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

For the month of: February 2023

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 ☐

On February 15, 2023, Akari Therapeutics, Plc, a public company with limited liability incorporated under the laws of England and Wales (the "Company"), issued a press release announcing updates on progress in the pre-clinical development program for long-acting PAS-nomacopan as a potential treatment for geographic atrophy secondary to dry age-related macular degeneration. A copy of such press release is furnished as Exhibit 99.1 to this Report on Form 6-K and incorporated herein by reference.

The information in the first, third, fifth and eighth paragraphs of such press release are hereby incorporated by reference into all effective registration statements filed by the Company under the Securities Act of 1933, as amended.

Exhibit No.	
99.1	Press Release issued by Akari Therapeutics, Plc on February 15, 2023.

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
Title: President and Chief Executive Officer

Date: February 15, 2023

Exhibit 99.1

Akari Therapeutics Announces Pre-Clinical Development Progress Toward Potential IND on Long-Acting PAS-Nomacopan for Geographic Atrophy (GA)

- Akari is targeting an Investigational New Drug (IND) application submission to the U.S. Food and Drug Administration in the first half of 2024
- Composition of matter patent application filed on long-acting PAS-nomacopan versions, which, if granted, provides patent protection until 2042
- Pre-clinical development on long-acting PAS-nomacopan has successfully produced multiple new and promising versions that are fully active, show high expression levels and have significantly enlarged hydrodynamic radii compared to earlier versions, which potentially increase the PAS-nomacopan target dosing interval beyond 3 months
- Development has progressed from lab scale to pre-GMP optimization and is on track to select the version of PAS-nomacopan that will advance to GMP manufacturing and non-clinical safety studies in preparation for an investigational new drug application (IND) and the start of clinical trials in GA

NEW YORK and LONDON, Feb. 15, 2023 (GLOBE NEWSWIRE) -- Akari Therapeutics, Plc (Nasdaq: AKTX), a late-stage biotechnology company developing advanced therapies for autoimmune and inflammatory diseases, today announced updates on progress in the pre-clinical development program for long-acting PAS-nomacopan as a potential treatment for geographic atrophy (GA) secondary to dry age-related macular degeneration (dAMD).

“Our pre-clinical development work has been focused on engineering, evaluating and selecting the version of long-acting PAS-nomacopan that will achieve the maximum dose interval, while not sacrificing manufacturability, as well as securing our intellectual property,” said Rachelle Jacques, President and CEO of Akari. “We have made significant development progress and I am pleased we are on track for an IND application submission next year to enable clinical trials for this potentially important treatment option for patients with geographic atrophy.”

Long-acting PAS-nomacopan is in pre-clinical development as a treatment for GA that addresses areas of significant unmet patient need including a long dose interval and reduction in the risk of choroidal neovascularization (CNV). PASylation® (PAS) technology is a biological alternative to the chemical conjugate polyethylene glycol (PEGylation) in the development of extended half-life recombinant protein therapeutics. The dual mechanism of long-acting PAS-nomacopan inhibits both complement C5 and leukotriene B4 (LTB4). Complement overactivation is a validated target and an important aspect in the pathophysiology of GA, while LTB4 may contribute to overexpression of VEGF-A, a key driver of CNV. Increased incidence of CNV is associated with late-stage complement-only inhibitors.[1]

“Patients being treated for chronic retinal diseases face a long treatment journey and experience significant burdens from frequent, repeated intravitreal injections into the eye, including high levels of anxiety and risks of serious clinical complications like infections, which can lead to discontinuation of the treatment they need. A longer dose interval with fewer injections into the eye is an area of significant unmet need for patients and the retinal specialists who treat them,” said Elias Reichel, M.D., Professor and Vice Chair, Department of Ophthalmology, Tufts University School of Medicine. “Patients who have geographic atrophy also are at risk of developing an additional sight-threatening condition known as choroidal neovascularization or CNV, which presents more hurdles in the fight to preserve sight. A dual mechanism treatment that inhibits both complement C5 and LTB4 simultaneously is a promising approach to address key drivers of both geographic atrophy lesions and CNV.”

