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

July 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): ☐

CONTENTS

On July 28, 2022, Akari Therapeutics, Plc (the “Company”) issued a press release announcing positive results from recent pre-clinical studies of investigational PASylated nomacopan that support the potential to advance research toward IND/IMPD for clinical trials in geographic atrophy.

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

The information in paragraphs one and three to eleven are hereby incorporated by reference into all effective registration statements filed by the Company under the Securities Act of 1933.

Exhibit No.

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: July 29, 2022

Exhibit 99.1

Akari Therapeutics Announces Positive Results from Recent Pre-Clinical Studies of Investigational PASylated Nomacopan That Support the Potential to Advance Research Toward IND/IMPD for Clinical Trials in Geographic Atrophy

- Positive results from recent pre-clinical studies support the potential of long-acting PASylated[â] nomacopan to advance toward IND/IMPD for clinical trials in geographic atrophy (GA) in dry age-related macular degeneration (dAMD), a disease with no approved treatments
- New PK measurements indicate the half-life within the eye of intravitreally injected early generation PAS-nomacopan (also referred to as PAS600 nomacopan) in a standard ophthalmic pre-clinical model can be accurately predicted; results support Akari's continuing work to develop new generation PAS-nomacopan that may enable dosing intervals for patients of more than three months between intravitreal injections
- Tolerability of early generation PAS-nomacopan was demonstrated across multiple measures in a standard ophthalmic pre-clinical model
- These new data showing extended dose intervals, together with data previously presented, showing LTB4 inhibition by PAS-nomacopan may also reduce the risk of sight-threatening choroidal neovascularization (CNV), suggest PAS-nomacopan may be a potential novel and effective treatment option for GA

NEW YORK and LONDON, July 28, 2022 (GLOBE NEWSWIRE) -- Akari Therapeutics, Plc (Nasdaq: AKTX), a late-stage biotechnology company focused on developing advanced therapies for autoimmune and inflammatory diseases, today announced positive results from recent pre-clinical studies on the tolerability and extended dose interval of long-acting PAS-nomacopan in development for geographic atrophy (GA) in dry age-related macular degeneration (dAMD). The results support the potential for PASylated nomacopan to advance toward the regulatory application(s) that would be required to begin clinical trials.

"These pre-clinical results contribute to the strong foundation we are building for a potential PAS-nomacopan clinical trial program in geographic atrophy," said Rachelle Jacques, President and CEO of Akari. "The work we have completed to show bispecific inhibition of complement C5 and LTB4 and to optimize PAS-nomacopan for dosing interval and dose volume, while achieving manufacturing scalability, positions us well to advance this program toward the clinic. We expect to have clarity on IND/IMPD timing by year end."

GA manifests as a chronic progressive degeneration of the macula, which occurs during late-stage dAMD and can lead to irreversible vision loss. Approximately five million people worldwide are affected,[1] with nearly one million in the U.S.[2] There are no approved treatment options.

Akari's pre-clinical research program investigating long-acting PAS-nomacopan in GA seeks to address three areas of significant unmet patient need including: providing longer intervals between intravitreal injections into the back of the eye, a dose volume that has little impact on intraocular pressure (IOP), and, through LTB4 inhibition, reduced risk of sight-threatening choroidal neovascularization (CNV), also known as wet age-related macular degeneration (wAMD), which can be a complication of certain late-stage complement-only inhibitors.[3,4]

An Akari pre-clinical study presented at ARVO 2022 used an industry standard model of laser induced CNV. Intravitreal (IVT) early generation PAS-nomacopan injected once during a 16-day treatment period was compared to an FDA-approved vascular endothelial growth factor (VEGF) inhibitor for impact on neovascularization. VEGF inhibitors are often used to treat CNV/wAMD. The IVT single dose of early generation PAS-nomacopan significantly reduced CNV ($p=0.022$) as compared to saline and was as effective as multiple IVT injections of the VEGF inhibitor ($p=0.019$.)

The CNV data also included an interesting result. Multiple IVT doses of early generation PAS-nomacopan were less effective than the single IVT dose of PAS-nomacopan. One explanation for the result might be presence of non-endotoxin pyrogens (NEPs) in the early generation PAS-nomacopan preparation, which may cause activation of monocytes through Toll-like receptor (TLR) signaling. Analysis of the early generation PAS-nomacopan used in the CNV study showed that the preparation did contain NEPs, which prompted Akari to develop an adapted purification process that produced early generation PAS-nomacopan without NEPs that no longer activates monocytic cells and TLR2/TLR4.

