be realized. The Company has recorded a full valuation allowance on its deferred tax assets as of March 31, 2021 and December 31, 2020.

**Uncertain Tax Positions** – The Company follows the provisions of ASC 740 "Accounting for Uncertainty in Income Taxes", which prescribes recognition thresholds that must be met before a tax position is recognized in the financial statements and provides guidance on de-recognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. Under ASC 740 "Accounting for Uncertainty in Income Taxes," an entity may only recognize or continue to recognize tax positions that meet a "more-likely-than-not" threshold. Interest and penalties related to uncertain tax positions are recognized as general and administrative expense. At March 31, 2021 and December 31, 2020, the Company had no uncertain tax positions.

Earnings (Loss) Per Share — Basic earnings (loss) per ordinary share is computed by dividing net income (loss) available to ordinary shareholders by the weighted-average number of ordinary shares outstanding during the period. Diluted earnings (loss) per ordinary share is computed by dividing net income (loss) available to ordinary shareholders by the sum of (1) the weighted-average number of ordinary shares outstanding during the period, (2) the dilutive effect of the assumed exercise of options and warrants using the treasury stock method and (3) the dilutive effect of other potentially dilutive securities. For purposes of the diluted net loss per share calculation, share options and warrants are considered to be potentially dilutive securities and are excluded from the calculation of diluted net loss per share because their effect would be anti-dilutive. Therefore, basic and diluted net loss per share was the same for the periods presented due to the Company's net loss position.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS - UNAUDITED March 31, 2021 (in U.S. dollars)

## **NOTE 2 – Summary of Significant Accounting Policies (cont.)**

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

The following table provides details with respect to changes in accumulated other comprehensive loss, which is comprised of foreign currency translation adjustments, as presented in the balance sheets at March 31, 2021:

| Balance, January 1, 2021                    | \$<br>(648,065) |
|---|-----------------|
| Net current period other comprehensive loss | 306,097         |
| Balance, March 31, 2021                     | \$<br>(341,968) |

#### **Recent Accounting Pronouncements**

#### Adopted during the period -

On December 2019, the FASB issued ASU 2019-12, *Simplifying the Accounting for Income Taxes*. ASU 2019-12 enhances and simplifies various aspects of the income tax accounting guidance in ASC 740 and removes certain exceptions for recognizing deferred taxes for investments, performing intra-period allocation and calculating income taxes in interim periods. The ASU also adds guidance to reduce complexity in certain areas, including recognizing deferred taxes for tax goodwill and allocating taxes to members of a consolidated group. This ASU is effective for fiscal years beginning after December 15, 2020, and interim periods within those fiscal years with early adoption permitted. The Company adopted this guidance effective January 1, 2021. The adoption of the guidance did not have a material impact on the consolidated financial statements.

## **NOTE 3 – Fair Value Measurements**

Fair value of financial instruments:

The estimated fair value of financial instruments has been determined by the Company using available market information and valuation methodologies. Considerable judgment is required in estimating fair values. Accordingly, the estimates may not be indicative of the amounts the Company could realize in a current market exchange.

The carrying amounts of cash, prepaid expenses and other current assets, accounts payable and accrued expenses approximate their fair value due to the short-term maturity of such instruments.

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  $\ensuremath{\mathtt{1}}$  - quoted prices in active markets for identical assets or 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; or

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.

The fair value hierarchy also requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value.

#### Warrants -

2019 Registered Direct Offering - On July 3, 2019, the Company sold to certain institutional investors, accredited investors and an existing shareholder, RPC Pharma Ltd., an affiliated entity of Dr. Ray Prudo, the Company's Chairman, an aggregate of 2,368,392 ADSs in a registered direct offering at \$1.90 per ADS, resulting in gross proceeds of approximately \$4.5 million (the "2019 Registered Direct Offering"). The Company also entered into a letter agreement with Paulson Investment Company, LLC (the "Placement Agent") to serve as the placement agent for the Company in connection with this offering. In connection with the sale of the ADSs in the 2019 Registered Direct Offering, the Company issued to the investors unregistered warrants to purchase an aggregate of 1,184,213 ADSs in a private placement ("2019 Investor Warrants"). The 2019 Investor Warrants are immediately exercisable and will expire five years from issuance at an exercise price of \$3.00 per ADS, subject to adjustment as set forth therein. Subject to certain conditions, the Company has the option to "call" the exercise of the warrants from time to time after any 10-consecutive trading day period during which the daily volume weighted average price of the ADSs exceeds \$4.50. The Company paid to the Placement Agent an aggregate of \$337,496 in placement agent fees and expenses and issued unregistered warrants to the Placement Agent to purchase an aggregate of 177,629 ADS ("2019 Placement Agent Warrants") on the same terms as the 2019 Investor Warrants, except that the 2019 Placement Agent Warrants are exercisable at \$2.85 per ADS. Both the 2019 Investor Warrants and the 2019 Placement Agent Warrants (together the "2019 Warrants") may be exercised on a cashless basis if six months after issuance there is no effective registration statement registering the ADSs underlying the warrants. Pursuant to the cashless exercise provision, the warrant holder must make

an additional payment to the Company equal to the nominal value of an ADS (i.e., \$0.0001) per warrant ADS actually to be issued pursuant to the cashless exercise. The total amount of 2019 Warrants issued in connection with this registered direct offering amounted to 1,361,842, all of which were outstanding as of March 31, 2021.

2020 Private Placements - On February 13, 2020, February 19, 2020, February 20, 2020 and February 28, 2020, the Company entered into securities purchase agreements with certain accredited and institutional investors, including Dr. Ray Prudo, the Company's Chairman, providing for the issuance of an aggregate of 5,620,296 ADSs in a private placement at \$1.70 per ADS for aggregate gross proceeds of approximately \$9.5 million, which subsequently closed (the "2020 Private Placements"). The Company also entered into a letter agreement with Paulson Investment Company, LLC to serve as the placement agent for the Company in connection with this offering. In connection with the offering, on February 21, 2020 and March 3, 2020, the Company issued to the investors unregistered warrants to purchase a total of 2,810,136 ADSs at \$2.20 per ADS ("2020 Investor Warrants").

On March 3, 2020, the Company also issued 449,623 ADSs to the Placement Agent at \$2.55 per ADS ("2020 Placement Warrants"). The 2020 Investor warrants and the 2020 Placement Agent Warrants (together the "2020 Warrants") will expire five years from issuance and are immediately exercisable, subject to adjustment as set forth therein. The Company paid to the Placement Agent an aggregate of \$808,362 in placement agent fees and expenses. The 2020 Warrants may be exercised on a cashless basis if six months after issuance there is no effective registration statement registering the ADSs underlying the warrants. Pursuant to the cashless exercise provision, the warrant holder must make an additional payment to the Company equal to the nominal value of an ADS (i.e., \$0.0001) per warrant ADS actually to be issued pursuant to the cashless exercise. The total amount of the 2020 Warrants issued in connection with the 2020 Private Placements amounted to 3,259,759, 3,247,259 of these warrants were outstanding as of March 31, 2021.

The portion of costs directly attributable to realizing proceeds of issuing ADSs such as placement agent fees, commissions, legal and accounting fees pertaining to the financing and other external, incremental fees and expenses paid to advisors are recognized on a proportional basis as (1) a component of General and Administrative Expenses in the Consolidated Statements of Operations, relative to the grant date fair value of the warrant liability as a portion of the total value of the equity raise, and (2) in the Shareholders' Equity in the Consolidated Balance Sheets in accordance with ASC 835-30-45-3, relative to the gross cash proceeds of the private placement as a portion of the total value of the equity raise at the time of the equity raise. The total value of the equity raises equal the sum of the grant date fair values of the warrant liability and the gross cash proceeds of the 2019 Registered Direct Offering and the 2020 Private Placements, respectively.

The Company has determined that at the time of their issuance, the 2019 Warrants and the 2020 Warrants (together the "Warrants") represent freestanding financial instruments whose foreign currency considerations pursuant to cash and cashless exercise require liability classification and should be recorded as liability-classified awards in accordance with ASC 815-40-25, Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock and ASC 815-40-15, Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock. In accordance with ASC 820, the Company measured its Warrants at grant date fair value. The fair value related to warrants are classified within the Level 3 value hierarchy because it is based on external valuation models whose inputs include market interest rates, required return on capital, and standard deviation. Unobservable inputs used in these models are significant. The Warrants were measured at their grant date fair value and subsequently remeasured at each reporting period with changes being recorded as a component of other income in the Consolidated Statements of Comprehensive Income (Loss). The total grant date fair value of the 2019 Warrants was \$1,213,816 and of the 2020 Warrants was \$2,749,369 and they were initially recognized within Current Liabilities in the Condensed Consolidated Balance Sheets. The change in fair value of liability related to Warrants from period to period, which represents a gain (loss), was recognized as changes in fair value of warrant liabilities - gain (loss) in the Consolidated Statements of Comprehensive Income (Loss). On December 8, 2020, the Company held a general meeting ("2020 General Meeting") and changed the currency of its ordinary shares from pounds sterling to US dollars ("2020 Redenomination"). As a consequence of the 2020 Redenomination, the Company is required to reassess, whether its financial instruments or other contracts that previously required derivative accounting within the scope of ASC 815 Financial Instruments either (a) no longer meet the definition of a derivative or (b) meet a scope exception to the derivative guidance due to a change in facts and circumstances. The Company concluded that due to the 2020 Redenomination, the Warrants now meet the requirements for classification as equity under ASC 815-40-25 as of December 8, 2020, the date of the 2020 General Meeting. The Company updated the carrying amount of the warrant liability to its fair value on December 8, 2020, with any changes recorded in the Consolidated Statements of Comprehensive Loss and then reclassed the warrant liability balance to additional paid in capital within Shareholders' Equity.