The new PAS-nomacopan versions are fully active, with binding kinetics to complement C5 equivalent to the parent drug nomacopan and earlier PAS-nomacopan versions. New versions show high expression levels in recombinant protein manufacturing. Development of PAS-nomacopan has progressed from lab scale to pre-GMP optimization. With these advances, Akari is on track to select the version that will advance to GMP manufacturing and non-clinical safety studies in preparation for an investigational new drug application (IND) and the start of clinical trials in GA. Importantly, the new versions of PAS-nomacopan have significantly increased hydrodynamic radii compared to previous versions, increasing the PAS-nomacopan target dosing interval beyond 3 months with the potential for only 3 or 4 intravitreal injections a year.

Intravitreal injections into the eye for the treatment of conditions like GA and choroidal neovascularization (CNV) are sources of significant anxiety, discontinuation of treatment, and clinical complications for patients.[2-3] Patients report depression, impacts on relationships and daily activities, financial and physical burdens. Long-term exposure to IVIs can have clinical complications, including eye infections and inflammation. A Medicare claims review of anti-VEGF IVIs used to treat conditions like CNV found a 4% overall risk per injection of severe complications. For anti-VEGF CNV IVI treatments, up to one third of patients may discontinue or not adhere to treatment.[3]

An overdevelopment of blood vessels in the retina,[4] CNV is a sight-threatening condition that has been associated with late-stage complement-only inhibitors. CNV starts with inflammation in the choroid, which is part of the vascular layer of the eye. The inflammation damages an epithelial layer of the retina, which leads to the release of leukotrienes, including LTB4.[5,6] LTB4 can upregulate the production of VEGF-A, which is responsible for the proliferation and migration of endothelial cells that form the inner layer of blood vessels. VEGF-A is a key driver of CNV. Inhibiting the action of excess LTB4 can lead to VEGF-A overexpression is a rational strategy in the reduction of CNV risk.

In pre-clinical studies presented at ARVO 2022, an earlier version of PAS-nomacopan injected once during a 16-day treatment period was compared to an FDA-approved VEGF inhibitor for impact on neovascularization. The single dose of PAS-nomacopan significantly reduced CNV as compared to saline ($p=0.022$) and was as effective as multiple injections of the VEGF inhibitor ($p=0.019$ compared to saline). Single IVT injection of PAS-nomacopan showed a trend towards reduced leakage on Day 14 ($p = 0.097$).

References

1. Medscape article on 24-month data presentation at AAO 2022 With Approval Pending, Pegcetacoplan Shows Mixed Results for Treating Geographic Atrophy https://www.medscape.com/viewarticle/981813#vp_2
2. McClard CK, et al. Questionnaire to Assess Life Impact of Treatment by Intravitreal Injections (QUALITII). BMJ Open Ophthalmol. 2021;6(1):e000669.
3. Day S, et al. Ocular complications after anti-vascular endothelial growth factor therapy in Medicare patients with age-related macular degeneration. Am J Ophthalmol. 2011;152(2):266-272.
4. Hejtmancik JF, Nickerson JM. Overview of the Visual System. Prog Mol Biol Transl Sci. 2015;134:1-4.
5. Grossniklaus HE, Green WR. Choroidal neovascularization. Am J Ophthalmol. 2004;137(3):496-503.
6. Sasaki F, Koga T, Ohba M, et al. Leukotriene B4 promotes neovascularization and macrophage recruitment in murine wet-type AMD models. JCI Insight. 2018;3(18):e96902. Published 2018 Sep 20.

About Akari Therapeutics

Akari Therapeutics, plc (Nasdaq: AKTX) is a biotechnology company developing advanced therapies for autoimmune and inflammatory diseases. Akari's lead asset, investigational nomacopan, is a bispecific recombinant inhibitor of complement C5 activation and leukotriene B4 (LTB4) activity. Akari's pipeline includes a Phase 3 clinical trial program investigating nomacopan for severe pediatric hematopoietic stem cell transplant-related thrombotic microangiopathy (HSCT-TMA). Akari has been granted Orphan Drug, Fast Track and Rare Pediatric Disease designations from the FDA for nomacopan for the treatment of pediatric HSCT-TMA. Akari’s pipeline also includes a clinical program developing nomacopan for adult HSCT-TMA and pre-clinical research of long-acting PAS-nomacopan in geographic atrophy (GA). 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 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 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

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