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: March 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 March 29, 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 regulatory authorities in Poland (Office for Registration of Medicinal Products, Medical Devices and Biocidal Products/URPL) and the U.K. (Medicines & Healthcare products Regulatory Agency/MHRA) have approved amendments to the Company's Investigational Medicinal Product Dossier (IMPD) and Clinical Trial Authorisation (CTA), respectively, for clinical use of the third-generation drug substance manufacturing process that increases the final yield of nomacopan by at least 5-fold. 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 paragraph 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 March 29, 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: March 29, 2023

Exhibit 99.1

Poland and U.K. Regulatory Authorities – URPL and MHRA – Approve Use of New, Higher-Yielding Manufacturing Process for Nomacopan in Pivotal Clinical Study

- Third generation drug substance manufacturing process increases the final yield of nomacopan by at least 5-fold, improving cost efficiencies in the continuing Phase 3 clinical trial of nomacopan in pediatric hematopoietic stem cell transplant-related thrombotic microangiopathy (HSCT-TMA) advancing to pivotal Part B later this year

NEW YORK and LONDON, March 29, 2023 (GLOBE NEWSWIRE) — Akari Therapeutics, Plc (Nasdaq: AKTX), a late-stage biotechnology company developing advanced therapies for autoimmune and inflammatory diseases, today announced regulatory authorities in Poland (Office for Registration of Medicinal Products, Medical Devices and Biocidal Products/URPL) and the U.K. (Medicines & Healthcare products Regulatory Agency/MHRA) have approved amendments to the company's Investigational Medicinal Product Dossier (IMPD) and Clinical Trial Authorisation (CTA), respectively, for clinical use of the third-generation drug substance manufacturing process that increases the final yield of nomacopan by at least 5-fold. Nomacopan is an investigational bispecific inhibitor of both complement C5 and leukotriene B4 (LTB4) currently in Phase 3 clinical trials for pediatric hematopoietic stem cell transplant-related thrombotic microangiopathy (HSCT-TMA).

"The clearance by regulators in the U.K. and Poland of Akari's newer, enhanced manufacturing process for nomacopan is another important step forward in our progress toward the pivotal Part B in our clinical trials in pediatric HSCT-TMA," said Rachelle Jacques, President and Chief Executive Officer of Akari Therapeutics.

The Phase 3 study of nomacopan in pediatric HSCT-TMA includes clinical trial sites in Poland, the U.K. and U.S.

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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