
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

October 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 October 25, 2021, Akari Therapeutics, Plc (the “Company”) issued a press release announcing new data with nomacopan from its surface of the eye program.

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

The information in paragraphs one, four, five, six, seven and eight 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 October 25, 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: October 25, 2021

Akari Therapeutics Announces New Data with Nomacopan from its Surface of the Eye Program

- Nomacopan eyedrops reduced inflammation more than both standard treatments cyclosporin and the steroid dexamethasone in a model of allergic eye disease
- Building on early clinical data in atopic keratoconjunctivitis (AKC), Akari is now advancing its surface of the eye program

NEW YORK and LONDON, Oct. 25, 2021 (GLOBE NEWSWIRE) -- 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 highlighting the potential of nomacopan in the surface of the eye in *Allergy, European Journal of Allergy and Clinical Immunology*.

A copy of the article in *Allergy*, in which some of the data has been published, is available on the Akari corporate website at www.akaritx.com and at <https://onlinelibrary.wiley.com/doi/10.1111/all.15128>.

Professor Virginia Calder, University College of London (UCL), Institute of Ophthalmology and study author, commented, “This new data supports a clear role for leukotriene LTB4 and complement C5 in the inflammatory pathways that drive allergic eye disease and points to nomacopan eyedrops as a potentially exciting new surface of the eye treatment option. Current treatments such as steroids are limited by side effects, variable efficacy and patient comfort. The role of nomacopan in reducing specific inflammatory mediators that can be detected in tear fluid as biomarkers is an exciting and novel feature and opens up the potential for patient targeted treatment management.”

The article in *Allergy* summarizes a large body of work undertaken with University College of London and Moorfields Eye Hospital. The underlying work demonstrates a clear dose response effect for nomacopan. The optimal dose of nomacopan showed a greater reduction in inflammation score than cyclosporin and dexamethasone compared to control at day 10 (79% [nomacopan], 41% [cyclosporin], and 73% [dexamethasone]) in an experimental allergic eye disease model.

The improvement in inflammation seen with nomacopan in this model is likely to be in part a consequence of the increased suppression of pro-inflammatory T helper 2 (Th2), Th9 cells and cytokine IL-9 by nomacopan in comparison to cyclosporin and dexamethasone. In surface of the eye diseases, Th2 cells are recognized as the main mediators of allergic responses although other inflammatory mediators are often also involved.

This model shares many features with vernal keratoconjunctivitis (VKC), a difficult to treat keratinizing eye disease like AKC. Tear fluid and tissue samples of VKC patients were analyzed and patients with the active disease had a similar biomarker profile to that seen in the allergy model with raised Th cells and IL-9 as well as increased expression of C5a and BLT1 (LTB4) receptors in infiltrating cells.

This data complements Akari’s Phase I/II study in severe AKC patients where nomacopan was comfortable and well tolerated (Sanchez-Tabernero et al 2021) and where Akari is exploring further patient targeted work in keratinizing and dry eye diseases.

Akari is now collaborating on a topical mucous membrane pemphigoid (MMP) program. Over half of MMP patients have a type of disease that affects the surface of the eye for which there are no approved treatments. MMP shares a similar pathology with bullous pemphigoid where Akari has initiated a Phase III study with nomacopan.

Clive Richardson, Chief Executive Officer of Akari, commented, “The new surface of the eye data is an important step forward in our program and highlights the potential benefits of nomacopan’s differentiated bi-specific mode of action. Taken together with prior data this collectively points to the more severe form of these diseases as important clinical targets for nomacopan within the \$6bn+ surface of the eye market.

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, regarding, among other things, statements related to the offering of securities described herein, 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; 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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