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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

October 2020

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 October 1, 2020, Akari Therapeutics, Plc (the “Company”) issued a press release announcing completion of a scientific advice meeting with the European Medicines Agency in advance of initiating a Phase III pivotal study of nomacopan for the treatment of bullous pemphigoid. A copy of the press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

The information in paragraphs one and three 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 October 1, 2020.

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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: October 1, 2020

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## Akari Therapeutics Announces Successful Scientific Advice Meeting with the European Medicines Agency (EMA) Establishing a Clear Path in Both U.S. and Europe for a Pivotal Phase III Study of Nomacopan for Treatment of Bullous Pemphigoid

- *The EMA and the FDA have both agreed to a Phase III randomized placebo-controlled study with nomacopan in moderate to severe bullous pemphigoid (BP) patients with a primary endpoint of disease remission on minimal oral corticosteroids (OCS)*
- *Nomacopan has been granted orphan drug designation by the EMA and the FDA for the treatment of BP*
- *Nomacopan, with its dual inhibition of complement (C5) and leukotriene (LTB4) together with downstream cytokines is a novel treatment for BP that has the potential to replace long term steroid treatment (standard of care), which has multiple adverse effects in this elderly and frail population*

NEW YORK and LONDON, October 1, 2020 – Akari Therapeutics, Plc (Nasdaq: AKTX), a biopharmaceutical company focused on innovative therapeutics to treat orphan autoimmune and inflammatory diseases where the complement and/or leukotriene systems are implicated, announces completion of a scientific advice meeting with the European Medicines Agency (EMA) in advance of initiating a Phase III pivotal study of nomacopan for the treatment of bullous pemphigoid (BP). Following prior similar agreement from the U.S. Food and Drug Administration (FDA) at an End of Phase II meeting, the EMA has agreed to Akari’s proposal for a Phase III randomized placebo-controlled study with nomacopan in patients with moderate to severe BP with a primary endpoint of disease remission on minimal oral corticosteroids (OCS). Akari believes the overlapping advice now received from both agencies allows the pivotal Phase III study design to satisfy both the FDA and EMA recommendations.

BP is a severe orphan autoimmune inflammatory blistering skin disease with no approved treatments in the U.S. and Europe with an approximately three-fold increase in mortality in the BP population treated with current standard of care. The prevalence of BP is estimated to be over 100,000 patients in the U.S. and Europe.

In the Phase III study, patients will be randomized to receive either nomacopan plus oral corticosteroids (OCS) or placebo plus OCS for six months. Following an initial stabilization phase, the steroids will be tapered according to disease response to a minimal level of OCS (< 0.1mg/kg/d prednisone or equivalent) which is considered safe. If disease response is rapid, as was seen in the nomacopan Phase II study in BP patients, OCS could be tapered to the minimal level within six weeks. Once patients are on minimal OCS plus either nomacopan or placebo, the primary endpoint will be achieved by those patients with complete disease remission on minimal OCS for eight weeks or longer during the 24-week treatment period. Patients will then enter an extension study to provide at least six months of additional data. An important secondary endpoint is reduction in cumulative OCS use on nomacopan as high dose OCS are regarded as unsafe in this vulnerable patient population.

Clive Richardson, Chief Executive Officer of Akari Therapeutics said, “Following our successful FDA End of Phase II meeting, we are very pleased that the EMA has also agreed that we can proceed with our proposed pivotal Phase III study. The advice received from both agencies provides a clear pathway to a potential approval in Europe and the U.S. for nomacopan in patients with BP. We plan to initiate the study in both the U.S. and Europe during the first half of 2021.”

### Background on Bullous Pemphigoid (BP)

In BP patients there is evidence that both terminal complement activation (via complement component C5) and the lipid mediator leukotriene B4 (LTB4) have a central role in driving the disease. Ex vivo data in BP patients, published in the August 2019 edition of JCI Insight, showed a pronounced accumulation of LTB4 and C5 and its activation products in the inflamed skin of BP patients. This underlies the rationale for treatment with nomacopan which is a unique bifunctional inhibitor of both C5 and LTB4 and a range of downstream cytokines. In addition to BP, the Company believes this unique mode of action underpins the activity of nomacopan across the Company’s other target conditions – TMA-HSCT, COVID pneumonia and ophthalmology as well as other emerging clinical indications.

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## **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.

## **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 outbreak of coronavirus; risks associated with the SEC investigation; 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.

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