
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

March 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 March 13, 2019, Akari Therapeutics, Plc, (the “Company”) issued a press release entitled “Positive FDA Meeting Outlines Path Ahead for Akari Therapeutics’s Coversin in Hematopoietic Stem Cell Transplant-Related Thrombotic Microangiopathy (HSCT-TMA)”.

A copy of the press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

The information in the first paragraph and “Forward Looking Statements” of the press release attached to this Form 6-K are 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 March 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
Interim Chief Executive Officer and Chief
Operating Officer

Date: March 13, 2019

Positive FDA Meeting Outlines Path Ahead for Akari Therapeutics's Coversin in Hematopoietic Stem Cell Transplant-Related Thrombotic Microangiopathy (HSCT-TMA)

- *HSCT-TMA trial in pediatric patients expected to start Q4 2019 following recent FDA feedback*

NEW YORK and LONDON, March 13, 2019 – Akari Therapeutics, Plc (Nasdaq: AKTX), a biopharmaceutical company focused on innovative therapeutics to treat orphan autoimmune and inflammatory diseases where the complement and/or leukotriene systems are implicated, announces that it had a successful Type B, pre-IND meeting with the Food and Drug Administration (FDA) regarding Akari's proposed pivotal clinical trial program for pediatric hematopoietic stem cell transplant-related thrombotic microangiopathy (HSCT-TMA). HSCT-TMA is an orphan condition with an estimated fatality rate of more than 80% in children with the severe disease.¹

A framework for the trial design was agreed to with the FDA in which the response to Coversin of selected, clinically meaningful treatment variables would be the primary endpoint in the proposed pivotal trial. These responder endpoints were based on work done by Sonata Jodele, M.D., a world-leading expert in treating pediatric HSCT-TMA.

In September 2018, Akari announced, in relation to treatment variables, that in the first two patients treated with Coversin as part of a UK named patient program, it had observed a rapid reduction of the markers of complement activation as well as normalization of markers that are elevated in thrombotic microangiopathy (TMA). These markers include platelet count, red blood cell fragments, thrombocytopenia, elevated lactate dehydrogenase (LDH) and hypertension.

Clive Richardson, interim CEO of Akari Therapeutics, said, "Akari plans to commence a trial in European and U.S. pediatric HSCT-TMA patients in the fourth quarter of 2019. We see HSCT-TMA as a gateway indication into a range of other poorly treated orphan TMAs, and are enthusiastic about the potential of Coversin to offer an improved standard of care for patients with these rare and usually fatal conditions."

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, Coversin, is a C5 complement inhibitor that also independently and specifically inhibits leukotriene B4 (LTB4) activity. Coversin is currently being clinically evaluated in four indications: bullous pemphigoid (BP), atopic keratoconjunctivitis (AKC), atypical hemolytic uremic syndrome (aHUS), and paroxysmal nocturnal hemoglobinuria (PNH). Akari believes that the dual action of Coversin on both C5 and LTB4 may be beneficial in AKC, BP, and aHUS. Akari is also developing other biopharmaceuticals, including longer acting versions of Coversin.

¹ Sonata Jodele, et al. New approaches in the diagnosis, pathophysiology, and treatment of pediatric hematopoietic stem cell transplantation associated thrombotic microangiopathy. *Transfus Apher Sci*. 2016 April; 54(2): 181–190

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 Coversin 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 Coversin 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 Coversin 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 Coversin may not be as large as expected; risks associated with the departure of our former Chief Executive Officers and other executive officers; risks related to material weaknesses in our internal controls over financial reporting and risks relating to the ineffectiveness of our disclosure controls and procedures; risks associated with the putative shareholder class action and 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 on July 18, 2018. 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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