
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: July 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 July 11, 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 certain updates on the development of long-acting PAS-nomacopan as a potential treatment for geographic atrophy (GA), including that the Company has selected the version of long-acting PAS-nomacopan that it plans to advance into clinical trials. 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 paragraph of such press release is 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 July 11, 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: July 11, 2023

Akari Therapeutics Provides Update on Development of Long-Acting PAS-Nomacopan for Treatment of Geographic Atrophy

- Akari has completed evaluation of long-acting PAS-nomacopan candidates and selected a single drug candidate to move forward into clinical trials for treatment of geographic atrophy (GA)
- The company remains on track for an IND submission in the first half of 2024 and the start of clinical trials in the second half of 2024
- Akari has selected Wacker Biotech GmbH as the manufacturing partner to support production of PAS-nomacopan for use in clinical trials

NEW YORK and LONDON, July 11, 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 the development of long-acting PAS-nomacopan as a potential treatment for geographic atrophy (GA). Resulting from extensive pre-clinical development work, Akari has selected the version of long-acting PAS-nomacopan that it plans to advance into clinical trials. The selected version has a product profile with characteristics important for a GA therapy, including fully active drug potency, planned small (<100µL) injection volume, viscosity enabling intravitreal injection with a fine needle, and pre-clinical half-life that supports a potential clinical dose interval of 3 months or longer. Akari remains on track for an IND submission in the first half of 2024 and the start of clinical trials in the second half of 2024. Akari has selected Wacker Biotech GmbH as the manufacturing partner to support production of PAS-nomacopan for use in clinical trials. Investigational PAS-nomacopan is a novel bispecific inhibitor of complement C5 and leukotriene B4 (LTB4).

“Our pre-clinical work has focused on identifying a single version of long-acting PAS-nomacopan with the strongest product profile to bring forward into clinical trials,” said Rachelle Jacques, Akari President and CEO. “As we complete the final stages before anticipated submission of an IND in first half of 2024, we are confident we’ve chosen the asset that positions us to succeed in the clinical trials we expect to initiate in the second half of 2024.”

Currently, there is one U.S. Food and Drug Administration (FDA)-approved treatment for GA, and one treatment filed with the FDA awaiting approval. These treatments are both complement-only inhibitors administered to patients through monthly or every-other-month intravitreal injections. However, frequent needle injections into the eye are a source of fear, discomfort and disruption for patients and have been shown to decrease compliance with efficacious dosing regimens. In clinical trials, discontinuation rates of up to 20% have been reported for the approved intravitreally-injected complement-only inhibitor for GA.

Approved and late-stage complement-only inhibitors used for the treatment of GA have been associated with as much as four times the risk of patients developing sight-threatening choroidal neovascularization (CNV) compared to sham in clinical trials. CNV is an overdevelopment of blood vessels and leakage in the retina that can significantly damage sight that is typically treated chronically with anti-VEGF intravitreal injections. If patients have both GA and CNV, they may be facing as many as 20 injections into the eye per year.

“Despite FDA approval of the first treatment for GA, there are still significant unmet needs,” said Elias Reichel, M.D., Professor of Ophthalmology at the Tufts University School of Medicine, during Akari’s recent key opinion leader event. “It’s important that we reduce the frequency of therapy, which must be administered through intravitreal injection into the eye. In addition, treating geographic atrophy while preventing choroidal neovascularization from developing is another important unmet need.” Hear more comments from Dr. Reichel’s presentation at the Akari key opinion leader event at <https://lifescievents.com/event/akari-event/>.

Long-acting PAS-nomacopan is being developed with the potential to address three areas of patient need in GA:

1. Efficacy benefits of prolonged complement C5 inhibition
 2. Meaningfully fewer injections than the approved and late-stage complement-only inhibitors for GA
 3. Significantly lower risk of sight threatening CNV, which occurs at a low rate spontaneously in GA and at an increased rate when GA is treated with the approved and the late-stage complement-only inhibitors
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In pre-clinical models of retinal disease, leukotriene B4 (LTB4) has been shown to cause the overexpression of VEGF-A, which can stimulate overproduction of the cells that form the inner layer of blood vessels, leading to CNV. LTB4 is inhibited by PAS-nomacopan.

The dual mechanism of PAS-nomacopan may offer important advantages for patients including the well-understood benefits of intravitreally-administered complement C5 inhibition in slowing the progression of GA lesions, while also providing LTB4 inhibition that has the potential to help prevent VEGF-A overexpression, reducing the likelihood of CNV.

Akari selected Wacker Biotech GmbH, a subsidiary of the Wacker group, as the manufacturing partner to support production of PAS-nomacopan for use in clinical trials. Wacker Biotech is a leading contract development and manufacturing organization (CDMO) of therapeutic proteins, live biotherapeutic products (LBPs), plasmid DNA (pDNA), messenger ribonucleic acid (mRNA) and vaccines based on microbial systems. Their ESETEC[®] expression technology is based on modified E. coli strains, enabling production and secretion of complex proteins at high quality and yields. The Wacker group is a global organization with 15,700 employees and 27 production sites and a portfolio of 3,200 products supplied in more than 100 countries.

Dr. Miles Nunn, Chief Scientific Officer of Akari said “We selected Wacker among competing CDMOs because their proprietary bacterial expression technology ESETEC[®] provides a significant yield of fully refolded PAS-nomacopan, and we believe working with Wacker provides the best path to GMP manufacturing of long-acting PAS-nomacopan for use in GA clinical trials. Wacker has proven to be an exceptional contract manufacturing partner for parent drug nomacopan, and we look forward to our continued relationship with them.”

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.

Investor Contact:

Mike Moyer
LifeSci Advisors
(617) 308-4306
mmoyer@lifesciadvisors.com

Media Contact:

Eliza Schleifstein
Schleifstein PR
(917) 763-8106
eliza@schleifsteinpr.com
