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 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 February 28, 2022, Akari Therapeutics, Plc (the “Company”) issued a press release announcing new data showing a significant role for complement activation in the clinical outcomes of U.S. Army trauma patients in Iraq and the therapeutic potential of nomacopan for treatment of trauma.

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

The information in paragraphs one, three, four, five, six, seven, eight and nine 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.

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 28, 2022

Exhibit 99.1

Akari Therapeutics Announces New Data Showing A Significant Role for Complement Activation in the Clinical Outcomes of U.S. Army Trauma Patients in Iraq and the Therapeutic Potential of Nomacopan for Treatment of Trauma

- Akari's complement and leukotriene inhibitor, nomacopan, demonstrated improved survival (80% vs. 30%) in a preclinical model of trauma
- A follow-on program relevant to both military and civilian trauma is planned as the next steps toward a clinical study
- Project was funded by the DoD U.S. Army Medical Research and Development Command

NEW YORK and LONDON, February 28, 2022 – 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 new data showing that clinical outcomes in U.S. Army trauma patients correlate with complement activation, and that nomacopan significantly improves survival from 30% to 80% in a clinically relevant preclinical model of traumatic hemorrhage. A full data set is available at https://doi.org/10.22541/au.164423459.98723938/v1.

Clive Richardson, Chief Executive Officer of Akari Therapeutics, commented: "This very exciting data generated from our collaboration with the U.S. Army supports the development of nomacopan as an organ protective drug for treatment of severe trauma patients that has the potential to significantly reduce mortality in both a military and civilian setting. There is now a planned pathway to the clinic, and we look forward to leveraging nomacopan's dual inhibition of the pro-inflammatory complement C5 and leukotriene LTB4 as a potential treatment for traumatic injury."

Traumatic hemorrhage (TH) is the leading cause of potentially preventable deaths that occur during the pre-hospital phase of care. Current treatments still largely rely on organ/tissue supportive approaches and fluid resuscitation, and no effective pharmacological therapeutics are available. Identifying new life-supporting treatment focused on the interval between point of injury to hospital is a key objective. Military blast injury accounted for 70%-80% of U.S. casualties in Iraq and Afghanistan, while in the U.S. there are approximately 500,000 civilian trauma hospital discharges a year which are defined as severe and could benefit from early drug intervention to reduce multi-organ dysfunction. Annual inpatient trauma-related hospital costs in the U.S. are approximately $30 billion a year[1].

An analysis of 54 military trauma patients in Baghdad with blast and gunshot injury showed that three key markers of complement activation – C5a, C5b9 and Bb – were elevated 300%-600% in the first eight hours after the traumatic event, compared to healthy controls. In addition, pro-inflammatory C5a and C5b9 plasma levels correlated with trauma severity, and complement activation correlated with clinical outcomes.

Nomacopan's mode of action may be particularly suited for treatment of TH as critically it inhibits terminal complement activation (C5a, C5b9) via all three complement pathways (classical, lectin and alternative) and additionally inhibits leukotriene B4 (LTB4) which is also implicated in exacerbation of TH.

To test the anticipated efficacy of nomacopan, a clinically relevant pre-clinical model of blast injury and hemorrhagic shock was undertaken by the United States Army Institute of Surgical Research (USAISR). The addition of nomacopan to damage control resuscitation protocol, significantly inhibited terminal complement activity, decreased local and systemic inflammatory responses, improved hemodynamics and metabolism, attenuated tissue and organ damage and increased survival (80% vs 30%; $p<0.05$).

Nomacopan’s therapeutic efficacy in this model of TH is likely a result of the drugs inhibition of multiple inflammatory pathways primarily:

- Inhibiting C5 and thereby preventing its cleavage into C5a and C5b9, both potent inflammatory mediators correlated with trauma severity.
- Significantly reducing levels of key pro-inflammatory cytokines (IL-6, TNF-α, IL-1β, KC/GRO) and the inflammatory mediator HMGB1 that were elevated post trauma in both patients and the pre-clinical model.
- Binding to and thereby removing LTB4 from circulation and disrupting neutrophil tissue swarming (indexed by a reduction in MPO), a key component of trauma.

Nomacopan is particularly well suited for pre-hospital use in both a battlefield/military or ambulance/ civilian setting due to the molecules thermostability and ease of administration. In addition, nomacopan is fast acting and clears the body within a matter of days is also important in that the optimal window for treatment by inhibiting complement is likely to be the first 24 hours following TH.

The planned next steps include an extension study following on from the reported USAISR program. Also, in parallel, a collaboration for a UK observational study with civilian traumatic brain injury patients to optimize the nomacopan clinical treatment regimen leading to a potential clinical study that could include both military and civilian patients.

[1] Source: (DiMaggio et al., 2016, Traumatic injury in the United States)

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. Nomacopan is currently being clinically evaluated in four areas: bullous pemphigoid (BP), thrombotic microangiopathy (TMA), as well as programs in the eye and lung.

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 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 U.S. Food and Drug Administration (FDA) and European Medicines Agency (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 Securities and Exchange Commission (SEC), 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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