
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

May 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 May 21, 2020, Akari Therapeutics, Plc (the “Company”) issued a press release announcing that the European Medicines Agency has issued a positive opinion on Akari’s application for orphan designation of nomacopan 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, three and four 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 May 21, 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: May 21, 2020

Akari Therapeutics Receives Positive EMA Opinion on Orphan Designation for Nomacopan for Bullous Pemphigoid

NEW YORK and LONDON, May 21, 2020 – Akari Therapeutics, Plc (Nasdaq: AKTX), a biopharmaceutical company focused on innovative therapeutics to treat orphan autoimmune and inflammatory diseases where the complement (C5) and/or leukotriene (LTB4) systems are implicated, today announced that the European Medicines Agency (EMA) has issued a positive opinion on Akari’s application for orphan designation of nomacopan for the treatment of bullous pemphigoid (BP).

Akari recently announced the successful completion of a Phase II study in BP where the combined therapeutic role of both complement (C5) and leukotriene (LTB4) has been well documented. The study achieved the primary endpoint of no reported drug-related serious adverse events and main efficacy endpoints with 7 of the 9 treated patients showing a rapid and clinically significant reduction in Bullous Pemphigoid Disease Area Index (BPDAI) score. In September 2019, nomacopan received Orphan Drug designation from the U.S. Food and Drug Administration (FDA) for BP.

The Company believes nomacopan’s dual inhibition of C5 and LTB4 also makes the drug potentially well suited for the treatment of patients with COVID-19 pneumonia and related COVID diseases. In pre-clinical lung inflammation models including a model of viral induced lung inflammation, nomacopan (formerly known as coversin) showed significant reductions in key lung inflammatory markers such as neutrophils and lung vascular leakage (Garcia et al., 2013; Roversi et al., 2013).

Akari is actively pursuing several clinical study opportunities in patients with COVID-19 pneumonia in the UK and U.S. The Company intends to provide additional detail when these programs are finalized and approved.

“BP, a severe blistering skin condition with no approved treatments, is an exciting therapeutic target for our drug candidate, nomacopan,” said Clive Richardson, Chief Executive Officer of Akari Therapeutics. “Orphan Designation is an important step in the development of this program and as a gateway into other dermatological conditions. We believe the dual C5 and LTB4 inhibition has relevance across a wide range of other inflammatory diseases, including COVID-19.”

The positive opinion issued by the EMA will be sent to the European Commission which is expected to grant the orphan designation within 30 days. Orphan designation in the EU allows Akari to benefit from a number of key incentives, including reduced regulatory fees, protocol assistance, and market exclusivity, to develop a medicine for the treatment of a rare disease affecting not more than five in 10,000 people in the European Union.

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 indications: bullous pemphigoid (BP), atopic keratoconjunctivitis (AKC), thrombotic microangiopathy (TMA), and paroxysmal nocturnal hemoglobinuria (PNH). Akari believes that the dual action of nomacopan on both C5 and LTB4 may be beneficial in AKC and BP. Akari is also developing other tick derived proteins, including longer acting versions.

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 regarding, among other things, statements related to the offering, the expected gross proceeds and the expected closing of the offering. 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; our ability to enter into collaborative, licensing, and other commercial relationships and on terms commercially reasonable to us; 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 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.

For more information

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