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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

January 2022

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):

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On January 19, 2022, Akari Therapeutics, Plc (the “Company”) issued a press release announcing that the U.S. Food and Drug Administration (FDA) agrees to use of new higher-yielding manufacturing process for nomacopan in pivotal clinical studies

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

The information in paragraphs one and two of Exhibit 99.1 is 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 dated January 19, 2022](#)

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**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: January 19, 2022

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## **FDA Agrees to Use of New Higher-Yielding Manufacturing Process for Nomacopan in Pivotal Clinical Studies**

*New manufacturing process increases the final yield of nomacopan by at least 5-fold thereby significantly lowering the cost of goods for clinical studies and commercialization*

NEW YORK and LONDON, January 19, 2022 – 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 that the U.S. Food and Drug Administration (FDA) has agreed, via a Type C meeting, to the clinical use of nomacopan derived from a next generation manufacturing process. Nomacopan is Akari's lead drug candidate currently in two Phase III programs.

The FDA agreed that the new manufacturing process produces drug that is comparable to nomacopan from the prior manufacturing process. The new manufacturing process increases the final yield of nomacopan at least 5-fold, compared to the previous manufacturing process, which will significantly decrease future commercial cost of goods and reduce the cost of ongoing Phase II/III and future clinical development programs for nomacopan.

“FDA's agreement for our use of the new and enhanced manufacturing process is a key milestone in the pathway to commercialization of nomacopan,” said Miles Nunn, Ph.D., Chief Scientific Officer of Akari Therapeutics. “The FDA's agreement is the culmination of several years' work, and I would like to thank Akari's Head of CMC, Mukesh Sehdev, and our long-term partners in the manufacture of nomacopan, Wacker Biotechnology GmbH and Solvias AG, for their strategic planning, commitment and the quality of their work.”

### **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. 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 U.S. Food and Drug Administration (FDA) and European Medicines Agency (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 Securities and Exchange Commission (SEC), 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.

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**For more information**

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