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

April 2021

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 April 12, 2021, Akari Therapeutics, Plc (the "Company") issued a press release announcing the Initiation of Pivotal Phase III Trial of Nomacopan in Bullous Pemphigoid (BP).

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

The information in paragraphs one, three, four and five 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 April 12, 2021

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: April 12, 2021

Exhibit 99.1

Akari Therapeutics Announces Initiation of Pivotal Phase III Trial of Nomacopan in Bullous Pemphigoid (BP)

- *FDA investigational new drug application (IND) now open*
- *Clinical sites expected to open for recruitment mid-2021*

NEW YORK and LONDON, April 12, 2021 – Akari Therapeutics, Plc (Nasdaq: AKTX), a biopharmaceutical company focused on innovative therapeutics to treat orphan autoimmune and inflammatory diseases where the complement and leukotriene systems are implicated, announces that an IND is now open with the U.S. Food and Drug Administration (FDA) for its multicenter Phase III study with nomacopan for the treatment of moderate and severe BP, allowing clinical sites to open mid-2021, subject to the ongoing impact of COVID related restrictions. Akari has been granted orphan drug designation for nomacopan for the treatment of BP by both the FDA and the European Medicines Agency (EMA).

“With the BP IND now open we look forward to starting the pivotal Phase III study of nomacopan in patients with this severe dermatological condition, for which there is no specific approved treatment in the U.S. or Europe,” commented Clive Richardson, Chief Executive Officer of Akari Therapeutics. “Success in BP could also open up a range of other severe dermatological conditions for treatment with nomacopan where C5 and LTB4 are implicated including hidradenitis suppurativa, epidermolysis bullosa acquisita and mucous membrane pemphigoid.”

BP may last several years in the absence of treatment, has a tendency to relapse and is most common in the elderly. It is primarily treated with potent oral steroids for six months or more which bring with them deleterious side effects and a three-fold or larger increase in mortality. The prevalence of BP is estimated to be approximately 120,000 patients in U.S. and EU with moderate and severe patients making up around three quarters of the patient population.

In patients with BP there is evidence that nomacopan’s ability to inhibit C5 and LTB4 gives it a unique potential therapeutic advantage which is upstream of other approaches (such as cytokine inhibitors) that are being investigated for treatment of BP. In the Phase II nomacopan study, patients with BP had elevated levels of LTB4 in their serum and in addition both C5 and LTB4 levels are elevated in blister fluid from BP patients, illustrating the local activation of both these inflammatory pathways. Moreover, in a pre-clinical model (Sezin et al 2019) the absolute body surface area affected by blisters was reduced by approximately 50% by inhibiting LTB4 alone but by approximately 80% by inhibiting both LTB4 and C5.

Akari’s pivotal Phase III trial design, which is a randomized placebo-controlled study with nomacopan in patients with moderate to severe BP with a primary endpoint of disease remission on minimal oral corticosteroids was based on the Company’s successful end-of-Phase II meetings held last year with both the FDA and the EMA.

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. 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; 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 departure of our former Chief Executive Officers and other executive officers; 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.

For more information

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