At December 8, 2020, the fair value of the 2019 Warrants and 2020 Warrants was \$882,237 and \$2,317,316, respectively, totaling \$3,199,553. The change in fair value of the 2019 Warrants from January 1, 2020 to December 8, 2020 was a decrease of \$132,632 and of the outstanding 2020 Warrants for the same period was a decrease of \$432,053. In addition, upon exercise of 12,500 of the 2020 Investor Warrant, the Company reclassified \$7,874 of the related warrant liability to shareholders' equity.

Below are the assumptions used for the fair value calculations of the 2019 Warrants as of:

|                                | December 8,<br>2019 | December 8,<br>2021 |
|--------------------------------|---------------------|---------------------|
| Standard deviation             | 110.00%             | 95.00%              |
| Annual risk-free interest rate | 1.66%               | 0.25%               |
| Required return on equity      | 19.90%              | 19.30%              |
| Expected life in years         | 4.50                | 3.55                |
| Annual turnover rate           | 0.00%               | 0.00%               |
| Period risk-free rate          | 0.08%               | 0.08%               |

Below are the assumptions used for the fair value calculations of the 2020 Warrants as of:

|                                | February 21,<br>2020 | March 3,<br>2020 | December 8,<br>2020 |
|--------------------------------|----------------------|------------------|---------------------|
| Standard deviation             | 110.00%              | 110.00%          | 95.00%              |
| Annual risk-free interest rate | 1.3%                 | 0.77%            | 0.25%               |
| Required return on equity      | 19.90%               | 19.90%           | 19.30%              |
| Expected life in years         | 5.0                  | 5.0              | 3.55                |
| Annual turnover rate           | 0.00%                | 0.00%            | 0.00%               |
| Period risk-free rate          | 0.08%                | 0.08%            | 0.08%               |

# NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS - UNAUDITED March 31, 2021 (in U.S. dollars)

## **NOTE 3 – Fair Value Measurements (cont.)**

As of March 31, 2021 and December, 31, 2020, the Company did not have any financial assets that require fair value measurement on a recurring basis. Until December 8, 2020, the Company accounted for unregistered warrants issued in connection with the 2019 Registered Direct Offering and the 2020 Private Placements as a warrant liability on the consolidated balance sheets and measured at their grant date fair values and subsequently re-measured at each reporting period, with changes being recorded as a component of Comprehensive Income/ (Loss) and included in changes in fair value of warrant liabilities – gain/ (loss). On December 8, 2020, the Company changed the nominal currency of its ordinary shares from pounds sterling to U.S. dollars and reclassified its warrants from liabilities to shareholders' equity.

Fair value measurements using significant unobservable inputs (Level 3):

|  | Ì  | nir value of<br>liabilities<br>related<br>o warrants |
|--|----|--|
| Balance at December 31, 2019   | \$ | 1,014,868  |
| Issuance of 2020 Paulson Warrants  |    | 2,749,369  |
| Reclassification of warrant liability to shareholders' equity upon exercise of 12,500 warrant ADSs |    | (7,874)  |
| Change in fair value of liabilities related to warrants  |    | (556,810)  |
| Balance at December 8, 2020  |    | 3,199,553  |
| Reclassification to Additional-Paid-In Capital (in) Shareholders' Equity                           |    | (3,199,553)  |
| Balance at December 31, 2020   | \$ | _  |

## NOTE 4 - Shareholders' Equity

## 2020 Purchase Agreement and Registration Rights Agreement with Aspire Capital -

On June 30, 2020, the Company entered into a Purchase Agreement ("2020 Purchase Agreement") with Aspire Capital, which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of \$30.0 million of the Company's ADS, with each ADS representing one hundred (100) ordinary shares, during a 30-month period beginning on the effective date of a registration statement related to the transaction. Concurrently with entering into the 2020 Purchase Agreement, the Company also entered into a registration rights agreement with Aspire Capital, in which the Company agreed to file one or more registration statements, as permissible and necessary to register under the Securities Act of 1933, as amended (the "Securities Act"), the sale of the Company's securities that have been and may be issued to Aspire Capital under the 2020 Purchase Agreement.

Under the 2020 Purchase Agreement, after the SEC declared effective the registration statement referred to above (which occurred in July 2020), on any trading day selected by the Company, the Company has the right, in its sole discretion, to present Aspire Capital with a purchase notice (each, a "Purchase Notice"), directing Aspire Capital (as principal) to purchase up to 150,000 ADSs per business day and up to \$30.0 million of the Company's ADSs in the aggregate at a per share price (the "Purchase Price") equal to the lesser of:

- $\cdot$   $\;$  the lowest sale price of the Company's ADSs on the purchase date; or
- the arithmetic average of the three (3) lowest closing sale prices for the ADSs during the ten (10) consecutive business days ending on the business day immediately preceding such Purchase Date (to be appropriately adjusted for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction).

In addition, on any date on which the Company submits a Purchase Notice to Aspire Capital in an amount of 150,000 ADSs, the Company also has the right, in its sole discretion, to present Aspire Capital with a volume-weighted average price purchase notice (each, a "VWAP Purchase Notice") directing Aspire Capital to purchase an amount of ADSs equal to up to 30% of the aggregate shares of the Company's ADSs traded on its principal market on the next trading day (the "VWAP Purchase Date"), subject to a maximum number of 250,000 ADSs. The purchase price per share pursuant to such VWAP Purchase Notice is generally 97% of the volume-weighted average price for the Company's ADSs traded on its principal market on the VWAP Purchase Date

The Purchase Price will be adjusted for any reorganization, recapitalization, non-cash dividend, stock split, or other similar transaction occurring during the period(s) used to compute the Purchase Price. The Company may deliver multiple Purchase Notices and VWAP Purchase Notices to Aspire Capital from time to time during the term of the Purchase Agreement, so long as the most recent purchase has been completed.

The 2020 Purchase Agreement provides that the Company and Aspire Capital shall not effect any sales under the Purchase Agreement on any purchase date where the closing sale price of the Company's ADSs is less than \$0.25. Additionally, governing law in the United Kingdom, where the Company is incorporated, requires a minimum payment per ADS to be issued pursuant to a purchase notice equal to the nominal value of an ADS (i.e., \$0.0001). There are no trading volume requirements or restrictions under the Purchase Agreement, and the Company will control the timing and amount of sales of the Company's ADSs to Aspire Capital. Aspire Capital has no right to require any sales by the Company, but is obligated to make purchases from the Company as directed by the Company in accordance with the Purchase Agreement. There are no limitations on use of proceeds, financial or business covenants, restrictions on future fundings, rights of first refusal, participation rights, penalties or liquidated damages in the Purchase Agreement.

In accordance with ASC 815-40-15, *Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock*, since the ultimate floor price, which is effectively the nominal value of the ADS which was denominated in GBP at the time of entering into the 2018 Purchase agreement as well as the 2020 Purchase Agreement (together "the Purchase Agreements") prior to the 2020 Redenomination, the number of shares issuable under the contract was impacted by foreign currency, therefore ASC 815-40-15-71 precluded the Purchase Agreements from being indexed to the Company's own stock. The Company determined that the right to sell shares to Aspire Capital under the Purchase Agreements represents a freestanding put option that met the criteria of a derivative pursuant to ASC 815 *Derivatives and Hedging*. Since the purchase price per share pursuant to the Purchase Agreements is at the market, the Company concluded that the put option has a fair value of zero, and therefore no additional accounting related to the put option was required.

In consideration for entering into the 2020 Purchase Agreement, the Company issued to Aspire Capital 40,760,900 ordinary shares of the Company (the "2020 Commitment Shares") which had a fair value of approximately \$900,000. Since the Company has determined that the 2020 Purchase Agreement was considered a freestanding put option derivative in accordance with ASC 815 *Derivatives and Hedging* when entering into the agreement, the Company recorded the value of the 2020 Commitment Shares in General and administrative expenses in the Consolidated Statements of Comprehensive Loss. The 2020 Purchase Agreement may be terminated by the Company at any time, at its discretion, without any cost to the Company. Aspire Capital has agreed that neither it nor any of its agents, representatives and affiliates shall engage in any direct or indirect short-selling or hedging of the Company's securities during any time prior to the termination of the 2020 Purchase Agreement. Any proceeds the Company receives under the 2020 Purchase Agreement are expected to be used for working capital and general corporate purposes.

During the twelve months ended December 31, 2020, the Company sold to Aspire Capital 460,758,800 ordinary shares of the Company for gross proceeds of approximately \$6,000,000. During the three months ended March 31, 2021, the Company did not sell any shares to Aspire Capital. As of March 31, 2021, \$24 million of the original purchase commitment of \$30 million remains available under the facility.

## 2020 Private Placements -

On February 13, 2020, February 19, 2020, February 20, 2020 and February 28, 2020, the Company entered into securities purchase agreements with certain accredited and institutional investors, including Dr. Ray Prudo, the Company's Chairman, providing for the issuance of an aggregate of 5,620,296 ADSs in a private placement at \$1.70 per ADS for aggregate gross proceeds of approximately \$9.5 million, which subsequently closed. The Company also entered into a letter agreement with Paulson Investment Company to serve as the placement agent for the Company in connection with this offering. In connection with the offering, the Company issued to the investors unregistered warrants to purchase 2,810,136 ADSs at \$2.20 per ADS and 449,623 ADSs to the Placement Agent at \$2.55 per ADS (See Note 3).

