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: July 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 July 13, 2023, Akari Therapeutics, Plc, a public company with limited liability incorporated under the laws of England and Wales (the "Company"), issued a press release announcing that the Company is advancing into the registrational Phase 3 study of nomacopan in pediatric HSCT-TMA and is planning to move into a Phase 3 double-blind placebo-controlled study of nomacopan in adult HSCT-TMA in 2023 and 2024, respectively. A copy of such press release is furnished as Exhibit 99.1 to this Report on Form 6-K and incorporated herein by reference.

The information in the first and sixth paragraphs of such press release is hereby incorporated by reference into all effective registration statements filed by the Company under the Securities Act of 1933, as amended.

Exhibit No.	
99.1	Press Release issued by Akari Therapeutics, Plc on July 13, 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: July 13, 2023

Exhibit 99.1

Akari Therapeutics Provides Updates on Development of Nomacopan in Pediatric and Adult HSCT-TMA

- Akari is on track for start of enrollment by the end of 2023 in the registrational Phase 3 study of nomacopan in pediatric HSCT-TMA
- Akari is moving forward into a Phase 3 double-blind placebo-controlled clinical trial of nomacopan in adult HSCT-TMA and will begin enrollment in 2024

NEW YORK and LONDON, July 13, 2023 (GLOBE NEWSWIRE) — Akari Therapeutics, Plc (Nasdaq: AKTX), a late-stage biotechnology company developing advanced therapies for autoimmune and inflammatory diseases, today announced updates in the development programs investigating nomacopan in pediatric and adult hematopoietic stem cell transplant-related thrombotic microangiopathy (HSCT-TMA). Akari is on track to begin patient enrollment in the registrational Phase 3 study of nomacopan in pediatric HSCT-TMA that is expected to produce safety and efficacy data supportive of a potential regulatory filing and approval. Akari also is planning to move forward into a Phase 3 double-blind placebo-controlled clinical trial of nomacopan in adult HSCT-TMA and to open enrollment in 2024.

“Our goal is to bring an approved treatment to both children and adults in desperate need, and we are deeply committed to making a positive impact on the standard of care now and down the road for patients facing this devastating condition,” said Rachelle Jacques, Akari President and CEO.

HSCT-TMA is a rare complication of stem cell transplant, and it is a clinical diagnosis which is based on signs, symptoms, patient history, and physical exam. Currently, there are no approved treatments for HSCT-TMA and among patients who have severe disease there is a mortality rate of about 80%. Of the approximately 22,000 hematopoietic stem cell transplants that take place each year in the U.S., about 7,920 (36%) lead to TMAs. Of these TMAs, approximately 4,250 are standard risk and 3,700 are high risk patients, with about 300 to 400 of these occurring in children and 3,200 to 3,300 occurring in adults (10 times the size of the pediatric patient population).

Consensus guidelines were recently published by an international panel of experts that harmonize diagnosis criteria and support earlier screening and diagnosis in the care of patients.[1] Historically, a lack of harmonization of diagnostic and prognostic markers has caused difficulties in the interpretation of patient outcomes. The consensus criteria are a crucial advancement to support earlier screening and diagnosis in the care of patients with transplant-associated TMAs that are associated with significant mortality once multiorgan dysfunction occurs, which is difficult to reverse. The Akari HSCT-TMA Phase 3 clinical trials design has been significantly informed by these consensus criteria for earlier diagnosis of high-risk (severe) patients.

“There is consensus that prospective screening and early diagnosis of TMA following transplantation can save lives by heading off the multiorgan dysfunction that is too often irreversible and fatal,” said Sonata Jodele, M.D., Cincinnati Children’s Hospital Medical Center.

Akari is advancing into Phase 3 open-label single-arm study of nomacopan in pediatric HSCT-TMA and is planning to move into a Phase 3 double-blind placebo-controlled study of nomacopan in adult HSCT-TMA in 2023 and 2024, respectively. These advancements to Phase 3 clinical trials were supported by Akari’s PK/PD data (in adults) and U.S. Food and Drug Administration (FDA) agreement that PK/PD modelling and predictions about pediatric dosing were sufficient to move forward.

“It is important that there is harmonization between adult and pediatric studies with the study design, such as inclusion criteria, because comparability in our clinical trials data will not only help future researchers but will also help bring clarity to regulators as they review our applications for approval,” said John Neylan, M.D., Akari Chief Medical Officer.

Orphan Drug, Fast Track, and Rare Pediatric Disease designations have been 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. Akari was recently issued a positive opinion by the European Medicines Agency (EMA) on the company’s application for orphan drug designation for nomacopan as a treatment in hematopoietic stem cell transplantation.

Reference

1. Schoettler ML, Carreras E, Cho B, et al. Harmonizing Definitions for Diagnostic Criteria and Prognostic Assessment of Transplantation-Associated Thrombotic Microangiopathy: A Report on Behalf of the European Society for Blood and Marrow Transplantation, American Society for Transplantation and Cellular Therapy, Asia-Pacific Blood and Marrow Transplantation Group, and Center for International Blood and Marrow Transplant Research. Transplant Cell Ther. 2023;29(3):151-163.

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 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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