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):_____

**CONTENTS**

On August 31, 2020, Akari Therapeutics, Plc (the “Company”) issued a press release announcing its intention to develop nomacopan as a potential treatment for COVID-19 pneumonia through integrated clinical trial programs in U.S., U.K. and Brazil.. 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 through fifteen 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 31, 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 31, 2020

**Exhibit 99.1**

**Akari Therapeutics Announces International Clinical Development Program of Nomacopan for the Potential Treatment of COVID-19 Pneumonia**

- *Clinical studies both underway and planned for patients with COVID-19 pneumonia in the U.S., U.K., and Brazil*
  - *Proposed multi-center U.S. randomized clinical program in regulatory submission following the treatment of patients via expanded access programs*
  - *In Brazil, patient recruitment completed for proof of principle (POP) clinical study; potential progression into follow-on randomized study expected early Q4 2020*
  - *Nomacopan selected by AGILE COVID-19 clinical trial initiative in the U.K.*
  - *Data from approximately 50 U.K. patients expected early Q4 2020 from an observational study focused on identifying potential therapeutic biomarkers for optimizing use of nomacopan for COVID-19 pneumonia patients*
- *Nomacopan has been shown in clinical trials to inhibit both complement C5 activation and leukotriene B4 (LTB4), and has significant potential to simultaneously inhibit both microthrombi as well as block multiple cytokines (the cytokine storm) which together drive COVID-19 pneumonia and associated organ damage.*
- *Ongoing clinical readouts expected throughout remainder of 2020*
- *Akari hosting webcast today at 8:30 am EDT (1:30 pm BST).*

NEW YORK and LONDON, August 31, 2020 – Akari Therapeutics, Plc (Nasdaq: AKTX), a Phase III biopharmaceutical company focused on innovative therapeutics to treat orphan autoimmune and inflammatory diseases where the complement and/or leukotriene systems are implicated, announces its intention to develop nomacopan as a potential treatment for COVID-19 pneumonia through integrated clinical trial programs in U.S., U.K. and Brazil.

Clive Richardson, Chief Executive Officer of Akari Therapeutics, said, “There remains an overwhelming need for more effective treatment of hospitalized COVID-19 pneumonia patients. I am pleased nomacopan has been selected by the U.K.’s AGILE clinical program. I can also report that we are now treating patients in Brazil and the U.S. in initial proof of principle studies, with the objective of progressing into randomized clinical studies in the fourth quarter of 2020. We believe nomacopan has the potential to inhibit the key proinflammatory and prothrombotic pathways driving this disease, and hence meaningfully reduce morbidity and mortality in this COVID-19 patient group.”

**Scientific rationale for potential use of nomacopan in COVID-19 pneumonia**

Nomacopan’s dual complement (C5) and leukotriene (LTB4) inhibition blocks several key inflammatory pathways that drive COVID-19 pneumonia.

Terminal complement activation by formation of C5a and the membrane attack complex (C5b9) is associated with direct vascular damage, microthrombi and long-term damage to the lung and other organs in COVID-19 patients[1]. A causative role for complement activation has been shown in other inflammatory diseases with shared pathophysiological components, such as hematopoietic stem cell transplant-related thrombotic microangiopathy (TMA-HSCT)[2] in which Akari has an open Phase III Investigational New Drug (IND) application.

Neutrophil accumulation in the lungs is another key feature of COVID-19 pneumonia, resulting in 'cytokine storm syndrome' and associated epithelial damage in lung and other organs. Leukotriene (LTB4) is one of the most potent known chemo attractants of neutrophils and other neutrophil chemo-attractants appear to rely on LTB4 synthesis for recruitment of neutrophils from distal sites. Leukotriene inhibitors are approved for treatment of asthma and are being tested in COVID-19 pneumonia[3] due to their ability to block multiple cytokines. Cytokines and chemokines inhibited by nomacopan[4] include GM-CSF, IL1 alpha, IL1beta, IL2, IL-6, IL17, TNF, RANTES, MCP1, MIP1alpha andMIP1beta all of which have been reported to be elevated in COVID-19 pneumonia patients[5].

The potential additive benefits of both C5 and LTB4 inhibition by nomacopan have previously been demonstrated in preclinical models of viral induced acute respiratory distress syndrome (ARDS) with reduced inflammation and mortality[6]. Moreover, the combined inhibition of both C5 and LTB4 demonstrated by nomacopan was superior to inhibition by either C5 or LTB4 alone in a mouse model of acute lung inflammation, highlighting the additive effect of inhibiting both these innate immune pathways[7].

Akari believes that this inhibition of multiple inflammatory pathways distinguishes nomacopan from other potential therapies focused on a single mechanism of action. In addition to nomacopan's fast onset of action, the rapid normalization of complement and LTB4 levels at the end of treatment has the potential to avoid the risks of longer-term immunosuppression typical of monoclonal antibodies.

**Staged clinical development plan with nomacopan for the treatment of COVID-19 pneumonia**

Akari's strategy for advancing clinical development of nomacopan as a potential COVID-19 pneumonia treatment includes: (1) identifying biomarkers to optimize patient selection; (2) completing initial proof of principle studies in hospitalised COVID-19 patients; (3) conducting integrated randomized clinical trials in the U.S., Brazil and the U.K, and (4) seeking regulatory approval if the results of the randomized clinical trials satisfactorily demonstrate the safety and efficacy of nomacopan as a treatment of COVID-19 pneumonia.