## 2019 Registered Direct Offering -

On July 3, 2019, the Company sold to certain institutional investors, accredited investors and an existing shareholder, RPC Pharma Ltd., an affiliated entity of Dr. Ray Prudo, the Company's Chairman, an aggregate of 2,368,392 ADSs in a registered direct offering at \$1.90 per ADS, resulting in gross proceeds of approximately \$4.5 million. The Company also entered into a letter agreement with the Paulson Investment Company to serve as the placement agent for the Company in connection with this offering. In connection with the sale of the ADSs in the 2019 Registered Direct Offering, the Company issued unregistered warrants to investors and the Placement Agent to purchase an aggregate of 1,361,842 ADSs in a private placement at \$3.00 per ADS and \$2.85 per ADS respectively (See Note 3).

| Description             |          | ercise<br>Price | Balance<br>December 31,<br>2019 | Warrants<br>Issued<br>in 2020 | Warrants<br>Exercised<br>in 2020 | Balance<br>December 31,<br>2020 | Balance<br>March 31,<br>2021 |
|-------------------------|----------|-----------------|---------------------------------|-------------------------------|----------------------------------|---------------------------------|------------------------------|
| 2019 Investor Warrants  | \$       | 3.00            | 1,184,213                       |                               |                                  | 1,184,213                       | 1,184,213                    |
| 2019 Placement Warrants | \$       | 2.85            | 177,629                         | -                             | -                                | 177,629                         | 177,629                      |
| 2020 Investor Warrants  | \$       | 2.20            | -                               | 2,810,136                     | (12,500)                         | 2,797,636                       | 2,797,636                    |
| 2020 Placement Warrants | \$       | 2.55            | -                               | 449,623                       | -                                | 449,623                         | 449,623                      |
|                         | <u> </u> |                 | 1,361,842                       | 3,259,759                     | (12,500)                         | 4,609,101                       | 4,609,101                    |

#### 2018 Purchase Agreement and Registration Rights Agreement with Aspire Capital –

On September 26, 2018, the Company entered into a Purchase Agreement ("2018 Purchase Agreement") with Aspire Capital, which provided that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital was committed to purchase up to an aggregate of \$20.0 million of the Company's ADS, with each ADS representing one hundred (100) ordinary shares, during a 30-month period beginning on the effective date of a registration statement related to the 2018 Purchase Agreement. Concurrently with entering into the 2018 Purchase Agreement, the Company also entered into a registration rights agreement with Aspire Capital, in which the Company agreed to file one or more registration statements, as permissible and necessary to register under the Securities Act, the sale of the Company's securities that have been and may be issued to Aspire Capital under the 2018 Purchase Agreement.

Under the 2018 Purchase Agreement, after the SEC declared effective the registration statement referred to above (which occurred in March 2019), on any trading day selected by the Company, the Company had the right, in its sole discretion, to present Aspire Capital with a purchase notice (each, a "Purchase Notice"), directing Aspire Capital (as principal) to purchase up to 150,000 ADSs per business day and up to \$20.0 million of the Company's ADSs in the aggregate at a per share price (the "Purchase Price") equal to the lesser of:

- the lowest sale price of the Company's ADSs on the purchase date; or
- the arithmetic average of the three (3) lowest closing sale prices for the ADSs during the ten (10) consecutive business days ending on the business day immediately preceding such Purchase Date (to be appropriately adjusted for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction).

In addition, on any date on which the Company submitted a Purchase Notice to Aspire Capital in an amount of 150,000 ADSs, the Company also had the right, in its sole discretion, to present Aspire Capital with a volume-weighted average price purchase notice (each, a "VWAP Purchase Notice") directing Aspire Capital to purchase an amount of ADSs equal to up to 30% of the aggregate shares of the Company's ADSs traded on its principal market on the next trading day (the "VWAP Purchase Date"), subject to a maximum number of 250,000 ADSs. The purchase price per share pursuant to such VWAP Purchase Notice was generally 97% of the volume-weighted average price for the Company's ADSs traded on its principal market on the VWAP Purchase Date.

The Purchase Price was adjustable for any reorganization, recapitalization, non-cash dividend, stock split, or other similar transaction occurring during the period(s) used to compute the Purchase Price. The Company could deliver multiple Purchase Notices and VWAP Purchase Notices to Aspire Capital from time to time during the term of the Purchase Agreement, so long as the most recent purchase has been completed.

The Purchase Agreement provided that the Company and Aspire Capital shall not effect any sales under the Purchase Agreement on any purchase date where the closing sale price of the Company's ADSs is less than \$0.25. There were no trading volume requirements or restrictions under the Purchase Agreement, and the Company controlled the timing and amount of sales of the Company's ADSs to Aspire Capital. Aspire Capital had no right to require any sales by the Company, but was obligated to make purchases from the Company as directed by the Company in accordance with the Purchase Agreement. There were no limitations on use of proceeds, financial or business covenants, restrictions on future fundings, rights of first refusal, participation rights, penalties or liquidated damages in the Purchase Agreement.

In consideration for entering into the Purchase Agreement, concurrently with the execution of the Purchase Agreement, the Company issued to Aspire Capital 30,000,000 ordinary shares of the Company (the "2018 Commitment Shares") and sold to Aspire Capital 25,000,000 ordinary shares (the "2018 Initial Shares") for gross proceeds of \$500,000. The Company recorded the value of the 2018 Commitment Shares as general and administrative expenses in its Consolidated Statements of Comprehensive Loss. Aspire Capital agreed that neither it nor any of its agents, representatives and affiliates shall engage in any direct or indirect short-selling or hedging of the Company's securities during any time prior to the termination of the 2018 Purchase Agreement. Any proceeds the Company received under the 2018 Purchase Agreement were used for working capital and general corporate purposes. The Company terminated the 2018 Purchase Agreement on June 30, 2020.

## Share option plan -

In accordance with the Company's 2014 Equity Incentive Plan (the "Plan"), the number of shares that may be issued upon exercise of options under the Plan shall not exceed 344,747,462 ordinary shares. At March 31, 2021, 229,098,427 ordinary shares are available for future issuance under the Plan. The option plan is administered by the Company's Board of Directors and grants are made pursuant thereto by the compensation committee. The per share exercise price for the shares to be issued pursuant to the exercise of an option shall be such price equal to the fair market value of the Company's ordinary shares on the grant date and set forth in the individual option agreement. Options expire ten years after the grant date and typically vest over one to four years.

The following is a summary of the Company's share option activity and related information for employees and directors for the period ended March 31, 2021:

|   | Number<br>of shares | Weighted<br>average<br>exercise<br>price | Weighted<br>average<br>grant date<br>fair value | Weighted average remaining contractual term (in years) | Aggregate<br>intrinsic<br>value |
|---|---------------------|--|---|--|---------------------------------|
| Options outstanding as of January 1, 2021 | 112,649,035         | \$<br>0.09                               |   | 7.1  | \$<br>9,550                     |
| Changes during the period:                |                     |  |   |  |                                 |
| Granted                                   | 3,000,000           | \$<br>0.02                               | 0.01  | 9.8  | \$<br>24,900                    |
| Forfeited                                 | -                   | -  | -   | -  | -                               |
| Options outstanding at March 31, 2021     | 115,649,035         | \$<br>0.09                               |   | 6.9  | \$<br>\$438,795                 |
| Exercisable options at March 31, 2021     | 78,317,785          | \$<br>0.12                               |   | 6.2  | \$<br>\$208,640                 |

The Company measures compensation cost for all share-based awards at fair value on the date of grant and recognizes compensation expense in general administrative and research and development expenses within its unaudited Condensed Consolidated Statements of Comprehensive Income (Loss) using the straight-line method over the service period over which it expects the awards to vest.

The Company estimates the fair value of all time-vested options as of the date of grant using the Black-Scholes option valuation model, which was developed for use in estimating the fair value of traded options that have no vesting restrictions and are fully transferable. Option valuation models require the input of highly subjective assumptions, including the expected share price volatility, which is calculated based on the historical volatility of peer companies. The Company uses a risk-free interest rate, based on the U.S. Treasury instruments in effect at the time of the grant, for the period comparable to the expected term of the option. Given its limited history with share option grants and exercises, the Company uses the "simplified" method in estimating the expected term, the period of time that options granted are expected to be outstanding, for its grants.

The Company classifies its stock-based payments which are settled in ordinary shares as equity-classified awards.

The Company measures equity-classified awards at their grant date fair value and does not subsequently re-measure them. Compensation costs related to equity-classified awards generally are equal to the grant date fair value of the award amortized over the vesting period of the award.

