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

December 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): ☐

CONTENTS

On December 1, 2021, Akari Therapeutics, Plc (the "Company") issued a press release announcing new data revealing a potential mechanism of action driving serious exacerbations across lung disorders.

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, 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.

99.1 Press release dated December 1, 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: December 1, 2021

Exhibit 99.1

Akari Therapeutics Presents New Data Revealing Potential Mechanism of Action Driving Serious Exacerbations Across Lung Disorders

Data suggest potential therapeutic role for nomacopan in exacerbations in severe lung conditions such as COPD and COVID pneumonia

NEW YORK and LONDON, December 1, 2021 – 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 announces data from observational studies in COVID pneumonia and chronic obstructive pulmonary disease (COPD) that highlight the potential role of complement and leukotriene hyperactivity in driving life threatening disease exacerbations and therefore a potential therapeutic role for nomacopan.

An observational study sponsored by Akari on COVID pneumonia undertaken at Portsmouth Hospitals University NHS Trust was reported at the recent British Thoracic Society Annual Meeting November 24-26, 2021 (1). Plasma levels of C5a, C5b9 and LTB4 in COVID pneumonia patients were elevated compared with control patients and increased with disease severity. In addition, the levels of C5a ($p = 0.001$) and C5b9 ($p = 0.019$). which are potential biomarkers for disease progression, rose significantly in patients that worsened (i.e., those requiring invasive mechanical ventilation or who died).

These findings align with a prior, separate Akari-sponsored observation study in COPD patients (2) that demonstrated that exacerbating patients have elevated C5a in sputum but not in serum and that the level of C5a was correlated with the duration/severity of the exacerbations ($p=0.01$). In exacerbations of COPD, Leukotriene B4 (LTB4) is also found in the sputum (3). All three of these inflammatory mediators, LTB4, C5a and C5b9 are inhibited by nomacopan.

Akari is targeting lung diseases such as asthma, COPD and COVID pneumonia where in certain patients, a hyperreactive response to external agents triggers a severe exacerbation. For example, it is estimated that 14% of COPD patients have severe annual exacerbations associated with hospitalization and increased mortality (4).

Complement (C5 and its by products C5a and C5b9) and leukotriene (LTB4) are key inflammatory mediators which through their inhibition by nomacopan may prevent disease progression. Their combined inhibition has been shown in several lung disease models to be more effective than inhibiting either LTB4 or C5 alone. Leukotriene inhibition is an established treatment for severe asthma and complement hyperactivity is increasingly associated with severe lung inflammation. Importantly, the observational data indicate that the inflammatory response may be driven by rising complement and leukotriene levels directly in the lung, indicating that an inhaled form of nomacopan may potentially be the most effective route of administration. Akari has demonstrated full activity and potential for deep delivery to the lung with a nebulized inhaled form of nomacopan.

Akari is investigating the pharmacokinetics of inhaled nomacopan in the lung and a proof of principle study in exacerbating COPD patients to further evaluate the impact of inhibiting C5 and LTB4 with nomacopan.

In addition, the COVID pneumonia observational findings are being further evaluated to explore the potential role of biomarkers in identifying the most appropriate COVID pneumonia patients to be treated with nomacopan.

Professor Tim Higenbottam DSc, MA, MD, FRCP, FPPM commented, “Lung exacerbations are a major problem yet to be adequately treated. There is growing evidence that these exacerbations are driven by both C5 and LTB4 which is important in their potential role as biomarkers of an excessive innate immune response and as a pointer of possible treatment. Nomacopan represents a potential new therapeutic option which could have applicability across COPD, severe Asthma, and COVID pneumonia where an over-reactive innate immune response puts patients at risk of a life-threatening hyperinflammatory response.”

References:

1. Wiffen L, Brown T, Chauhan, M et al., Measures of inflammation, complement activation and coagulation in patients with COVID-19. A38 Thorax 2021; 76 (Suppl 2) : A1 – A205.

2. Westwood J-P, Mackay AJ, Donaldson G….Wedzicha JA. The role of complement activation in COPD exacerbation recovery. ERJ Open Res 2016; 2: 00027-2016 | DOI: 10.1183/23120541.00027-2016.

3. Drozdovszky O, Barta I, Antus B. Sputum Eicosanoid Profiling in Exacerbations of Chronic Obstructive Pulmonary Disease. Respiration 2014;87:408–415. DOI: 10.1159/000358099.

4. Wise RA, Calverley PMA, Carter K,. et al., Seasonal variations in exacerbations and deaths in patients with COPD during the TIO SPIR© trial. Int J COPD. 2018: 13; 605-616.

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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