An observational study relating to biomarkers that may identify COVID-19 patients who are particularly suitable for nomacopan treatment is ongoing in the U.K. Data has been collected on approximately 50 patients with COVID-19 pneumonia and analysis of the samples is in process with data expected early in the fourth quarter of 2020. The second part of the program, a longitudinal study taking repeat samples from COVID-19 patients with worsening disease is ongoing.

Initial POP treatment in patients with COVID-19 pneumonia via expanded access programs (EAPs) are ongoing in the US. In Brazil, recruitment to a similar POP treatment study has been completed and the data will be reviewed for safety by the Data and Safety Monitoring Board (DSMB). If the DSMB concludes that the drug is safe, the program in Brazil will progress to a randomized study in the fourth quarter of 2020.

These COVID-19 programs build on the existing Akari clinical experience in the use of nomacopan, underpinned by 35 cumulative patient-years of nomacopan safety data with no reported drug related SAEs, and clinical response across a range of inflammatory conditions in Phase II and Phase III development.

**Planned randomized clinical studies**

Akari intends to conduct multiple randomized controlled studies in the U.S., U.K. and Brazil based on the same clinical study design.

In the U.S., Akari is collaborating on a proposed investigator-led multi-center randomized study the commencement of which is subject to U.S. Food and Drug Administration (FDA) approval of a related IND. In Brazil, the POP study is expected to progress into a similar randomized trial, pending successful outcome of the DSMB review.

In the U.K., nomacopan has been selected by the AGILE platform as a new potential treatment for patients with COVID-19 pneumonia. AGILE is a dedicated therapeutic development platform supported by the Wellcome Trust and UNITAID to identify, support and develop promising treatments for COVID-19. The AGILE program is sponsored by the Royal Liverpool Hospital, U.K. With AGILE's support, Akari is also exploring extending the nomacopan COVID-19 clinical program into multiple countries in Africa, with potential patient recruitment starting in the fourth quarter of 2020.

Subject to additional comments from regulators, the trial protocols for the planned randomized clinical trials would provide for patients to be randomized 2:1 nomacopan plus standard of care (SoC) or SoC alone, with an initial target of around 60 patients in each of the individual study settings. Patients would be on supportive oxygen (not intubated) and be recruited following admission to hospital. The primary endpoint is time to normalization of oxygen, while the secondary endpoint will include need for intubation and mortality. Patients will receive a daily subcutaneous dose of nomacopan for up to 14 days, with study monitoring and completion after two months. The SoC arm for the trials incorporates the latest treatments where available, including dexamethasone and remdesivir, both of which have a different mode of action to nomacopan and as such, nomacopan has the potential to add additional efficacy to either or both of these treatments. In examining the efficacy of nomacopan Akari expects to consider the totality of the data across these studies using the same endpoints.

Professor Tim Higenbottam, President Faculty of the Pharmaceutical Medicine of the Royal Colleges of Physicians U.K., said, "It is increasingly clear that the complexity in treating COVID-19 pneumonia relates to its impact on multiple pro-inflammatory pathways. For an effective treatment, we need a broad acting anti-inflammatory and the fact that nomacopan has been shown in clinical trials to inhibit the pathways that underpin this severe devastating disease creates a promising platform for its current clinical investigation."

1. Ramlall, et al., *Immune complement and coagulation dysfunction in adverse outcomes of SARS-CoV-2 infection*, 2020

2. Merrill, et al., *Emerging evidence of a COVID-19 thrombotic syndrome has treatment implications*, 2020

3. Funk, et al., *A Novel Strategy to Mitigate the Hyperinflammatory Response to COVID-19 by Targeting Leukotrienes*, 2020

4. Huber-Lang, et al., *Double Blockade of CD14 and Complement C5 Abolishes the Cytokine Storm and Improves Morbidity and Survival in Polymicrobial Sepsis in Mice*, 2014

5. Mehta P, et al., *COVID-19: consider cytokine storm syndromes and immunosuppression*, 2020

6. Garcia, et al., *Complement C5 Activation during Influenza A Infection in Mice Contributes to Neutrophil Recruitment and Lung Injury*, 2013

7. Roversi, et al., *Bifunctional Lipocalin Ameliorates Murine Immune complex-induced Acute Lung Injury*, 2013

**Conference call and webcast**

Akari will host a conference call and webcast today, August 31, 2020, at 8:30 a.m. EDT (1:30 p.m. BST). The conference call may be accessed by dialing (844) 461-9933 (Toll-Free) or (636) 812-6633 (international) using the conference ID 2469894. The webcast can be accessed live via the Investor Relations section of the Akari website at http://investor.akaritx.com/news-and-events/events.

**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 U.S. 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 successfully develop nomacopan as a treatment for COVID-19 related pneumonia and to successfully commercialize any product in that indication; our ability to obtain orphan drug designation in additional indications; risks inherent in drug development in general and risks specific to the development of potential treatments for COVID-19 related illnesses; 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 U.S.; 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 US 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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