Below are the assumptions used for the options granted during the three months ended March 31, 2021:

|                         | March 31,<br>2021 |
|-------------------------|-------------------|
| Expected dividend yield | 0%                |
| Expected volatility     | 82.22%            |
| Risk-free interest      | 0.64%             |
| Expected life           | 6.25 years        |

The following is a summary of the Company's share options granted separated into ranges of exercise price as of March 31, 2021:

| Exercise<br>price<br>(range) (\$) | Options<br>outstanding | Weighted<br>average<br>remaining<br>contractual<br>life (years) | Weighted<br>average<br>exercise<br>price (\$) | Options<br>exercisable | Remaining contractual life (years for exercisable options) | Weighted<br>average<br>exercise<br>price (\$) |
|-----------------------------------|------------------------|---|---|------------------------|--|---|
| 0.02-0.05                         | 80,600,000             | 7.86  | 0.02  | 43,362,500             | 7.34   | 0.03  |
| 0.12-0.19                         | 18,334,629             | 5.06  | 0.15  | 18,240,879             | 5.05   | 0.15  |
| 0.32                              | 16,714,406             | 4.48  | 0.32  | 16,714,406             | 4.48   | 0.32  |
|                                   | 115,649,035            |   |   | 78,317,785             |  |   |

# NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS - UNAUDITED March 31, 2021 (in U.S. dollars)

## NOTE 4 – Shareholders' Equity (cont.)

During the three months ended March 31, 2021 and 2020, the Company recorded approximately \$84,892 and \$100,504, respectively, in stock-based compensation expenses for employees and directors. At March 31, 2021, there was approximately \$347,571 of unrecognized compensation cost related to unvested share-based compensation arrangements granted under the Company's share option plans which the Company expects to recognize over a weighted average of 2.0 years.

#### **NOTE 5 – Related Party Transactions**

**Office Lease** - The Company leases its offices in London from The Doctors Laboratory ("TDL") and has incurred expenses of approximately \$38,000 and \$31,000 plus VAT during the three months ended March 31, 2021 and 2020, respectively. David Byrne, a non-employee director of the Company is also the Chief Executive Officer of TDL (see Note 6).

**Laboratory Testing Services** - The Company has received laboratory testing services for its clinical trials provided by TDL and has incurred expenses of approximately \$72,000 and \$148,000 plus VAT during the three months ended March 31, 2021 and 2020, respectively. The Company has outstanding accounts payables with TDL of \$132,000 and \$142,000 as of March 31, 2021 and 2020, respectively.

**Consulting** - A non-employee director of the Company began providing business development consulting services in January 2018. The Company has incurred expenses of approximately \$25,000 and \$25,000 during the three months ended March 31, 2021 and 2020, respectively, relating to these consulting services.

#### **NOTE 6 – Commitments and Contingencies**

**Lease commitment** – The Company's lease agreement for offices in London expired in March 2019. The Company currently leases its offices in London on the same terms of the expired lease except on a month-to-month basis. (See Note 4).

The Company's lease for offices in New York, New York ended early in December 2018. The Company currently leases office space in New York, New York on a month-to-month basis.

For the three months ended March 31, 2021 and 2020, the Company incurred rental expense in the amount of approximately \$46,000 and \$41,000, respectively.

## **NOTE 7 – Loss Per Share**

For purposes of the diluted net loss per share calculation, share options and warrants are considered to be potentially dilutive securities and are excluded from the calculation of diluted net loss per share because their effect would be anti-dilutive. Therefore, basic and diluted net loss per share was the same for the periods presented in the unaudited Condensed Consolidated Statement of Comprehensive Loss due to the Company's net loss position.

The following table shows the number of share equivalents that were excluded from the computation of diluted loss per share for the respective periods because the effect would have been anti-dilutive:

|                                       | Three<br>Months Ended<br>March 31,<br>2021 | Three<br>Months Ended<br>March 31,<br>2020 |
|---------------------------------------|--|--|
| Share options                         | 115,649,035                                | 94,349,035                                 |
| Warrants                              | 460,910,100                                | 462,160,100                                |
| Total Anti-Dilutive Share Equivalents | 576,559,135                                | 556,509,135                                |
|                                       |  |  |

## **NOTE 8 – Subsequent Event**

In May 2021, the Company sold to Aspire Capital a total of 1,176,471 ADSs of the Company for total gross proceeds of \$2,000,001 under the 2020 Purchase Agreement.

#### Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read this discussion together with the unaudited condensed consolidated financial statements, related notes and other financial information included elsewhere in this Report on Form 6-K. The following discussion may contain predictions, estimates and other forward-looking statements that involve a number of risks and uncertainties, including those set forth under Item 3D "Risk Factors" in our Annual Report on Form 20-F for the year ended December 31, 2020. These risks could cause our actual results to differ materially from any future performance suggested below and elsewhere in the report.

Unless the context otherwise requires, all references to "Akari," "we," "us," "our," the "Company" and similar designations refer to Akari Therapeutics, PLC and its subsidiaries.

#### Overview

We are a clinical-stage biopharmaceutical company focused on developing treatments for autoinflammatory diseases involving the complement (C5) and leukotriene (LTB4) pathways. The Company's activities since inception have consisted of performing research and development activities and raising capital. 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 lead product candidate, nomacopan (formerly known as Coversin), is a recombinant small protein 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 acts on complement component-C5, preventing release of C5a and formation of C5b–9 (also known as the membrane attack complex, or MAC), and independently and specifically also inhibits leukotriene B4, or LTB4, activity, both elements that are co-located as part of the immune/inflammatory response. The importance of nomacopan's dual inhibitory action is therefore twofold. First, it can prevent inflammatory and prothrombotic activities of two key pathways, and second, the pathways can be independently activated. Additionally, nomacopan's bio-physical properties allow it to be potentially used in a variety of formulations, including subcutaneous, intravenous, topical or inhaled routes of administration.

Our clinical targets for nomacopan are orphan inflammatory diseases where the inhibition of both C5 and LTB4 are implicated, including bullous pemphigoid, or BP, thrombotic microangiopathy bone marrow transplant, or TMA-HSCT as well as inflammatory conditions in the eye and lung including dry eye, dry AMD and COVID-19 pneumonia.

In February and March 2020, we sold to certain accredited and institutional investors, led by some of our existing investors, including Dr. Ray Prudo, our Chairman, an aggregate of 5,620,296 ADSs in a private placement at \$1.70 per ADS for aggregate gross proceeds of approximately \$9.5 million. We also entered into a letter agreement with Paulson Investment Company, LLC, or the Placement Agent, to serve as our placement agent in connection with this offering. In connection with the offering, we issued to the investors and the Placement Agent unregistered warrants to purchase 2,810,136 ADSs at \$2.20 per ADS and 449,623 ADSs at \$2.55 per ADS, respectively. See "Liquidity and Capital Resources –2020 Private Placements".

In June 2020, we entered into a Purchase Agreement with Aspire Capital, or 2020 Purchase Agreement, which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of \$30.0 million of our ADSs during a 30-month period beginning on the effective date of a registration statement related to the transaction. Concurrently with entering into the 2020 Purchase Agreement, we also entered into a registration rights agreement with Aspire Capital, in which we agreed to file one or more registration statements, as permissible and necessary to register under the Securities Act of 1933, as amended, or the Securities Act, the sale of our securities that have been and may be issued to Aspire Capital under the 2020 Purchase Agreement. See "Liquidity and Capital Resources – Aspire Capital Financing Arrangements".

## **Impact of COVID-19**

The global outbreak of COVID-19, also known as coronavirus, and public health epidemics can adversely impact the Company's business as a result of disruptions, such as travel bans, quarantines, 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. Moreover, as a result of COVID-19, there is a general unease of conducting unnecessary activities in medical centers. As a consequence, during 2020 the Company's ongoing trials have been halted or disrupted. It is too early to assess the full impact of the coronavirus outbreak on trials for nomacopan, but COVID-19 has affected the Company's ability to complete recruitment in the original timeframe. For example, the Phase I/II clinical trial in patients with AKC study was halted and the opening of sites for the Phase III clinical trial in pediatric patients with HSCT-TMA was delayed until the end of 2020 and is now open for enrollment of patients. The extent to which COVID-19 impacts operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration and continued severity of the outbreak, and the actions that may be required to contain the coronavirus or treat its impact. In particular, the continued spread of COVID-19 globally could adversely impact the Company's operations and workforce, including research and clinical trials and the ability to raise capital, could affect the operations of key governmental agencies, such as the FDA, which may delay the development of the Company's product candidates, and could result in the inability of suppliers to deliver components or raw materials on a timely basis or at all, each of which in turn could have an adverse impact on the Company's business, financial condition and results of operation.

## **Critical Accounting Policies and Use of Estimates**

The preparation of the consolidated financial statements in conformity with United States generally accepted accounting principles, or U.S. GAAP, requires management to make estimates, judgments and assumptions. We believe that the estimates, judgments and assumptions used are reasonable based upon information available at the time they are made. These estimates, judgments and assumptions can affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the dates of the financial statements, and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

## Share-Based Compensation and Fair Value of Ordinary Shares

We account for awards of equity instruments issued to employees and directors under the fair value method of accounting and recognize such amounts in our unaudited Condensed Consolidated Statements of Comprehensive Loss. We measure compensation cost for all stock-based awards at fair value on the date of grant and recognize compensation expense in general administrative and research and development expenses in our Consolidated Statements of Comprehensive Loss using the straight-line method over the service period over which we expect the awards to vest.

We estimate the fair value of all time-vested options as of the date of grant using the Black-Scholes option valuation model, which was developed for use in estimating the fair value of traded options that have no vesting restrictions and are fully transferable. Option valuation models require the input of highly subjective assumptions, including the expected share price volatility, which we calculate based on the historical volatility of peer companies. We use a risk-free interest rate, based on U.S. Treasury instruments in effect at the time of the grant, for the period comparable to the expected term of the option. Given our limited history with share option grants and exercises, we use the "simplified" method in estimating the expected term, the period of time that options granted are expected to be outstanding, for our grants.

We classify our stock-based payments which are settled in our ordinary shares as equity-classified awards. We measure equity-classified awards at their grant date fair value and do not subsequently remeasure them. Compensation costs related to equity-classified awards generally are equal to the grant date fair value of the award amortized over the vesting period of the award.

