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 2022

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 9, 2022, Akari Therapeutics, Plc (the "Company") issued a press release announcing the presentation of results from two preclinical development programs of long-acting PAS-nomacopan in geographic atropy (GA) dry age-related macular degeneration and nomacopan in experimental immune-mediated conjunctival disease (EIC)

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

The information in paragraphs three to twelve 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 9, 2022

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/ Rachelle Jacques
Name: Rachelle Jacques
President and Chief Executive Officer

Date: May 9, 2022

Exhibit 99.1

Akari Presents Results from Two Preclinical Development Programs of Long-Acting PAS-Nomacopan in Geographic Atropy (GA) Dry Age-Related Macular Degeneration and Nomacopan in Experimental Immune-Mediated Conjunctival Disease (EIC)

- Preclinical data show investigational intravitreal long-acting PASylated-nomacopan (PAS-nomacopan) effective in inhibiting choroidal neovascularization (CNV), which is a risk related to certain complement inhibitors that otherwise appear to be effective in the treatment of GA[1, 2]

- Initial pharmacokinetic (PK) and pharmacodynamic (PD) data from a standard model confirm bioavailability of PAS-nomacopan in the retina and suggest that a clinical dose interval of three months or more may be possible; frequent intravitreal injections are a significant burden on patients in the treatment of retinal diseases

- In a separate preclinical study, investigational nomacopan downregulated cells implicated in surface-of-the eye inflammation in EIC compared to dexamethasone and cyclosporin

NEW YORK and LONDON, May 9, 2022 (GLOBE NEWSWIRE) – Akari Therapeutics, plc (Nasdaq: AKTX), a late-stage biotechnology company focused on the development of advanced therapies for autoimmune and inflammatory diseases, presented positive results from two preclinical studies of its lead asset, investigational nomacopan, in diseases of the eye at the Association of Research in Vision and Ophthalmology (ARVO) 2022 Annual Meeting. The two presentations are available at www.investor.akaritx.com/news-and-events/presentations.

“There is significant unmet need in ophthalmology, and we are encouraged by the results of our work so far in the development of long-acting PAS-nomacopan for geographic atrophy,” said Rachelle Jacques, President and CEO of Akari Therapeutics. “This will be an area of focus and investment for Akari as we drive this program forward.”

Development of long-acting PASylated-nomacopan for treatment of GA and other retinal diseases

Geographic atrophy (GA) is a chronic progressive degeneration of the macula, which occurs during late-stage dry age-related macular degeneration (dAMD). Over time, GA can lead to permanent vision loss. It is estimated that more than 8 million people worldwide are affected by GA in AMD and currently there are no approved treatments.

Studies have indicated that while certain complement inhibitors slow the progression of GA, they may also promote choroidal neovascularisation (CNV), which can harm the macula, damage vision,[1,2] and require VEGF rescue therapy.

Leukotriene B4 (LTB4) is a potent leukotactic agent that can increase retinal vascular endothelial growth factor (VEGF) a key driver of CNV. Inhibition of LTB4 may decrease the risk of CNV.[3] Akari has conducted pre-clinical studies that explore the importance of the LTB4-VEGF axis and the potential role of nomacopan’s bispecific inhibition of both C5 and LTB4 in treating GA/dAMD. In a non-infectious allergic uveitis animal model, PAS-nomacopan reduced VEGF by more than 50% compared to saline control, equivalent to the inhibition caused by an anti-VEGF antibody. In addition, PAS-nomacopan was significantly more effective in reducing retinal inflammation than the anti-VEGF antibody.

One of the pre-clincal studies presented at ARVO 2022 used an industry standard model of laser-induced CNV. Intraveitreal (IVT) PAS-nomacopan injected once during a 16-day treatment period was compared to a U.S. Food and Drug Administration-approved VEGF inhibitor for impact on neo-vascularization. The IVT single dose of PAS-nomacopan significantly reduced CNV ($p=0.022$) as compared to saline and was as effective as multiple IVT injections of the VEGF inhibitor ($p=0.019$.) Single IVT injection of PAS-nomacopan showed a trend towards reduced leakage on Day 14 ($p = 0.097$).

Currently approved therapies for retinal diseases injected directly into the vitreous cavity are typically administered monthly. Studies have shown that due to adverse effects (such as an increase in intraocular pressure [IOP]), discomfort and anxiety, IVT injection presents a heavy burden on patients. PASylation of nomacopan has the potential to make it long-lasting in the back of the eye and may provide a dosing interval that is more attractive to patients.

Akari is continuing PK and PD work to optimize PAS-nomacopan with the aim of achieving safety and efficacy in GA, and meeting patient preferences for less frequent injections.

Comparison of topical nomacopan, a dual complement and LTB4 inhibitor with dexamethasone in downregulating experimental immune-mediated conjunctival disease (EIC)

Steroid-resistant allergic conjunctivitis, including atopic keratoconjunctivitis (AKC) and vernal keratoconjunctivitis (VKC), is difficult to treat and can lead to corneal scarring and vision loss. Topical or systemic dexamethasone and/or cyclosporin A (CsA) is often required, however dexamethasone may be associated with adverse reactions, including increased IOP.

Topical administration of nomacopan, a therapeutic protein, was recently shown to be effective at attenuating inflammation in a model of experimental immune-mediated conjunctivitis (EIC). The aim of the study presented at ARVO 2022 was to compare the anti-inflammatory effects of nomacopan with topical dexamethasone.

IL-9 expressing mast cells and CD4+T cells are upregulated during ovalbumin (OVA)-induced EIC.

In the preclinical study presented at ARVO 2022, nomacopan preferentially downregulated conjunctival Th2 IL9 producing, Th2 and Th9 CD4+T-cells and nomacopan, dexamethasone and cyclosporin A all effectively decreased Th2 and Th9 cells in draining lymphnodes (dLNs). These findings support use of topical nomacopan to treat allergic eye diseases including VKC and AKC.

References:

1. Liao DS, et al. Ophthalmology. 2020 Feb;127(2)
2. Jaffe GJ et al. Ophthalmology. 2021 Apr;128(4)
3. Sasaki F et al. JCI Insight. 2018 Sep 20;3(18)

About Akari Therapeutics

Akari Therapeutics, plc (Nasdaq: AKTX) is a biotechnology company focused on developing advanced therapies for autoimmune and inflammatory diseases. Akari's lead asset, investigational nomacopan, is a bispecific recombinant inhibitor of C5 complement activation and leukotriene B4 (LTB4) activity. The Akari pipeline includes two late-stage programs for bullous pemphigoid (BP) and thrombotic microangiopathy (TMA), as well as earlier stage research and development programs in eye and lung diseases with significant unmet need. For more information about Akari, please visit akaritx.com.

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 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 there; 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; 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.

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