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

For the month of: May 2023

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 ☐

On May 1, 2023, Akari Therapeutics, Plc (the "Company") issued a press release announcing its financial results for the full year ended December 31, 2022, as well as highlights on recent clinical progress.

A copy of the press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

The statements under "Full Year 2022 Highlights and Recent Updates" and "Full Year 2022 Financial Results" of Exhibit 99.1 are hereby incorporated by reference into all effective registration statements filed by the Company under the Securities Act of 1933.

| **Exhibit No.** | |
|---|---|
| 99.1 | Press Release issued by Akari Therapeutics, Plc on May 1, 2023. |

**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/ Rachelle Jacques
Name: Rachelle Jacques
Title: President and Chief Executive Officer

Date: May 1, 2023

**Exhibit 99.1**

**Akari Therapeutics Reports Full-Year 2022**
**Financial Results and Highlights**

- Development of lead asset nomacopan, a novel dual-mechanism inhibitor of complement C5 and leukotriene B4 (LTB4), is focused on two priority pipeline programs with potential to transform the complement inhibition category, as well as standard of care in a rare pediatric condition and mass market retinal disease
- Phase 3 clinical trial of nomacopan in pediatric hematopoietic stem cell transplant-related thrombotic microangiopathy (HSCT-TMA), a rare condition with no approved treatment options and an 80% mortality rate, progressing more quickly than expected into the portion of the study designed to generate pivotal data to support a potential U.S. Food and Drug Administration (FDA) application for marketing approval; enrollment in this pivotal portion anticipated to begin later this year
- Pre-clinical development of long-acting PAS-nomacopan also was accelerated during the last year toward regulatory filings to begin clinical trials in geographic atrophy (GA), a sight-threatening condition with an estimated 1 million patients in the U.S.; IND submission on track for the first half of 2024
- Akari was granted a 180-day extension by Nasdaq to meet the minimum price bid requirement; Akari's American Depository Shares (ADSs) will continue to trade during this period on the Nasdaq Capital Market under the symbol AKTX

NEW YORK and LONDON, May 1, 2023 (GLOBE NEWSWIRE) — Akari Therapeutics, Plc (Nasdaq: AKTX), a late-stage biotechnology company developing advanced therapies for autoimmune and inflammatory diseases, today announced financial results and highlights for the full year ended December 31, 2022, as well as recent company updates. Akari's lead asset is investigational nomacopan, a novel bispecific inhibitor of both complement C5 and leukotriene B4 (LTB4). Nomacopan is currently in a Phase 3 clinical trial for pediatric hematopoietic stem cell transplant-related thrombotic microangiopathy (HSCT-TMA). Long-acting PAS-nomacopan is in pre-clinical development as a potential treatment for geographic atrophy (GA).

“Nomacopan’s distinctive dual mechanism of action against two key proinflammatory mediators, C5 and LTB4, we believe has blockbuster potential with the versatility to take the complement inhibitor category to the next level across multiple rare diseases and mass markets,” said Rachelle Jacques, Akari President and CEO. “During the last twelve months, Akari has made significant progress in realizing the promise of this novel asset by advancing to the registrational part of the Phase 3 clinical trials in pediatric HSCT-TMA and toward a regulatory filing for PAS-nomacopan to begin clinical trials in GA in the first half of 2024.”

**Full Year 2022 Highlights and Recent Updates**

*Phase 3 clinical trials of nomacopan in pediatric hematopoietic stem cell transplant-related thrombotic microangiopathy (HSCT-TMA)*

- Thrombotic microangiopathy (TMA) is a rare complication that can occur following a stem-cell transplant in adults or children; blood clots that develop in small blood vessels and capillaries can lead to multi-organ failure and death
- There are no approved therapies to treat HSCT-TMA; across adults and children with severe HSCT-TMA, the mortality rate is estimated to be 80%
- Complement activity is known to be implicated in moderate-to-severe HSCT-TMA with sC5b-9 and CH50 identified as key markers of disease; LTB4, which is also inhibited by nomacopan, may also be implicated by causing uncontrolled functioning of certain immune cells (such as neutrophils) that may lead to inflammation, tissue damage, and development of thrombosis
- Akari accelerated the Phase 3 clinical trial of nomacopan for treatment of pediatric HSCT-TMA toward the portion of the study that is designed to generate the safety and efficacy data needed to support potential regulatory filings for marketing approval; enrollment in the pivotal portion is expected to begin by the end of 2023