## Warrants issued in connection with our 2019 Registered Direct Offering

In connection with the sale of the ADSs in the 2019 Registered Direct Offering, we issued to investors unregistered warrants to purchase an aggregate of 1,184,213 ADSs in a private placement, or the 2019 Investor Warrants. The 2019 Investor Warrants are immediately exercisable at an exercise price of \$3.00 per ADS, subject to adjustment as set forth therein and will expire five years from issuance. We also issued unregistered warrants to the Placement Agent to purchase an aggregate of 177,629 ADSs, or the 2019 Placement Agent Warrants, on the same terms as the 2019 Investor Warrants, except that the 2019 Placement Agent Warrants are exercisable at \$2.85 per ADS. The total amount of warrants issued in connection with this registered direct offering amounted to warrants to purchase an aggregate of 1,361,842 ADSs, all of which were outstanding as of March 31, 2021. At grant date, the 2019 Investor Warrants and the 2019 Placement Agent Warrants, or, together, the 2019 Warrants, were recorded as liability-classified awards and accounted for in accordance with ASC 815-40-25, Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock and ASC 815-40-15, Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock. In accordance with ASC 820, we measured the 2019 Warrants at grant date fair value. The total grant date fair value of the 2019 Warrants was \$1,213,816. On December 8, 2020, the Company held a general meeting ("2020 General Meeting") and changed the currency of its ordinary shares from pounds sterling to US dollars ("2020 Redenomination"). As a consequence of the 2020 Redenomination, the Company was required to reassess, whether its financial instruments or other contracts that previously required derivative accounting within the scope of ASC 815 Financial Instruments either (a) no longer meet the definition of a derivative or (b) meet a scope exception to the derivative guidance due to a change in facts and circumstances. The Company concluded that due to the 2020 Redenomination, the 2019 Warrants now meet the requirements for classification as equity under ASC 815-40-25 as of December 8, 2020, the date of the 2020 General Meeting. The Company updated the carrying amount of the warrant liability to its fair value on December 8, 2020, with any changes recorded in the Consolidated Statements of Comprehensive Loss and then reclassed the warrant liability balance to additional paid in capital within Shareholders' Equity.

#### Warrants issued in connection with the 2020 Private Placements

In connection with the sale of the ADSs in the 2020 Private Placements, we issued to investors unregistered warrants to purchase an aggregate of 2,810,136 ADSs in a private placement, or the 2020 Investor Warrants. The warrants are immediately exercisable at an exercise price of \$2.20 per ADS, subject to adjustment as set forth therein and will expire five years from issuance. We also issued unregistered warrants to the Placement Agent to purchase an aggregate of 449,623 ADSs, or February 2020 Placement Agent Warrants, on the same terms as the 2020 Investor Warrants, except that the 2020 Placement Agent Warrants are exercisable at \$2.55 per ADS. The total amount of warrants issued in connection with this private placement amounted to warrants to purchase an aggregate of 3,259,759 ADSs. 3,247,259 of these warrants were outstanding as of March 31, 2021. At grant date, the 2020 Investor Warrants and the 2020 Placement Agent Warrants, or, together, the 2020 Warrants were recorded as liability-classified awards and accounted for in accordance with ASC 815-40-25, Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock and ASC 815-40-15, Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock. In accordance with ASC 820, we measured the 2020 Warrants at grant date fair value. The total grant date fair value of the 2020 Warrants was \$2,749,369. The Company concluded that due to the 2020 Redenomination, the 2020 Warrants now meet the requirements for classification as equity under ASC 815-40-25 as of December 8, 2020, the date of the 2020 General Meeting. The Company updated the carrying amount of the warrant liability to its fair value on December 8, 2020, with any changes recorded in the Consolidated Statements of Comprehensive Loss and then reclassed the warrant liability balance to additional paid in capital within Shareholders' Equity.

#### Commitment Shares issued in connection with the 2020 Purchase Agreement

In consideration for entering into the 2020 Purchase Agreement, we agreed to issue to Aspire Capital 40,760,900 ordinary shares of the Company (the "2020 Commitment Shares") which had a fair value of approximately \$900,000. Since we have determined that the 2020 Purchase Agreement includes a freestanding put option that meets the criteria of a derivative in accordance with ASC 815-40-15, *Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock*, we recorded the fair value of the 2020 Commitment Shares in General and administrative expenses in the unaudited Condensed Consolidated Statements of Comprehensive Income (Loss).

## **Functional Currency**

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

The reporting currency of the Company is U.S. Dollars. The Company translated 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) income. Gains or losses from foreign currency transactions and the remeasurement of intercompany balances are included in foreign currency exchange (losses) gains.

#### **Results of Operations**

## For the Three Months Ended March 31, 2021 and March 31, 2020

Research and development expenses

Research and development expenses for the three months ended March 31, 2021 were approximately \$3,529,000 compared to approximately \$2,732,000 for the three months ended March 31, 2020. This increase of 29% or \$797,000 in expenses was primarily due to higher expenses incurred for manufacturing to support ongoing clinical trials.

We expect our clinical expenses including other research development expenses to increase in the future as we plan to conduct additional trials to support the development of nomacopan, and advance other product candidates into pre-clinical and clinical development.

General and administrative expenses

General and administrative expenses for the three months ended March 31, 2021 were approximately \$2,019,000 compared to approximately \$2,195,000 for the three months ended March 31, 2020. This decrease of 8% or \$176,000 was primarily due to compensation expense incurred for fundraising activities in the first quarter of 2020 not similarly incurred in the first quarter of 2021.

We expect our general and administrative expenses to increase due to increased legal, accounting and professional fees associated with being a publicly reporting company in the United States and rental expense associated with offices in the United States and London to support the Company's operations and anticipated growth.

Other Income (expenses)

Other expense for the three months ended March 31, 2021 was approximately \$290,000 compared to other income of approximately \$1,181,000 for the three months ended March 31, 2020. This \$1,471,000 decrease was primarily attributed to the reclassification of warrant liabilities to equity under ASC 815-40-25 as of December 8, 2020, compared to gain related to the fair value of these warrants liabilities in the first quarter of 2020.

## **Liquidity and Capital Resources**

At March 31, 2021, we had \$6,668,325 in cash and an accumulated deficit in the amount of \$188,119,312. Since inception, we have funded our operations primarily through the sale of equity securities. In May 2021, we sold to Aspire Capital approximately \$2,000,000 of ADSs under the 2020 Purchase Agreement.

In September 2018, we entered into a Purchase Agreement with Aspire Capital which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital was committed to purchase up to an aggregate of \$20.0 million of our ADSs beginning on the effective date of a registration statement related to the transaction. To date, we have sold to Aspire Capital a total of \$19,628,379 of ordinary shares under the 2018 Purchase Agreement. On June 30, 2020, we terminated the 2018 Purchase Agreement in connection with the entry of the 2020 Purchase Agreement. See "Aspire Capital Financing Arrangements – 2018 Purchase Agreement" below.

In July 2019, we sold to certain institutional investors, accredited investors and an existing shareholder, RPC Pharma Ltd., an affiliated entity of Dr. Ray Prudo, our Chairman, an aggregate of 2,368,392 ADSs in the Registered Direct Offering resulting in gross proceeds of approximately \$4.5 million. We also entered into a letter agreement with the Placement Agent to serve as our placement agent in connection with this offering. In connection with the sale of the ADSs in this Registered Direct Offering, we issued unregistered warrants to investors and the Placement Agent to purchase an aggregate of 1,361,842 ADSs in a private placement at \$3.00 per ADS and \$2.85 per ADS respectively. As of the date of the issuance of this Report on Form 6-K, all 1,361,842 of such warrants were outstanding. See "Liquidity and Capital Resources – 2019 Registered Direct Offering" below.

In February 2020, we sold to certain accredited and institutional investors, led by some of our existing investors, including our Chairman Dr. Ray Prudo, an aggregate of 5,620,296 ADSs in a private placement at \$1.70 per ADS for aggregate gross proceeds of approximately \$9.5 million. We also entered into a letter agreement with the Placement Agent to serve as our placement agent in connection with this offering. In connection with the offering, we issued to the investors and the Placement Agent unregistered warrants to purchase 2,810,136 ADSs at \$2.20 per ADS and 449,623 ADSs at \$2.55 per ADS, respectively. As of the date of the issuance of this Report on Form 6-K, 3,247,259 of such warrants were outstanding. See "Liquidity and Capital Resources –2020 Private Placements" below.

In June 2020, we entered into a Purchase Agreement with Aspire Capital which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of \$30.0 million of our ADSs beginning on the effective date of a registration statement related to the transaction. To date, we have sold to Aspire Capital a total of approximately \$8 million of ADSs and \$22 million of the original purchase commitment remains available for draw down under the 2020 Purchase Agreement. See "Aspire Capital Financing Arrangements – 2020 Purchase Agreements" below.

We believe our current capital resources are sufficient to support our operations into September 2021 without giving effect to the sale of additional shares to Aspire Capital under the 2020 Purchase Agreement.

We are subject to a number of risks similar to those of clinical stage companies, including dependence on key individuals, uncertainty of product development and generation of revenues, dependence on outside sources of capital, risks associated with clinical trials of products, dependence on third-party collaborators for research operations, need for regulatory approval of products, risks associated with protection of intellectual property, and competition with larger, better-capitalized companies. We are closely monitoring ongoing developments in connection with the coronavirus pandemic, which has resulted in the halting of and disruptions to our ongoing clinical trials and may negatively impact our ability to raise capital. To fully execute our business plan, we will need, among other things, to complete our 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.

