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

August 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 August 12, 2020, Akari Therapeutics, Plc (the "Company") issued a press release announcing a successful End of Phase 2 meeting with the U.S. Food and Drug Administration regarding Akari's proposed pivotal Phase III program 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, two, 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 August 12, 2020.

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: August 12, 2020

Exhibit 99.1

Akari Therapeutics Announces Successful End-of-Phase II Meeting With FDA to Initiate Pivotal Phase III Study for Treatment of Bullous Pemphigoid With Nomacopan

- *Phase III randomized placebo-controlled study in moderate to severe bullous pemphigoid (BP) patients with a primary endpoint of complete disease remission on minimal oral corticosteroids (OCS) agreed to with the FDA.*
- *Treatment arms will be tapered to minimal OCS and an important secondary endpoint is reduction in cumulative OCS on nomacopan as high dose OCS are regarded as unsafe in this vulnerable patient population.*
- *BP Phase III trial expected to start H1 2021*
- *Nomacopan has been granted orphan drug designation by the FDA and the EMA for the treatment of BP*
- *Nomacopan has potential to replace long term steroid treatment (standard of care) in BP, which has multiple adverse effects in this elderly and frail population*

NEW YORK and LONDON, August 12, 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 a successful End of Phase 2 (EOP2) meeting with the U.S. Food and Drug Administration (FDA) regarding Akari's proposed pivotal Phase III program for the treatment of BP.

The FDA has agreed to a two-part pivotal trial with Part A and Part B having the same structure, duration, endpoints and target population of moderate and severe BP patients.

In the Phase III study, patients will be randomized to receive either nomacopan plus oral corticosteroids (OCS) or placebo plus OCS. 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 patients with BP, OCS could be tapered to the minimal level within six weeks. The goal of conventional OCS tapering is to achieve minimal therapy (prednisone $\leq$0.1mg/kg/day) within four to six months after initiation of treatment[1]. Patients will only have their OCS tapered if their disease continues to respond to treatment as the OCS dose is decreased.

[1] *Feliciani et al (2015)*

Once patients are on minimal OCS plus either nomacopan or placebo, the primary endpoint will be achieved by those patients with complete disease remission for eight weeks or longer. The duration of the study is six months after which patients may be eligible to enter a separate one-year long-term safety study to provide at least six months of additional safety data.

Part A of the study is the same design as Part B but smaller and with the objective of comparing the Company's target dose (comparable to dosing used in the Company's hematopoietic stem cell transplant-related thrombotic microangiopathy (HSCT-TMA) and paroxysmal nocturnal hemoglobinuria (PNH) Phase III programs) with a lower dose of nomacopan and with placebo. Following Part A and discussion with the FDA, Part B will be conducted at the same trial sites using the optimal dose from Part A.

Clive Richardson, Chief Executive Officer of Akari Therapeutics said. "Following our positive Phase II study, we are very pleased that the FDA has agreed with the pivotal study design and provided a clear pathway to a potential approval for nomacopan in patients with BP. Success in this study would also open up a range of other dermatological conditions with related pathology."

Russell P. Hall, M.D., Professor of Dermatology, Duke University School of Medicine, who attended Akari's EOP2 meeting, said, "These proposed studies are expected to provide the critical data needed to assess the efficacy of nomacopan in providing rapid control of the inflammation in the skin of patients with bullous pemphigoid and minimize the need for high dose systemic corticosteroids in this very vulnerable patient population."

Background on Bullous Pemphigoid (BP)

BP is a severe orphan autoimmune inflammatory blistering skin disease with no approved treatments in the U.S. and Europe. This chronic disease may last several years in the absence of treatment and has a tendency to relapse. BP is most common in the elderly and is primarily treated with steroids and immunosuppressants for six months or more which bring with them deleterious side effects and an approximately three-fold increase in mortality in the BP treated population. The prevalence of BP is estimated to be over 100,000 patients in U.S. and Europe.

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 [LINK], 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.

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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