
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

March 2020

Commission file number: 001-36288

Akari Therapeutics, Plc

(Translation of registrant's name into English)

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London W1G 9RT
United Kingdom
Tel: (646) 448-8743

(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 March 31, 2020, Akari Therapeutics, Plc (the “Company”) issued a press release announcing its financial results for the fourth quarter and full year ended December 31, 2019, as well as recent business highlights. A copy of the press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

The statements under “Fourth Quarter and Full Year 2019 Financial Results”, the accompanying financial statements and “Forward-Looking Statements” of Exhibit 99.1 are 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 March 31, 2020

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: March 31, 2020

Akari Therapeutics Reports Fourth Quarter and Full Year 2019 Financial Results and Business Highlights

Significant Clinical Progress Across Target Indications during 2019 and 2020 Year-to-Date

- *Interim Phase II bullous pemphigoid (BP) data demonstrated a rapid and significant improvement in symptoms with a mean 63% decline in Bullous Pemphigoid Disease Area Index (BPDAI) score and mean 68% decline in blister score by day 42 in patients with moderate BP.*
- *Opened an Investigational New Drug (IND) application for pivotal Phase III trial of nomacopan in pediatric hematopoietic stem cell transplant-related thrombotic microangiopathy (HSCT-TMA) during fourth quarter 2019.*
- *Part A of atopic keratoconjunctivitis (AKC) Phase I/II study completed with rapid mean 55% improvement in composite clinical score at Day 56 across both signs and symptoms.*
- *Positive interim data from Phase III CAPSTONE paroxysmal nocturnal hemoglobinuria (PNH) study showed that of the first eight patients enrolled into the study, all four patients treated with nomacopan achieved primary endpoint of transfusion independence while all four patients on standard of care continued to be transfusion dependent.*
- *Preclinical ophthalmic data showing nomacopan reduced both vascular endothelial growth factor (VEGF) and retinal inflammation, supporting nomacopan as potential treatment option for back-of-the-eye diseases.*
- *Fast Track designation for pediatric HSCT-TMA granted by the U.S. Food and Drug Administration (FDA).*
- *Orphan drug designation for BP and HSCT-TMA granted by the FDA.*
- *Over 30 cumulative patient-years of nomacopan treatment data with no reported drug related serious adverse events in any patients treated to date across the four conditions.*

NEW YORK and LONDON, March 31, 2020 - Akari Therapeutics, Plc (Nasdaq: AKTX), a 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 financial results for the fourth quarter and full year ended December 31, 2019, as well as recent business highlights.

“2019 was a very important year for the company as we generated positive clinical data across all four of our programs. For BP, AKC and HSCT-TMA, the rapid patient response we generally saw in our clinical studies validates these disease targets for nomacopan where the specific dual action of the drug provides a potential significant differentiation with its inhibition of both the complement (C5) and leukotriene (LTB4) pathways,” said Clive Richardson, Chief Executive Officer of Akari Therapeutics. “In 2020, we look forward to expanding these programs further and plan on focusing on preparatory work for potential pivotal studies in anticipation of lessening the impact of the COVID-19 pandemic. At the same time we are working with our employees, partners and patients to help ensure their safety and maintain continuity where possible.”

Full Year 2019 and Recent Business Highlights

Akari’s strategy is to focus on orphan inflammatory diseases with significant unmet medical need, where the role of the complement and leukotriene systems are implicated. Akari’s lead programs are in BP, AKC, and HSCT-TMA where clinical data with nomacopan has shown rapid and sustained clinical improvement in patients. These diseases have no approved treatments.

The Company is working with clinical sites and is following regulatory and health agency guidance related to the COVID-19 pandemic to help ensure the safety of its employees and patients. Our BP study has completed recruitment while our AKC study has halted recruitment with around two thirds of patients recruited. We expect delays in opening sites for our HSCT-TMA program. We expect our long-term safety program will shift to being managed on a country by country basis and some disruption is expected.