For the three months ended March 31, 2021, we reported a net loss of \$5,838,501 and we expect to continue to incur substantial losses over the next several years during our development phase. To fund our capital needs, we plan to raise additional funds through equity or debt financings or other sources, such as strategic partnerships and alliance and licensing arrangements, and in the long term, from the proceeds from sales of commercial products. To the extent that we raise additional funds by issuing equity securities, our shareholders may experience significant dilution.

These additional funds may not be available when we need them, on terms that are acceptable to us, or at all. Specifically, the COVID-19 pandemic has disrupted global financial markets, and may limit our ability to access capital, which could in the future negatively affect our liquidity. Therefore, there can be no assurance that we will be successful in obtaining an adequate level of financing needed for our research and development efforts and clinical and regulatory activities, which may take several years and will require significant operating and capital expenditures in the foreseeable future. If we are unable to raise sufficient capital resources, we will not be able to continue the development of all of our products, or may be required to delay part of our development programs and significantly reduce our activities in order to maintain our operations. These matters raise substantial doubt about our ability to continue as a going concern. Our independent registered public accounting firm, in its report on our audited financial statements for the year ended December 31, 2020 expressed substantial doubt about our ability to continue as a going concern. The financial statements do not include any adjustments to the carrying amounts and classifications of assets and liabilities that would result if we were unable to continue as a going concern.

## Aspire Capital Financing Arrangements

## 2020 Purchase Agreement

On June 30, 2020, we entered into a second Purchase Agreement with Aspire Capital ("2020 Purchase Agreement") which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of \$30.0 million of our ADSs, during a 30-month period beginning July 27, 2020 on the effective date of a registration statement related to the transaction. Concurrently with entering into the 2020 Purchase Agreement, we also entered into a registration rights agreement with Aspire Capital, or the Registration Rights Agreements in which we agreed to file one or more registration statements, as permissible and necessary to register under the Securities Act, the sale of our securities that have been and may be issued to Aspire Capital under the 2020 Purchase Agreement. On July 17, 2020, we filed the registration statement on Form F-1 to register the resale of such securities and such registration statement was declared effective on July 27, 2020.

Under the 2020 Purchase Agreement, after the SEC has declared effective the registration statement referred to above, on any trading day selected by us, we have the right, in our sole discretion, to present Aspire Capital with a purchase notice, each, a Purchase Notice, directing Aspire Capital (as principal) to purchase up to 150,000 ADSs per business day and up to \$30.0 million of our ADSs in the aggregate at a per share price, or the Purchase Price, equal to the lesser of:

- the lowest sale price of our ADSs on the purchase date; or
- the arithmetic average of the three (3) lowest closing sale prices for the ADSs during the ten (10) consecutive business days ending on the business day immediately preceding such Purchase Date (to be appropriately adjusted for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction).

In addition, on any date on which we submit a Purchase Notice to Aspire Capital in an amount of 150,000 ADSs, the Company also has the right, in its sole discretion, to present Aspire Capital with a volume-weighted average price purchase notice, each, a VWAP Purchase Notice, directing Aspire Capital to purchase an amount of ADSs equal to up to 30% of the aggregate shares of our ADSs traded on our principal market on the next trading day, or the VWAP Purchase Date, subject to a maximum number of 250,000 ADSs. The purchase price per share pursuant to such VWAP Purchase Notice is generally 97% of the volume-weighted average price for our ADSs traded on our principal market on the VWAP Purchase Date.

The Purchase Price will be adjusted for any reorganization, recapitalization, non-cash dividend, stock split, or other similar transaction occurring during the period(s) used to compute the Purchase Price. We may deliver multiple Purchase Notices and VWAP Purchase Notices to Aspire Capital from time to time during the term of the 2020 Purchase Agreement, so long as the most recent purchase has been completed.

The 2020 Purchase Agreement provides that we and Aspire Capital shall not effect any sales under the 2020 Purchase Agreement on any purchase date where the closing sale price of our ADSs is less than \$0.25. Additionally, governing law in the United Kingdom, where the Company is incorporated, requires a minimum payment per ADS to be issued pursuant to a purchase notice equal to the nominal value of an ADS (i.e., £1). There are no trading volume requirements or restrictions under the 2020 Purchase Agreement, and the Company will control the timing and amount of sales of the Company's ADSs to Aspire Capital. Aspire Capital has no right to require any sales by the Company, but is obligated to make purchases from the Company as directed by the Company in accordance with the 2020 Purchase Agreement. There are no limitations on use of proceeds, financial or business covenants, restrictions on future fundings, rights of first refusal, participation rights, penalties or liquidated damages in the 2020 Purchase Agreement. In accordance with ASC 815-40-15, *Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock*, since the ultimate floor price which is effectively the nominal value of the ADS which was denominated in GBP at the time of entering into the 2018 Purchase agreement as well as the 2020 Purchase Agreement (together "the Purchase Agreements") prior to the 2020 Redenomination, the number of shares issuable under the contract was impacted by foreign currency, therefore ASC 815-40-15-71 precluded the Purchase Agreements from being indexed to the Company's own stock. The Company determined that the right to sell shares to Aspire Capital under the Purchase Agreements represents a freestanding put option that met the criteria of a derivative pursuant to ASC 815 *Derivatives and Hedging*. Since the purchase price per share pursuant to the Purchase Agreements is at the market, the Company concluded that the put option has a fair value of zero, and therefore no additional accounting rel

In consideration for entering into the 2020 Purchase Agreement, the Company agreed to issue to Aspire Capital 40,760,900 ordinary shares of the Company, the 2020 Commitment Shares, which had a fair value of approximately \$900,000. Because the Company has determined that the 2020 Purchase Agreement is considered a freestanding put option derivative, the Company recorded the value of the 2020 Commitment Shares in the twelve months ended December 31, 2020 in General and Administrative Expenses in the Consolidated Statements of Comprehensive Income (Loss). The 2020 Purchase Agreement may be terminated by us at any time, at our discretion, without any cost to us. Aspire Capital has agreed that neither it nor any of its agents, representatives and affiliates shall engage in any direct or indirect short-selling or hedging of our securities during any time prior to the termination of the 2020 Purchase Agreement. Any proceeds we receive under the 2020 Purchase Agreement are expected to be used for working capital and general corporate purposes.

To date, we have sold to Aspire Capital a total of approximately \$8 million of ADSs and \$22 million of the original purchase commitment remains available for draw down under the 2020 Purchase Agreements.

#### Cash Flows

Net cash used in operating activities was approximately \$7,418,000 during the three months ended March 31, 2021 compared to \$7,740,000 during the three months ended March 31, 2020. Net cash flow used in operating activities was primarily attributed to our ongoing research activities to develop nomacopan, including manufacturing, clinical trial and preclinical activities as well as to our general and administrative activities.

There were no investing activities during the three months ended March 31, 2021 and March 31, 2020.

There were no financing activities during the three months ended March 31, 2021.

Net cash provided by financing activities, after related expenses, was approximately \$9,878,000 during the three months ended March 31, 2020. This was from net proceeds from our February 2020 Private Placements in the approximate amount of \$8,778,000 as well as from issuance of shares to Aspire Capital under the 2018 Purchase Agreement in the approximate amount of \$1,100,000.

## Research and Development Expenditures, Patents and Licenses

Our research and development expenses were approximately \$3,529,000 and \$2,732,000 for the three months ended March 31, 2021 and 2020, respectively. Most of such research and development expenditures were in the form of payments to third parties to carry out our manufacturing, pre-clinical and clinical research activities.

We incurred the following research and development expenses for the three months ended March 31, 2021 and 2020:

|     | March 31,            |  |  |  |
|-----|----------------------|--|--|--|
|     |                      |  |  |  |
| ·   | 2021<br>(in \$000's) |  | 2020<br>(in \$000's)   |  |
| (in |                      |  |  |  |
|     |                      |  |  |  |
| \$  | 1,648                | \$   | 872  |  |
|     | 959                  |  | 823  |  |
|     | 291                  |  | 245  |  |
|     | 2,898                |  | 1,940  |  |
|     |                      | <u> </u>   |  |  |
|     |                      |  |  |  |
|     | 505                  |  | 613  |  |
|     | 126                  |  | 179  |  |
|     | 631                  |  | 792  |  |
|     | _                    |  | _  |  |
| \$  | 3,529                | \$   | 2,732  |  |
|     | (in                  | \$ 1,648<br>959<br>291<br>2,898<br>505<br>126<br>631 | March 31,  2021 (in \$000's) (in  \$ 1,648 \$ 959 291 2,898  505 126 631 |  |

Three Months ended

#### **Trend Information**

We are a clinical-stage drug development company and it is not possible for us to predict with any degree of accuracy the outcome of our research, development or commercialization efforts. As such, it is not possible for us to predict with any degree of accuracy any significant trends, uncertainties, demands, commitments or events that are reasonably likely to have a material effect on our net sales or revenues, income from continuing operations, profitability, liquidity or capital resources, or that would cause financial information to not necessarily be indicative of future operating results or financial condition.

## **Off-balance Sheet Arrangements**

We currently do not have any off-balance sheet arrangements.

## **Contractual Obligations**

We do not have any significant contractual obligations as of March 31, 2021.

We lease office space in London, UK and New York, NY on a short-term basis.

