### 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 2018

Commission file number: 001-36288

# <u>Akari Therapeutics, Plc</u>

(Translation of registrant's name into English)

75/76 Wimpole Street London W1G 9RT United Kingdom Tel: (646) 448-8743 (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 12, 2018, Akari Therapeutics, Plc, (the "Company") issued a press release announcing new preclinical rheumatoid arthritis data and new clinical data in patients with Bullous Pemphigoid, highlighting potential advantages of Coversin's bifunctional activity inhibiting both the complement and leukotriene inflammatory pathways. A copy of the press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

The first, third and fifth paragraphs 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 September 12, 2018.

# **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.

<u>Akari Therapeutics, Plc</u> (Registrant)

By: /s/ Clive Richardson Name: Clive Richardson

Clive Richardson Interim Chief Executive Officer and Chief Operating Officer

Date: September 12, 2018

# Akari Therapeutics Announces New Preclinical Rheumatoid Arthritis Data and New Clinical Data in Patients with Bullous Pemphigoid, Highlighting Potential Advantages of Coversin's bifunctional activity inhibiting both the Complement and Leukotriene Inflammatory Pathways

- Combined inhibition of LTB4 and C5 by Coversin showed reversal of disease symptoms in preclinical rheumatoid arthritis (RA) model
- Ex vivo data from bullous pemphigoid (BP) patients showed presence of both LTB4 and C5 at similar elevated concentrations
- These new data support the potential advantage of Coversin's bifunctional inhibitory activity in ongoing Phase II BP trial and a range of other poorly treated inflammatory diseases.

NEW YORK and LONDON, September 12, 2018 - Akari Therapeutics, Plc (NASDAQ:AKTX), a biopharmaceutical company focused on the development and commercialization of innovative therapeutics to treat orphan autoimmune and inflammatory diseases, today announced results that demonstrate the potential advantages of Coversin's unique bifunctional mode-of-action inhibiting both the complement and leukotriene pathways.

"The combined inhibition of C5 and LTB4 presents a potential novel therapeutic option. We believe that the bifunctional modality of Coversin could enable us to target a growing range of orphan diseases with unmet need where both complement and leukotriene pathways are believed to be implicated," commented Clive Richardson, interim Chief Executive Officer of Akari Therapeutics. "In the first quarter of 2019 we anticipate announcing Phase II clinical data in two trials that focus on this bifunctionality: BP, a blistering skin disease, and atopic keratoconjunctivitis (AKC), a severe allergic eye condition. The trials will be run in conjunction with our existing clinical program for the complement mediated diseases, paroxysmal nocturnal hemoglobinuria (PNH) and atypical haemolytic syndrome (aHUS)."

# Preclinical rheumatoid arthritis model data

Coversin has a unique bifunctional mode-of-action that appears to independently inhibit C5 and LTB4 by binding tightly both molecules. In an RA mouse model, performed in the laboratory of Prof. Andrew D. Luster, M.D., Ph.D., Harvard Medical School, the effectiveness of Coversin (PASylated), which binds to C5 and LTB4, is compared to PAS LTB4-Coversin, which binds to LTB4 alone and to Zileuton, an FDA-approved leukotriene inhibitor. The PASylated version of Coversin, which is designed to allow weekly subcutaneous dosing, was chosen in order to help validate this as a treatment option. The graph below shows therapeutic use of the two distinct PASylated forms of Coversin and Zileuton administered from day four of the experiment onwards, once arthritic symptoms had appeared. PAS-Coversin, inhibiting both C5 and LTB4, appeared more effective than Zileuton and PAS LTB4-Coversin, reversing symptoms by day 10 in this acute model.

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Dr. Luster stated, "The effect of Coversin (PASYlated) used therapeutically in our mouse model of rheumatoid arthritis was impressive with apparent total disease reversal. This highlights that the novel strategy offered by Coversin of simultaneously blocking both C5 and LTB4 may make it an effective anti-inflammatory and offers the potential to provide an alternative therapy for RA patients who are unresponsive to current marketed therapies."

#### Ex vivo bullous pemphigoid data

In an *ex vivo* study on four BP patients performed by Dr. Christian Sadik, M.D., Department of Dermatology, University of Lubeck, Germany, a major center for the diagnosis and treatment of pemphigoid diseases, blister fluid from BP patients showed an LTB4 concentration markedly higher than seen in the serum of healthy patients, likely indicating synthesis of LTB4 in the vicinity of human blisters<sup>1</sup>. The presence of C5a in blister fluid implies local activation of C5. Furthermore, the presence of both activators in human blister fluid provides support for therapeutic use of Coversin for treatment of BP.

These new findings support earlier data from a mouse model of immune complex induced alveolitis where combined inhibition of LTB4 and C5 by Coversin was significantly more effective than inhibiting either C5 or LTB4 alone<sup>2</sup>.

## **REFERENCE:**

<sup>1</sup>Jore M.M., Johnson S., Sheppard D., Barber N.M., Li Y.M., Nunn M.A., Elmlund H., Lea S.M. (2016) Structural basis for therapeutic inhibition of complement C5. Nat Struct Biol. 23:378-386.

<sup>2</sup>Roversi, P. et al. J. Biol. Chem.; published online April 26, 2013.

# **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 system or leukotrienes or both complement and leukotrienes together play a primary role in disease progression. Akari's lead drug candidate Coversin<sup>™</sup> is a C5 complement inhibitor currently being evaluated in paroxysmal nocturnal hemoglobinuria (PNH) and atypical hemolytic uremic syndrome (aHUS). In addition to its C5 inhibitory activity, Coversin independently and specifically inhibits leukotriene B4 (LTB4) activity. Akari is currently evaluating Coversin in two conditions, the skin and eye diseases bullous pemphigoid and atopic keratoconjunctivitis, where the dual action of Coversin on both C5 and LTB4 may be beneficial. Akari is also developing other tick derived proteins, including long 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. 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 associate 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.

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# For more information

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