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 26, 2022, Akari Therapeutics, Plc (the “Company”) issued a press release announcing that the Company advances its lung program with inhaled nomacopan focused on early treatment of severe exacerbations in lung diseases.

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, five and six 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.

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 26, 2022

Exhibit 99.1

Akari Advances Lung Program with Inhaled Nomacopan Focused on Early Treatment of Severe Exacerbations in Lung Diseases

NEW YORK and LONDON, January 26, 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 further development of a program for the inhaled delivery of nomacopan to the lung, working with Inhalation Sciences AB to refine dosing and pharmacokinetics of nomacopan for both dry powder and nebulized delivery.

Clive Richardson, Chief Executive Officer of Akari Therapeutics said," Accumulating data with nomacopan indicate that the innate immune response driven by complement and leukotriene pathways could be critical in determining the severity of the inflammatory response across a range of diseases including in the lung. Gaining control of the dysregulation in innate responses by inhibiting C5 and LTB4 with an inhaled form of nomacopan could provide relief from often life-threatening exacerbations in lung illnesses such as COPD and severe asthma. We are therefore delighted to be working with Inhalation Biosciences AB to further develop an inhaled drug delivery system for nomacopan."

Data from Akari-sponsored observational studies in exacerbating chronic obstructive pulmonary disease (COPD) (n=24) and COVID-pneumonia (n= 72) indicated complement C5 and LTB4 levels were elevated and the severity of exacerbations in COPD patients was associated with the initial levels of C5. This points to the potential for nomacopan, a potent inhibitor of both C5 and LTB4, as a focused treatment for disease exacerbations across multiple severe lung disorders, including severe asthma, COPD and COVID-pneumonia.

Importantly, given both the acute nature of exacerbations which typically last 2-4 weeks and evidence from the COPD observational studies that much of the excess C5 and LTB4 is generated in the lung, a fast-acting inhaled delivery system is likely to be the preferred delivery route for exacerbating patients. Therefore, to optimize the potential clinical utility of nomacopan, Akari is now in development of an inhaled formulation of nomacopan with Inhalation Sciences AB.

Prior data indicate that nomacopan can be nebulized by conventional devices and achieve a median particle size suitable for deep lung delivery while maintaining its inhibitory activity. In addition, in preclinical models, C5 and LTB4 inhibition by nomacopan significantly decreases both eosinophils and neutrophils, key drivers of disease. Furthermore, in multiple preclinical lung models nomacopan is more effective than C5 and LTB4 inhibition alone, including leukotriene inhibitors, approved for treatment of the lung, such as Zileuton.

Akari is focused on developing nomacopan for treating exacerbations with a patient-friendly inhaled formulation for early intervention to prevent the potentially serious clinical consequences. Exacerbations are a significant driver of hospitalizations and mortality across multiple lung diseases, including severe asthma and COPD. For example, focusing on only asthma exacerbations in the U.S., the Centers for Disease Control and Prevention (CDC) estimates that over 11 million people reported having at least one asthma exacerbation in the last 12 months. Furthermore, there were 1.8 million emergency department visits, nearly 200,000 hospitalizations and about 3,500 deaths.

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.

For more information

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