
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

September 2019

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 September 13, 2019, Akari Therapeutics, Plc (the “Company”) issued a press release announcing that the US Food and Drug Administration has granted orphan-drug designation for nomacopan for the treatment of bullous pemphigoid (BP). A copy of the press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

The information in this Form 6-K including the first paragraph 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 September 13, 2019.

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: September 13, 2019

Akari Therapeutics' Nomacopan Granted U.S. Orphan Drug Designation for Bullous Pemphigoid

NEW YORK and LONDON, September 13, 2019 – 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 U.S. Food and Drug Administration (FDA) has granted orphan drug designation for nomacopan for the treatment of bullous pemphigoid (BP).

“BP, a severe blistering skin condition with no approved treatments, is an exciting therapeutic target for our lead drug candidate, nomacopan. It is also a disease of increasing prevalence due to an aging population and improving diagnosis,” said Clive Richardson, Chief Executive Officer of Akari Therapeutics. “Orphan drug designation for nomacopan is a major step forward for the program, positioning nomacopan for eligibility for an additional seven years of marketing exclusivity in BP if nomacopan is approved by the FDA. This news is in addition to the recent orphan drug designation received for our HSCT-TMA program.”

The Company plans to release new safety and efficacy data from an ongoing Phase II trial with nomacopan in patients with BP at an oral presentation by Dr. Christian Sadik at the 28th European Academy of Dermatology and Venereology (EADV) Congress on October 10, 2019. In August, the Company announced new data demonstrating the synergistic benefits of nomacopan’s dual C5 and LTB4 inhibitory activity in pemphigoid disease, generated by Dr. Christian Sadik’s group at University of Lubeck, Germany, and published in the August 2019 edition of JCI Insight [https://insight.jci.org/articles/view/128239?utm_source=submission_site&utm_medium=email&utm_campaign=notice-of-publication].

Orphan drug designation by the FDA is granted to promote the development of drugs that target conditions affecting 200,000 or fewer U.S. patients annually and that are expected to provide significant therapeutic advantage over existing treatments. Orphan designation qualifies Akari for various benefits, including seven years of market exclusivity following marketing approval, tax credits on U.S. clinical trials, eligibility for orphan drug grants, and a waiver of certain administrative fees.

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 both AKC and BP.

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; 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 departure of our former Chief Executive Officers and other executive officers; 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

Investor Contact:

Peter Vozzo
Westwicke
(443) 213-0505
peter.vozzo@westwicke.com

Media Contact:

Sukaina Virji / Nicholas Brown / Lizzie Seeley
Consilium Strategic Communications
+44 (0)20 3709 5700
[Akari@consilium-comms.com](mailto:Skari@consilium-comms.com)
