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

February 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 February 1, 2021, Akari Therapeutics, Plc (the “Company”) issued a press release announcing that the Company adds the histamine inhibitor Votucalis to its pipeline to treat neuropathic pain and dermatological disease.

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

The information in paragraphs one, two, five, six and seven 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 February 1, 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: February 1, 2021

**Exhibit 99.1**

**Akari Therapeutics Adds Histamine Inhibitor Votucalis to Pipeline to treat Neuropathic Pain and Dermatological Disease**

- *Building on the positive clinical and safety data from its lead drug nomacopan, Akari is developing a second related therapeutic candidate (votucalis) focusing on new clinical targets*
- *Votucalis captures histamine and thereby has the unique potential to prevent activation of all four histamine G-protein coupled receptors (GPCRs) which can induce diverse pathophysiological processes, including chronic pain, itch and inflammation*
- *New pre-clinical data showed votucalis blocks symptoms of neuropathic pain that result from damage to the peripheral somatosensory nervous system. In addition, data from an itch model demonstrated a potential for votucalis to treat atopic dermatitis and attendant chronic pruritis*
- *Local administration of votucalis was shown to be more effective than systemic administration*
- *Neuropathic pain is a global health problem. Most current treatments, including opioids, act via the central nervous system, while votucalis offers a new approach without entering the central nervous system, thereby potentially avoiding attendant side effects and drug dependency*

NEW YORK and LONDON, February 1 , 2021 - 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 announced that it is developing a second clinical candidate, votucalis, which specifically inhibits histamine.

Votucalis originates from the same research program as nomacopan and it shares a similar unique mode of action - specifically capturing and tightly binding to small highly potent ligands such as C5 plus LTB4 (nomacopan) or histamine (votucalis). By inhibiting the host immune response, ticks can feed for extensive periods without damage from an inflammatory response, benefiting from circa 300 million years of evolutionary development. The inhibition of the histamine pathway affords Akari the potential to target a range of new diseases, separate from those of nomacopan.

Dr Ilona Obara (Newcastle University, UK; Senior Lecturer of pain pharmacology, council member of European Histamine Research Society EHRS) said, “Votucalis is a unique centrally sparing natural product-based drug which captures histamine within a high-affinity internal binding site. In our studies we used a pre-clinical model of neuropathic pain and observed that selective targeting of peripheral histamine by votucalis resulted in highly effective inhibition of mechanical hypersensitivity. It is very exciting to see that votucalis may represent a novel and safe therapeutic strategy for chronic neuropathic pain and other conditions such as atopic dermatitis and psoriasis, where raised endogenous histamine is a known mediator,”

Dr Paul Chazot (FBPhS University of Durham, UK; Chair of NC-IUPHAR subcommittee for histamine pharmacology, past-President of EHRS) said, “Chronic pain has been recently recognised by the WHO as a priority disease area lacking in effective and safe therapeutics. The majority of therapeutic issues are associated with side effects of current medications acting on the brain. In addition, the current opioid crisis in the U.S. and Europe, and recent shifts in national policies for chronic pain management prescriptions necessitates the need for a new way to treat chronic pain. The natural product drug, votucalis offers this potential based on its unique mode of action, the work we have done and the known role of histamine and its receptors in chronic peripheral pain mechanisms.”

Votucalis, which is related to nomacopan, has a different mechanism of action and by specifically inhibiting histamine opens a new range of clinical targets. Like complement and LTB4 (inhibited by nomacopan), histamine is part of the innate immune response and is dysregulated in many diseases.

Inhibiting histamine is a well-established treatment route with drugs targeting individual histamine receptors primarily H1R and H2R. By contrast, votucalis has the unique potential to inhibit all 4 histamine-dependent GPCRS (H1R, H2R, H3R, and H4R) by sequestering histamine within the body of the protein thereby preventing histamine binding to its receptors. A further desirable feature of votucalis, is that due to its size (21kDa) votucalis does not enter the central nervous system or brain and thus acts peripherally and is centrally sparing and is hence less likely to cause side effects or drug dependencies.

New preclinical data using a mouse model of neuropathic pain shows votucalis blocks chronic neuropathic pain symptoms. In addition, data from an itch model demonstrated a potential for votucalis to treat atopic dermatitis and attendant chronic pruritis. In both cases local subcutaneous administration of votucalis was more effective than systemic administration - requiring a far lower dose and lasting for longer than systemic treatment.

Akari is continuing their work with Dr Paul Chazot and Dr Ilona Obara focused on progressing votucalis into the clinic around two targets both based on local administration. These are for treatment of neuropathic pain, and for dermatological conditions associated with inflammation and itch – especially diseases where H4R may have a role in disease pathology, given there are currently no marketed anti H4R drugs.

Votucalis has been GMP manufactured and following ongoing evaluation and safety studies, proof of principle Phase II trials in 2022 under an IND would enable this project to be potentially partnered in neuropathic pain and further developed as part of the Akari dermatological franchise.

Dr Miles Nunn, Chief Scientific Officer of Akari Therapeutics said, “The further development of votucalis affords Akari the potential to expand our pipeline and target a range of new diseases. The planned work will allow us to evaluate the clinical route forward for votucalis which potentially provides a new means to ameliorate neuropathic pain and treat dermatological diseases where more than one histamine activated GPCR contributes to disease pathology.”

**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.

**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. You should not place undue reliance upon the Company’s forward-looking statements. Except as required by law, the Company undertakes no obligation to revise or update any forward-looking statements in order to reflect any event or circumstance that may arise after the date of this press release. 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 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; risks associated with the SEC investigation; 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:**
Peter Vozzo
Westwicke
+1 (443) 213-0505
peter.vozzo@westwicke.com

**Media Contact:**
Sukaina Virji / Lizzie Seeley
Consilium Strategic Communications
+44 (0)20 3709 5700
Akari@consilium-comms.com