The NEP-free early generation PAS-nomacopan was used in a tolerability and pharmacokinetic (PK) study.

- A single intravitreal dose of highly purified PAS-nomacopan was shown to be free of endotoxins and non-endotoxin pyrogens and suitable for use in the eye in either low or high (3x) concentration

New PK measurements from the recent pre-clinical studies support Akari's ongoing work to engineer new generation PAS-nomacopan that has the potential to offer patients extended intravitreal dose intervals of more than three months.

- PK measurements indicate the predicted half-life based of early generation PAS-nomacopan matches the actual half-life within the eye of intravitreally injected NEP-free PAS-nomacopan in a standard ophthalmic pre-clinical model

- The new PK measurements show half-life of early generation PAS-nomacopan without NEPs in vitreous increased to seven days compared with a half-life of five days for the same PAS-nomacopan with NEPs (in data presented at ARVO 2022)

    - The ability to accurately predict half-life supports Akari's work to develop a new form of PAS-nomacopan that may permit longer dosing intervals of more than three months between IVT injections. Extending half-life has the potential to achieve a dose volume that has little impact on intraocular pressure (IOP).

    - A study evaluating the patient burden of repeated IVT (median frequency of once every 4.5 weeks) found that anxiety, discomfort and disruption to normal activities and inconvenience were common experiences. The most common source of anxiety is the fear of the injection into the eye and associated discomfort. Patients related discomfort to what they felt after anesthesia wears off. Patients experiencing disruption reported being debilitated after each IVT, requiring an average of eight hours to recover.[5]

Occasional dystrophic retina (retinal degeneration) was observed in some test subjects in the recent pre-clinical studies and was unrelated to PAS-nomacopan as the incidence was equivalent in untreated eyes and controls as in treated test subjects. Some signs of ocular inflammation and anterior cell infiltration were observed that occurred 14 days or more after IVT administration suggesting they were not due to drug toxicity or an innate immune response, which typically peaks two to three days after IVT injection.

In summary, LTB4 signaling has shown to be involved in VEGF expression,[6,7] which is a key driver of the damaging angiogenesis (blood vessel development) and retinal inflammation in CNV/wAMD. The nomacopan bispecific inhibition of both complement C5 and LTB4 may be a novel approach to treating GA/dAMD, while potentially helping to reduce the sight-threatening risk of CNV/wAMD.

Akari's pre-clinical studies for PAS-nomacopan in GA are conducted in collaboration with ophthalmology specialty contract research organization IRIS Pharma.

References

1. Wong WL, et al. Global prevalence of age-related macular degeneration and disease burden projection for 2020 and 2040: a systematic review and meta-analysis. Lancet Glob Health. 2014;2(2):e106-e116.
2. Friedman DS, et al. Prevalence of age-related macular degeneration in the United States [published correction appears in Arch Ophthalmol. 2011 Sep;129(9):1188]. Arch Ophthalmol. 2004;122(4):564-572.
3. Liao DS, et al. Complement C3 Inhibitor Pegcetacoplan for Geographic Atrophy Secondary to Age-Related Macular Degeneration: A Randomized Phase 2 Trial. Ophthalmology. 2020;127(2):186-195.
4. Jaffe GJ, et al. C5 Inhibitor Avacincaptad Pegol for Geographic Atrophy Due to Age-Related Macular Degeneration: A Randomized Pivotal Phase 2/3 Trial. Ophthalmology. 2021;128(4):576-586.
5. McClard CK, et al. Questionnaire to Assess Life Impact of Treatment by Intravitreal Injections (QUALITII): Development of a patient-reported measure to assess treatment burden of repeat intravitreal injections. BMJ Open Ophthalmol. 2021;6(1):e000669. Published 2021 Apr 7.
6. Sasaki F, 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.
7. Eskandarpour et al. Immune-Mediated Retinal Vasculitis in Posterior Uveitis and Experimental Models: The Leukotriene (LT)B4-VEGF Axis. Cells. 2021;10(2):396. Published 2021 Feb 15

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. Akari's pipeline includes two Phase 3 clinical trial programs investigating nomacopan for bullous pemphigoid (BP) and pediatric hematopoietic stem cell transplant-related (HSCT) thrombotic microangiopathy (TMA), as well as pre-clinical research of long-acting PAS-nomacopan in geographic atrophy (GA).

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

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

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