- In November 2022, the FDA granted the Rare Pediatric Disease Designation to nomacopan for the treatment of pediatric HSCT-TMA
    - The FDA Rare Pediatric Disease Designation is a recognition of the significant need that exists for approved treatments in rare pediatric diseases and is intended to encourage development of these treatments; the designation is an important addition to the Orphan Drug and Fast Track designations previously granted by the FDA for nomacopan in pediatric HSCT-TMA
    - With the Rare Pediatric Disease Designation, a sponsor who receives an approval of a new drug application (NDA) or biologics license application (BLA) is eligible for a Priority Review Voucher (PRV) to either redeem for priority review of a subsequent marketing application for a different product or sell to a third party
    - In the past year, other companies sold PRVs to third parties for prices ranging from $95 million to $110 million

- A case study of the first patient to complete treatment in the Phase 3 clinical study of nomacopan in pediatric HSCT-TMA was presented as a late-breaker at the Transplantation & Cellular Therapy Tandem Meetings on February 16 and as a poster presentation at the European Society for Blood and Marrow Transplantation (EBMT) 49th Annual Meeting on April 23.
    - A 6-year-old male patient with severe HSCT-TMA was enrolled in the Phase 3 Part A clinical trial, and began treatment with a single age- and weight-based ablating dose of nomacopan followed by maintenance dosing for 21 days
    - Pharmacodynamic data demonstrated that the patient's sC5b-9 had normalized and CH50 was reduced by >95% within the first 24-48 hours after initiating treatment
    - Treatment continued for 46 days until the patient's urine protein creatinine ratio was corrected for ≥28 days; gut pathology and thrombocytopenia were resolved
    - The patient was discharged from the hospital and no adverse events related to nomacopan were experienced during the treatment period

- Akari added a new pipeline program that will develop nomacopan for HSCT-TMA in adults
    - The adult HSCT-TMA population is >10 times the size of the pediatric population
    - There are no approved therapies for the treatment of adult HSCT-TMA
    - Study enrollment for the adult program is expected in 2024

*Pre-clinical development of long-acting PAS-nomacopan for geographic atrophy (GA) which is estimated to affect the vision of approximately one million people in the U.S. alone*

- GA is a chronic progressive degeneration of the macula in the aging eye leading to lesions on the outer retina that can cause irreversible vision loss
- There is currently one FDA-approved therapy for treatment of GA and one filed with the FDA, both are complement inhibitors; treatments are administered to patients through monthly or every-other-month needle injections into the eye (intravitreal injections/IVTs)
    - Frequent needle injections into the eye are a source of fear, discomfort, disruption for patients and has been shown to decrease patient compliance with optimal dosing regimens
    - Long-acting PAS-nomacopan has the potential to deliver efficacy benefits of complement inhibition using a fraction of the annual doses/injections of approved and late-stage complement-only inhibitors for GA

- Sight-threatening choroidal neovascularization (CNV) is a safety risk associated with currently approved and late-stage complement-only inhibitors used for the treatment of GA; CNV is typically treated chronically with anti-VEGF intravitreal injections
    - CNV is an overdevelopment of blood vessels and leakage in the retina that can significantly damage sight; LTB4 can cause the overexpression of VEGF-A, which can stimulate overproduction of the cells that form the inner layer of blood vessels, leading to CNV

- The dual mechanism of PAS-nomacopan may offer the well-understood benefits of intravitreally-administered complement C5 inhibition in slowing the progression of GA lesions, while also providing LTB4 inhibition that also has the potential to help prevent VEGF-A overexpression, reducing the likelihood of CNV and the need for chronic IVT injection or therapies to control CNV

· During the past year, Akari significantly advanced the pre-clinical development of long-acting PAS-nomacopan as a potential treatment for GA; the program is on track to submit an Investigational New Drug (IND) application to the FDA in the first half of 2024 for clinical trials