# Akari Therapeutics Reports Q1 2021 Financial Results and Highlights Recent Clinical Progress

- Open Investigational New Drug Application (IND) with U.S. Food and Drug Administration (FDA) for Phase III study of nomacopan in bullous pemphigoid (BP)
- Phase III study of nomacopan in severe pediatric hematopoietic stem cell transplant-related thrombotic microangiopathy (HSCT-TMA), a
  disease with no approved treatment, is open for enrollment in the U.S. and Europe.
- Ongoing pharmacokinetic (PK) study to evaluate the potential for nomacopan as a treatment for dry age-related macular degeneration (AMD), where the demonstrated inhibition of both complement (C5) and VEGF by nomacopan may provide a new treatment option.
- Lung program focused on treating exacerbations in diseases including COVID-19 pneumonia and severe asthma where both complement (C5) and leukotriene (LTB4) are implicated and where nomacopan can be potentially delivered directly to the lung in a nebulizer or via a dry powder.
- Ongoing severe trauma studies under a Cooperative Research and Development Agreement (CRADA) with the U.S. Army Institute of Surgical Research (USAISR). Separately, investigating the potential for nomacopan in brain injury due to subarachnoid hemorrhage.
- Active pipeline development including a new anti-histamine, votucalis, a biopharmaceutical with a similar structure to nomacopan, in preclinical development in dermatology and neurology.

NEW YORK and LONDON, June [29], 2021 - Akari Therapeutics, Plc (Nasdaq: AKTX), a late-stage biopharmaceutical company focused on innovative therapeutics to treat orphan autoimmune and inflammatory diseases where complement (C5) and/or leukotriene (LTB4) systems are implicated, today announced financial results for the first quarter of 2021, as well as recent clinical progress.

Akari's two lead programs, in BP and HSCT-TMA, are in Phase III clinical development and have been granted both Orphan Drug and Fast Track designations. The Company also has earlier stage programs addressing ophthalmology, pulmonary diseases and trauma.

## **Corporate**

The Company is expanding its senior operational team in the U.S. and the UK, and recently appointed a new senior medical director, Dr. Sanjeev Khindri, former acting CMO at Galecto Biotech AB and global clinical leader within Johnson & Johnson with Phase II and Phase III experience. Dr. Khindri has responsibility for the BP and HSCT-TMA pivotal Phase III programs.

Over the last two years, Akari has made good progress in the development of its drug substance and drug product. Recently, it has successfully released the first commercial-scale GMP batch of an advanced strain for nomacopan expression, which provides at least a five-fold increase in yield of the 'to be marketed' drug substance.

"Akari continues to make progress advancing clinical development of nomacopan in multiple indications, including BP, HSCT-TMA, as well as eye and lung diseases", said Clive Richardson, Chief Executive Officer of Akari Therapeutics. "Our commercial strategy is to focus on progressing our current orphan disease programs while partnering in other larger disease areas such as the eye and lung which utilize different routes of administration."

## PHASE III TRIALS

Two ongoing pivotal Phase III programs in orphan diseases with no specific approved treatments.

## Phase III clinical trial in patients with BP

BP is a severe autoimmune blistering disease of the elderly.

- § The Company anticipates recruitment in the U.S. and Europe in the third quarter of 2021 in a multicenter Phase III study of nomacopan for the treatment of BP following the recent opening of an U.S. Food and Drug Administration (FDA) IND.
- § The FDA and the European Medicines Agency (EMA) have granted Orphan Drug designation for nomacopan for the treatment of BP, and the FDA has granted Fast Track designation to nomacopan in BP.
- § Opportunities to expand into other dermatological conditions such as hidradenitis suppurativa (HS) which is a disease that may impact over 1% of the population in developed economies. Both complement C5 activation and LTB4 are believed to have key roles in driving the disease pathology.

## Phase III clinical trial in patients with HSCT-TMA

HSCT-TMA is a severe disease in pediatric patients with an estimated 80% mortality rate and no approved treatments.

- § Phase III study in pediatric HSCT-TMA is now open for enrollment at sites in the U.S. and Europe, subject to the ongoing impact of COVID-19 related restrictions.
- § Akari has FDA Fast Track and Orphan Drug designations for pediatric HSCT-TMA patients.
- § Success in pediatric HSCT-TMA would provide opportunities to expand into adult HSCT-TMA and related TMA-like diseases where complement and LTB4 have important roles such as atypical hemolytic uremic syndrome, systemic lupus erythematosus and anti-phospholipid syndrome.

## PNH - long term data

Long-term treatment data for PNH patients in phase II and phase III studies shows nomacopan is well tolerated, maintains its drug effect over multiple years, and shows a marked clinical effect with 79% of formerly transfusion dependent patients becoming transfusion independent. Akari believes this long-term clinical data de-risks key aspects of their clinical programs going forward.

## OTHER CLINICAL PROGRAMS

These studies are primarily focused on large disease areas with high unmet need. For these programs we are using alternative formulations of nomacopan (topical, nebulized or long acting), which provides an opportunity for separate partnering options for different formulations.

## **Ophthalmology program**

- § In our surface of the eye program, nomacopan delivered topically has been shown to have a positive safety profile and was well tolerated in a Phase I/II study in atopic keratoconjunctivitis. There remains an unmet need for severe surface of the eye inflammatory diseases and leveraging our open IND application we are currently exploring a Phase II study.
- § Recent publications (Eskandarpour et al 2020 and 2021) support a potential therapeutic role for long-acting PAS-nomacopan in sight threatening retinal diseases given its demonstrated inhibition of both complement and VEGF (via LTB4) which are both implicated in multiple conditions. This unique dual acting combination may be particularly relevant to dry AMD where complement is a key treatment target and VEGF inhibition may prevent the risk of conversion to wet AMD where VEGF inhibitors are the primary treatment.
- § PAS-nomcopan is an engineered form of nomacopan which increases the molecular weight (MW) of nomacopan from 17Kda to an effective MW of over 500 Kda. This significantly extends the half-life of nomacopan and as such provides a potential opportunity to significantly reduce the patient injection frequency for back of the eye diseases. PK studies to evaluate residence time and hence injection interval are ongoing and expected to read out later this year.
- § To maximize the potential of nomacopan in the ophthalmology market, Akari is exploring opportunities to collaborate with partners to accelerate the development of these ophthalmology programs.

#### Lung program

- § There are multiple poorly treated lung inflammatory conditions, including COVID-19 pneumonia, where the combined role of complement and LTB4 has been implicated. In addition, the potential to deliver nomacopan directly to the lung in nebulized or potentially dry powder form provides further potential benefit to patients.
- We are exploring the development of nomacopan in severe asthma, which is one of several large lung inflammatory conditions diseases with exacerbations which still has limited treatment options. Pre-clinical work with nomacopan has demonstrated significant reduction of neutrophils and eosinophils which are key drivers of inflammation.
- Proposed publication of the Akari sponsored observational study and role of nomacopan in COVID-19 patients is in preparation. Initiation of further COVID-19 randomized studies later in the year is subject to optimizing patient selection to align with the findings of the paper.

#### Trauma

- Working under a CRADA with the USAISR, nomacopan is currently being investigated in a model of blast injury and hemorrhagic shock. Alongside pre-clinical work, Akari is separately exploring the potential for nomacopan in traumatic brain injury and subarachnoid hemorrhage where the role of C5 and LTB4 are implicated.
- § Trauma is a global health issue. In the U.S., there are approximately 500,000 trauma hospital discharges a year which are defined as severe and might benefit from early drug intervention to reduce multi-organ dysfunction following trauma.

#### **Histamine inhibitor**

§ Votucalis is a new histamine inhibitor with a similar structure to nomacopan and a unique mode of action that prevents activation of all four histamine G-protein coupled receptors. Ongoing work in collaboration with two United Kingdom University Centers using votucalis is focused on expanding the Company's existing dermatology franchise in atopic dermatitis and pain management. In both cases initial skin penetration data indicates a potential opportunity for topical delivery. Additional data is expected later in 2021.

#### First Quarter 2021 Financial Results

- § As of March 31, 2021, the Company had cash of approximately \$6.7 million, compared to cash of approximately \$14.1 million at December 31, 2020.
- § In June 2020, Akari entered into a securities purchase agreement (Purchase Agreement) with Aspire Capital Fund, LLC (Aspire Capital) whereby Aspire Capital is committed to purchase up to an aggregate of \$30.0 million of the Company's ADSs. During the three months ended March 31, 2021, the Company did not sell any shares to Aspire Capital. As of March 31, 2021, \$24 million of the original purchase commitment of \$30 million remains available under the facility. A further \$2 million has been drawn down following the end of the quarter.
- § Research and development expenses for first quarter 2021 were approximately \$3.5 million, as compared to approximately \$2.7 million in the same quarter the prior year. The increase was due to additional manufacturing costs for Phase III studies.
- § General and administrative expenses for the first quarter 2021 were approximately \$2.0 million, as compared to approximately \$2.2 million in the same quarter the prior year.
- § For the first quarter 2021, total other expense was approximately \$0.3 million as compared to total other income of approximately \$1.2 million in the first quarter of 2020. This change was primarily due to higher other income related to the change in the fair value of warrant liabilities in the first quarter of 2020.
- § Net loss for the first quarter 2021 was approximately \$5.8 million, as compared to approximately \$3.7 million for the same quarter the prior year. The increase in net loss was primarily due to the aforementioned higher research and development expenses as well as lower other income.

## **About Akari Therapeutics**

Akari is a biopharmaceutical company focused on developing inhibitors of acute and chronic inflammation, specifically for the treatment of rare and orphan diseases, in particular those where the complement (C5) or leukotriene (LTB4) systems, or both complement and leukotrienes together, play a primary role in disease progression. Akari's lead drug candidate, Nomacopan (formerly known as Coversin), is a C5 complement inhibitor that also independently and specifically inhibits leukotriene B4 (LTB4) activity. Nomacopan is currently being clinically evaluated in four areas: bullous pemphigoid (BP), thrombotic microangiopathy (TMA), as well as programs in the eye and lung.