Phase II clinical trial in patients with BP

- § In the fourth quarter of 2019, interim Phase II trial results with nomacopan were presented at the 28th European Academy of Dermatology and Venereology (EADV) Congress. The data showed that four of the six patients were classified as at the upper limit of moderate BP. The four patients saw a rapid and significant improvement in symptoms, with a mean 63% decline in BPDAI score and mean 68% decline in blister score by Day 42, with either no or minimal early steroid treatment with one moderate patient having a flare up post Day-28. The data showed nomacopan’s potential as a possible treatment for BP with the additional and important benefit of reducing steroid use which has multiple adverse effects including a threefold increased risk of mortality. The Phase II trial has completed recruitment, with full data expected in the second quarter of 2020.
- § During the third quarter of 2019, the FDA granted orphan drug designation for nomacopan for the treatment of BP. The Company is now evaluating pivotal trial designs.

Phase III clinical trial in pediatric patients with HSCT-TMA

Initiated a pivotal Phase III trial for HSCT-TMA with nomacopan following the opening of an IND by the FDA. As a result of the COVID-19 pandemic, although we are looking to continue the process of site openings, we anticipate this will be delayed and hence any enrollment. This two-part Phase III study in pediatric patients with HSCT-TMA is based on guidance from the Company's end-of-Phase II meeting with the FDA. Part A of the trial is a dose confirmation study with the dosing agreed with FDA via their Model Informed Drug Development Program (MIDD). Part B of the trial is a single arm responder-based efficacy study that will follow an interim analysis of Part A and a meeting with the FDA. This devastating condition has an estimated 80% mortality rate in children, at elevated risk of dying who will be recruited to the trial and has no approved treatments. Akari has both FDA fast track pediatric patients and orphan drug designation status for this program.

Phase I/II clinical trial in patients with AKC

- § In 2019, the Company successfully completed Part A of the Phase I/II clinical trial in severe AKC patients who showed a rapid overall improvement of a mean 55% in the composite clinical score. The nomacopan eye drops were found to be comfortable and well tolerated with no reported drug related serious adverse events. Enrolment in the Part B placebo-controlled efficacy arm of the study has now stopped due to the COVID outbreak, but recruited patients continue to be treated. We anticipate that when the trial closes, we will have data on around two thirds of the target 19 patient study.
- § During the first quarter of 2020, the Company announced new preclinical data indicating that PAS-nomacopan, the long acting form of the drug, significantly reduced both retinal inflammation and intraocular VEGF. PAS-nomacopan was found to reduce intraocular VEGF levels by as much as the anti-VEGF antibody with 74% (p=0.04) and 68% (p=0.05) reductions respectively, compared to saline control. Furthermore, while clinically assessed inflammation increased in both the control and anti-VEGF groups by 49% and 33%, respectively, PAS-nomacopan treatment resulted in a 9% reduction in inflammation which represents a 58% difference compared to control assessed by retinal fundoscopy (p=0.02). This therapeutic activity across multiple pathogenic pathways (VEGF, inflammation and complement) supports the potential for nomacopan as a new mode of action for the treatment of back of the eye diseases.

PNH program

- § The Company continues to accumulate positive long-term treatment data, which includes more than 30 cumulative patient-years of data with 14 PNH patients across four clinical trials with no reported drug related serious adverse events. Interim data from the Phase III CAPSTONE study on the first eight PNH patients who were all transfusion dependent at entry to the CAPSTONE trial show that all four patients randomized to nomacopan were transfusion independent for the first six months of treatment while all four patients on standard of care (SOC) remained transfusion dependent. Recruitment into the Phase III CAPSTONE study has been discontinued, although a PNH program may be re-initiated to potentially take advantage of the new high concentration formulation.

§ The Company is currently developing a new higher concentration formulation of nomacopan allowing a small volume (0.3mL), low viscosity injection, with an insulin pen-like injector holding one week's daily dosing stable at room temperature, improving both patient comfort and convenience. This drug presentation is relevant to all of the diseases that the Company plans to treat by subcutaneous dosing including BP and HSCT-TMA.

§ Akari has been granted orphan status from the FDA and the European Medicines Agency (EMA) for nomacopan for treatment of PNH.