*Chemical Manufacturing and Controls (CMC)*

· U.K, and Poland regulatory authorities –Medicines & Healthcare products Regulatory Agency (MHRA) and Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (URPL) have approved the use of a new, approximately 5X higher-yielding manufacturing process (compared to the previous process) in the pivotal Phase 3 clinical trial of nomacopan in pediatric HSCT-TMA

*Patents/Intellectual Property (IP)*

· A composition of matter patent application was filed on long-acting PAS-nomacopan versions, which, if granted, provides patent protection until 2042
· Akari continues to secure IP for lead asset nomacopan in pipeline programs beyond current priority programs in preparation for future development by the company, licensing or partnering

- In April 2023, the European Patent Office granted a patent for nomacopan in the treatment of autoimmune blistering diseases (including bullous pemphigoid)

*Management Team*

- The Akari management team was expanded with industry veterans John Neylan, M.D., Executive Vice President and Chief Medical Officer, and Melissa Bradford Klug, Chief Operating Officer

**Full Year 2022 Financial Results**

- At December 31, 2022, the Company had cash of approximately $13.2 million, compared to cash of approximately $9.4 million at December 31, 2021
- Since the beginning of 2022, Akari entered into agreements with Paulson Investment Company, LLC as well as A.G.P./ Alliance Global Partners to serve as placement agents in connection with a total of three registered direct offerings for total gross proceeds of approximately $27.7 million
- Research and development expenses for full year 2022 were approximately $9.6 million, as compared to approximately $9.1 million for full year 2021. The change was the net impact of multiple factors. The Company's research and development expenses increased due to the receipt of a lower tax credit in 2022 as compared to 2021 and increased maintenance and renewal costs for our patents. These increases were partially offset by decreases in staffing costs and decreases in clinical trial costs resulting from the Company's decision to close the BP trial in August 2022.
- General and administrative expenses for full year 2022 were approximately $13.5 million, as compared to approximately $8.1 million for full year 2021. The increase was due to several factors including hiring of a new CEO and COO, severance paid to our departing CEO, issuance costs from our September 2022 registered direct offering, and external costs for consulting personnel, investor relations and corporate communications.
- For full year 2022, total other income was approximately $5.3 million as compared to total other expense of approximately $0.2 million for full year 2021. The change was primarily attributed to the classification of our warrants, issued as part of the September 2022 offering, which are accounted for as liabilities and subject to revaluation at each reporting period.

- Net loss for the full year 2022 was approximately $17.8 million, as compared to net loss of approximately $17.4 million for full year 2021.

A copy of the Company's Annual Report on Form 20-F for the year ended December 31, 2022 will be filed with the Securities and Exchange Commission and posted on the Company's website at http://investor.akaritx.com/financial-information/sec-filings. The Company will deliver a hard copy of its Annual Report, including its complete audited consolidated financial statements, free of charge, to its shareholders upon request to Akari Investor Relations at 75/76 Wimpole Street, London W1G 9RT, United Kingdom, Israel or by phone at +44 20 8004 0270.

**About Akari Therapeutics**

Akari Therapeutics, plc (Nasdaq: AKTX) is a biotechnology company developing advanced therapies for autoimmune and inflammatory diseases. Akari's lead asset, investigational nomacopan, is a bispecific recombinant inhibitor of complement C5 activation and leukotriene B4 (LTB4) activity. Akari's pipeline includes a Phase 3 clinical trial program investigating nomacopan for severe pediatric hematopoietic stem cell transplant-related thrombotic microangiopathy (HSCT-TMA). Akari has been granted Orphan Drug, Fast Track and Rare Pediatric Disease designations from the FDA for nomacopan for the treatment of pediatric HSCT-TMA. Akari's pipeline also includes a clinical program developing nomacopan for adult HSCT-TMA and pre-clinical research of long-acting PAS-nomacopan in geographic atrophy (GA). For more information about Akari, please visit akaritx.com.

**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. 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 there; difficulties enrolling patients in our clinical trials; 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 a resurgence 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.

For more information

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