## **Cautionary Note Regarding Forward-Looking Statements**

Certain statements in this press release constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. You should not place undue reliance upon the Company's forward-looking statements. Except as required by law, the Company undertakes No obligation to revise or update any forward-looking statements in order to reflect any event or circumstance that may arise after the date of this press release. These forward-looking statements reflect our current views about our plans, intentions, expectations, strategies and prospects, which are based on the information currently available to us and on assumptions we have made. Although we believe that our plans, intentions, expectations, strategies and prospects as reflected in or suggested by those forward-looking statements are reasonable, we can give No assurance that the plans, intentions, expectations or strategies will be attained or achieved. Furthermore, actual results may differ materially from those described in the forward-looking statements and will be affected by a variety of risks and factors that are beyond our control. Such risks and uncertainties for our company include, but are not limited to: needs for additional capital to fund our operations, our ability to continue as a going concern; uncertainties of cash flows and inability to meet working capital needs; an inability or delay in obtaining required regulatory approvals for nomacopan and any other product candidates, which may result in unexpected cost expenditures; our ability to obtain orphan drug designation in additional indications; risks inherent in drug development in general; uncertainties in obtaining successful clinical results for nomacopan and any other product candidates and unexpected costs that may result therefrom; difficulties enrolling patients in our clinical trials; our ability to enter into collaborative, licensing, and other commercial relationships and on terms commercially reasonable to us; failure to realize any value of nomacopan and any other product candidates developed and being developed in light of inherent risks and difficulties involved in successfully bringing product candidates to market; inability to develop new product candidates and support existing product candidates; the approval by the FDA and EMA and any other similar foreign regulatory authorities of other competing or superior products brought to market; risks resulting from unforeseen side effects; risk that the market for nomacopan may not be as large as expected; risks associated with the impact of the COVID-19 pandemic; inability to obtain, maintain and enforce patents and other intellectual property rights or the unexpected costs associated with such enforcement or litigation; inability to obtain and maintain commercial manufacturing arrangements with third party manufacturers or establish commercial scale manufacturing capabilities; the inability to timely source adequate supply of our active pharmaceutical ingredients from third party manufacturers on whom the company depends; unexpected cost increases and pricing pressures and risks and other risk factors detailed in our public filings with the U.S. Securities and Exchange Commission, including our most recently filed Annual Report on Form 20-F filed with the SEC. Except as otherwise noted, these forward-looking statements speak only as of the date of this press release and we undertake No obligation to update or revise any of these statements to reflect events or circumstances occurring after this press release. We caution investors not to place considerable reliance on the forward-looking statements contained in this press release.

# CONDENSED CONSOLIDATED BALANCE SHEETS

As of March 31, 2021 and December 31, 2020 (in U.S. dollars, except share data)

| Total Current Assets       7,813,285       14,57         Property and equipment, net       -       -         Patent acquisition costs, net       26,460       2         Total Assets       \$ 7,839,745       \$ 14,60         Liabilities and Shareholders' Equity         Current Liabilities:       -         Accounts payable Accrued expenses       \$ 2,831,779       \$ 3,38         9 1,071,159       1,83  | December 31,<br>2020 |  |
|---|----------------------|--|
| Cash       \$ 6,668,325       \$ 14,05         Prepaid expenses and other current assets       1,144,960       52         Total Current Assets       7,813,285       14,57         Property and equipment, net       -       -         Patent acquisition costs, net       26,460       2         Total Assets       \$ 7,839,745       \$ 14,60         Liabilities and Shareholders' Equity         Current Liabilities:         Accounts payable       \$ 2,831,779       \$ 3,38         Accrued expenses       1,071,159       1,83         Total Liabilities       3,902,938       5,22 |                      |  |
| Cash       \$ 6,668,325       \$ 14,05         Prepaid expenses and other current assets       1,144,960       52         Total Current Assets       7,813,285       14,57         Property and equipment, net       -       -         Patent acquisition costs, net       26,460       2         Total Assets       \$ 7,839,745       \$ 14,60         Liabilities and Shareholders' Equity         Current Liabilities:         Accounts payable       \$ 2,831,779       \$ 3,38         Accrued expenses       1,071,159       1,83         Total Liabilities       3,902,938       5,22 |                      |  |
| Prepaid expenses and other current assets       1,144,960       52         Total Current Assets       7,813,285       14,57         Property and equipment, net       -       -         Patent acquisition costs, net       26,460       2         Total Assets       \$ 7,839,745       \$ 14,60         Liabilities and Shareholders' Equity         Current Liabilities:         Accounts payable       \$ 2,831,779       \$ 3,38         Accrued expenses       1,071,159       1,83         Total Liabilities       3,902,938       5,22  | 5.777                |  |
| Total Current Assets       7,813,285       14,57         Property and equipment, net       -       -         Patent acquisition costs, net       26,460       2         Total Assets       \$ 7,839,745       \$ 14,60         Liabilities and Shareholders' Equity         Current Liabilities:       -       -         Accounts payable       \$ 2,831,779       \$ 3,38         Accrued expenses       1,071,159       1,83         Total Liabilities       3,902,938       5,22   | 1,880                |  |
| Patent acquisition costs, net       26,460       2         Total Assets       \$ 7,839,745       \$ 14,60         Liabilities and Shareholders' Equity         Current Liabilities:         Accounts payable       \$ 2,831,779       \$ 3,38         Accrued expenses       1,071,159       1,83         Total Liabilities       3,902,938       5,22  |                      |  |
| Patent acquisition costs, net       26,460       2         Total Assets       \$ 7,839,745       \$ 14,60         Liabilities and Shareholders' Equity         Current Liabilities:         Accounts payable       \$ 2,831,779       \$ 3,38         Accrued expenses       1,071,159       1,83         Total Liabilities       3,902,938       5,22  | -                    |  |
| Total Assets         \$ 7,839,745         \$ 14,60           Liabilities and Shareholders' Equity           Current Liabilities:         \$ 2,831,779         \$ 3,38           Accounts payable         \$ 2,831,779         \$ 3,38           Accrued expenses         1,071,159         1,83           Total Liabilities         3,902,938         5,22  | 7,150                |  |
| Current Liabilities:       \$ 2,831,779       \$ 3,38         Accounts payable       \$ 1,071,159       1,83         Accrued expenses       3,902,938       5,22  | 1,807                |  |
| Accounts payable       \$ 2,831,779       \$ 3,38         Accrued expenses       1,071,159       1,83         Total Liabilities       3,902,938       5,22  |                      |  |
| Accounts payable       \$ 2,831,779       \$ 3,38         Accrued expenses       1,071,159       1,83         Total Liabilities       3,902,938       5,22  |                      |  |
| Accrued expenses       1,071,159       1,83         Total Liabilities       3,902,938       5,22  | 782                  |  |
| Total Liabilities 3,902,938 5,22  |                      |  |
| Commitments and Contingencies   | ),488                |  |
|   |                      |  |
| Shareholders' Equity:   |                      |  |
| Share capital of \$0.0001 par value par value  Authorized: 10,000,000,000 ordinary shares; issued and outstanding: 3,847,331,923 and  |                      |  |
|   | 1,733                |  |
| Additional paid-in capital 139,819,543 139,73   | 1,651                |  |
| Capital Redemption Reserve 52,193,811 52,19   | 3,811                |  |
| Accumulated other comprehensive loss (341,968) (64  | 3,065)               |  |
| Accumulated deficit (188,119,312) (182,28   | ),811)               |  |
| Total Shareholders' Equity 3,936,807 9,38   | 1,319                |  |
| Total Liabilities and Shareholders' Equity \$ 7,839,745 \$ 14,60  | 1,807                |  |

## CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS - UNAUDITED

# For the Three Months Ended March 31, 2021 and 2020

(in U.S. dollars)

|  | Three Mo       | Three Months Ended |  |  |
|--|----------------|--------------------|--|--|
|  | March 31, 2021 | March 31, 2020     |  |  |
| Operating Expenses:  |                |                    |  |  |
| Research and development expenses                                | \$ 3,529,384   | \$ 2,732,165       |  |  |
| General and administrative expenses                              | 2,019,286      | 2,194,809          |  |  |
| Total Operating Expenses   | 5,548,670      | 4,926,974          |  |  |
| Loss from Operations   | (5,548,670)    | (4,926,974)        |  |  |
| Other (Expenses) Income:   |                |                    |  |  |
| Interest income  | 3,735          | 1,010              |  |  |
| Changes in fair value of warrant liabilities – gain              | -              | 949,456            |  |  |
| Foreign currency exchange gains (losses)                         | (285,854)      | 233,404            |  |  |
| Other expenses   | (7,712)        | (2,303)            |  |  |
| Total Other (Expenses) Income                                    | (289,831)      | 1,181,567          |  |  |
| Net Loss   | (5,838,501)    | (3,745,407)        |  |  |
| Other Comprehensive Income (Loss):                               |                |                    |  |  |
| Foreign Currency Translation Adjustment                          | 306,097        | (222,725)          |  |  |
| Comprehensive Loss   | \$ (5,532,404) | \$ (3,968,132)     |  |  |
| Loss per ordinary share (basic and diluted)                      | \$ (0.00)      | \$ (0.00)          |  |  |
| Weighted average ordinary shares outstanding (basic and diluted) | 3,847,331,923  | 2,516,280,709      |  |  |

## For more information

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