Fourth Quarter and Full Year 2019 Financial Results

§ As of December 31, 2019, the Company had cash of approximately \$5.7 million, compared to cash of \$5.4 million as of December 31, 2018. In March 2020, the Company issued an aggregate of 5,620,296 American Depositary Shares (the "ADSs") at \$1.70 per ADS for aggregate gross proceeds of approximately \$9.5 million. The offering was led by existing investors of the Company, including Dr. Ray Prudo, the Company's chairman, as well as certain accredited and institutional investors.

§ During the year ended December 31, 2019, the Company sold to Aspire Capital Fund, LLC (Aspire Capital) a total of approximately \$8.8 million of ordinary shares. Subsequent to December 31, 2019, the Company sold a total of approximately \$1.1 million of ordinary shares and approximately \$9.6 million of the original \$20 million facility remains available for draw down under the equity purchase agreement entered into with Aspire Capital.

§ Research and development (R&D) expenses in the fourth quarter of 2019 were approximately \$5.7 million, as compared to approximately \$2.4 million in the same quarter the prior year. This increase was primarily due to higher manufacturing costs for nomacopan in the fourth quarter of 2019. R&D expenses for full year 2019 were approximately \$8.7 million, as compared to approximately \$11.8 million for the prior year. This decrease was primarily due to larger R&D tax credits received in 2019 compared to 2018, which offset overall R&D expenses.

§ General and administrative (G&A) expenses in the fourth quarter of 2019 were approximately \$2.1 million, as compared to approximately \$2.4 million in the same quarter last year. This decrease was primarily due to lower expenses associated with professional fees and rent. G&A expenses for the full year 2019 were approximately \$8.2 million, as compared to approximately \$10.9 million in 2018. This decrease was primarily due to lower expenses associated with legal fees, non-cash stock-based compensation, professional fees and rent.

§ Total other expense for the fourth quarter of 2019 was approximately \$50,000, as compared to total other income of \$1.2 million in the same period the prior year, and, for the full year 2019, total other expense was approximately \$140,000 as compared to total other income of approximately \$3.5 million in 2018. This change was primarily due to approximately \$3.3 million of higher expense related to the change in the fair value of the stock option liabilities in 2019 compared to 2018.

§ Net loss for the fourth quarter of 2019 was approximately \$7.9 million, compared to a net loss of approximately \$3.5 million for the same period in 2018. Net loss for full year 2019 was approximately \$17.1 million, as compared to approximately \$16.5 million for the prior year.

A copy of the Company's Annual Report on Form 20-F for the year ended December 31, 2019 has been filed with the Securities and Exchange Commission and posted on the Company's website at <http://investor.akaritx.com/financial-information/sec-filings>. You may request a copy of the Company's Form 20-F, at no cost to you, by writing to the Financial Controller of the Company at 75/76 Wimpole Street, London W1G 9RT, United Kingdom or by calling the Company at +44 20 8004 0261.

Important Message Regarding COVID-19

Public health epidemics or outbreaks could adversely impact our business. In late 2019, a novel strain of COVID-19, also known as coronavirus, was reported in Wuhan, China. While initially the outbreak was largely concentrated in China, it has now spread to several other countries, including in the United Kingdom and the United States, and infections have been reported globally. In particular, our clinical trial sites are based in areas currently affected by coronavirus. Epidemics such as this can adversely impact our business as a result of disruptions, such as travel bans, quarantines, and interruptions to access the trial sites and supply chain, which could result in material delays and complications with respect to our research and development programs and clinical trials. Moreover, as a result of coronavirus, there is a general unease of conducting unnecessary activities in medical centers. As a consequence, our ongoing trials have been halted or disrupted. It is too early to assess the full impact of the coronavirus outbreak on trials for nomacopan, but coronavirus is expected to affect our ability to complete recruitment in our original timeframe. The extent to which the coronavirus impacts our operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration and severity of the outbreak, and the actions that may be required to contain the coronavirus or treat its impact. In particular, the continued spread of the coronavirus globally, could adversely impact our operations and workforce, including our research and clinical trials and our ability to raise capital, could affect the operations of key governmental agencies, such as the FDA, which may delay the development of our product candidates and could result in the inability of our suppliers to deliver components or raw materials on a timely basis or at all, each of which in turn could have an adverse impact on our business, financial condition and results of operation.

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 indications: bullous pemphigoid (BP), atopic keratoconjunctivitis (AKC), thrombotic microangiopathy (TMA), and paroxysmal nocturnal hemoglobinuria (PNH). Akari believes that the dual action of nomacopan on both C5 and LTB4 may be beneficial in AKC and BP. Akari is also developing other tick derived proteins, including longer acting versions.

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 regarding, among other things, statements related to the offering, the expected gross proceeds and the expected closing of the offering. 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; our ability to enter into collaborative, licensing, and other commercial relationships and on terms commercially reasonable to us; 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 outbreak of coronavirus;; 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.

AKARI THERAPEUTICS, Plc
CONSOLIDATED BALANCE SHEETS
(in U.S. Dollars, except share data)

	<u>December 31, 2019</u>	<u>December 31, 2018</u>
Assets		
Current Assets:		
Cash	\$ 5,731,691	\$ 5,446,138
Prepaid expenses and other current assets	712,975	1,423,184
Deferred Financing Costs	321,956	585,000
Total Current Assets	<u>6,766,622</u>	<u>7,454,322</u>
Restricted cash	-	521,829
Property and equipment, net	5,013	20,425
Patent acquisition costs, net	30,163	32,978
Total Assets	<u>\$ 6,801,798</u>	<u>\$ 8,029,554</u>
Liabilities and Shareholders' Equity		
Current Liabilities:		
Accounts payable	\$ 1,228,772	\$ 1,586,285
Accrued expenses	4,228,604	1,489,558
Liabilities related to options and warrants	3,116,880	1,842,424
Total Current Liabilities	<u>8,574,256</u>	<u>4,918,267</u>
Other long-term liability	-	-
Total liabilities	<u>8,574,256</u>	<u>4,918,267</u>
Commitments and Contingencies		
Shareholders' (Deficit) Equity:		
Share capital of £0.01 par value		
Authorized: 10,000,000,000 ordinary shares; issued and outstanding: 2,245,865,913 and 1,580,693,413 at December 31, 2019 and 2018, respectively	31,987,016	23,651,277
Additional paid-in capital	110,498,824	106,616,083
Accumulated other comprehensive loss	(348,860)	(352,426)
Accumulated deficit	(143,909,438)	(126,803,647)
Total Shareholders' (Deficit) Equity	<u>(1,772,458)</u>	<u>3,111,287</u>
Total Liabilities and Shareholders' (Deficit) Equity	<u>\$ 6,801,798</u>	<u>\$ 8,029,554</u>

AKARI THERAPEUTICS, Plc
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(in U.S. Dollars)

	Twelve Months Ended			Three Months
	Dec 31, 2019	Dec 31, 2018	Dec 31, 2019	Ended Dec 31, 2018
Operating Expenses:				
Research and development expenses	\$ 8,739,420	\$ 11,795,376	\$ 5,701,382	\$ 2,362,358
General and administrative expenses	8,223,700	10,896,158	2,124,933	2,370,206
Litigation settlement (gain) loss	-	(2,700,000)	-	-
Total Operating Expenses	16,963,120	19,991,534	7,826,315	4,732,564
Loss from Operations	(16,963,120)	(19,991,534)	(7,826,315)	(4,732,564)
Other Income (Expense):				
Interest income	5,531	222,256	1,739	24,110
Changes in fair value of option and warrant liabilities - (loss) gain	(60,640)	3,238,911	(48,046)	1,161,783
Foreign currency exchange gain (loss)	(67,256)	81,501	4,733	39,020
Other expenses	(20,306)	(17,914)	(10,182)	(5,103)
Total Other Income (Expenses)	(142,671)	3,524,754	(51,756)	1,219,810
Net Loss	(17,105,791)	(16,466,780)	(7,878,071)	(3,512,754)
Foreign Currency Translation Adjustment	3,566	(116,180)	53,233	(55,943)
Comprehensive Loss	\$ (17,102,225)	\$ (16,582,960)	\$ (7,824,838)	\$ (3,568,697)
Loss per ordinary share (basic and diluted)	\$ (0.01)	\$ (0.01)	\$ (0.00)	\$ (0.00)
Weighted average ordinary shares (basic and diluted)	1,830,998,609	1,540,309,840	2,157,115,913	1,580,693,413

For more information

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