
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

April 2021

Commission file number: 001-36288

Akari Therapeutics, Plc
(Translation of registrant's name into English)

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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 April 20, 2021, Akari Therapeutics, Plc (the “Company”) issued a press release announcing its financial results for the full year ended December 31, 2020, as well as highlights on recent clinical progress. A copy of the press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

The statements under “Full Year 2020 Financial Results”, the accompanying financial statements and “Cautionary Note Regarding 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 April 20, 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: April 20, 2021

Akari Therapeutics Reports Full Year 2020 Financial Results and Highlights Recent Clinical Progress

- *Opening of Investigational New Drug Application (IND) with U.S. Food and Drug Administration (FDA) for Phase III study of nomacopan in bullous pemphigoid (BP), a severe dermatological disease with no specific approved treatments*
- *Phase III study in severe pediatric hematopoietic stem cell transplant-related thrombotic microangiopathy (HSCT-TMA) is open for enrollment in the U.S. and Europe*
- *New data supports potential for nomacopan as a treatment for dry age-related macular degeneration (AMD), a sight-threatening disease with significant unmet need*
- *New data shows elevated levels of LTB4 in patients with COVID-19 pneumonia further supporting the potential therapeutic role of nomacopan*
- *Cooperative Research and Development Agreement (CRADA) signed with the U.S. Army Institute of Surgical Research (USAISR) for ongoing studies using nomacopan to treat trauma*
- *30+ cumulative patient-years of data in patients with paroxysmal nocturnal hemoglobinuria (PNH) supports nomacopan’s clinical potential by showing nomacopan is well-tolerated and reduces transfusion dependence in formerly transfusion dependent patients by 79%*

NEW YORK and LONDON, April 20, 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 financial results for the full year ended December 31, 2020, as well as recent clinical progress.

“2020 saw us successfully complete a Phase II study in BP and align with the FDA and the European Medicines Agency (EMA) on a regulatory pathway to initiate a Phase III pivotal study in BP. In addition, we have initiated a Phase III study in HSCT-TMA. We have also seen further positive data support development of our back of the eye and surface of the eye programs,” said Clive Richardson, Chief Executive Officer of Akari Therapeutics. “In 2021, we look forward to progressing our Phase III studies and advancing development of our ophthalmology, lung and trauma programs as we continue to leverage nomacopan’s unique bifunctional action as a dual highly specific inhibitor of LTB4 and complement C5.”

Full Year 2020 and Recent Clinical Highlights

Akari's two lead programs – in BP and HSCT-TMA – are in Phase III development. The Company also has early-stage programs addressing ophthalmology, pulmonary diseases and trauma.

PHASE III TRIALS

Phase III clinical trial in patients with BP

- § Initiation of a multicenter Phase III study of nomacopan for the treatment of BP with nomacopan following opening of FDA IND. Clinical sites expected to open for recruitment mid-2021.
- § The FDA and EMA have granted orphan drug designation for nomacopan for the treatment of BP.

Phase III clinical trial in pediatric patients with HSCT-TMA

- § Phase III study in pediatric HSCT-TMA is now open for enrollment at sites in the U.S. and Europe, subject to the ongoing impact of COVID-19 related restrictions.
- § Akari has FDA fast track and orphan drug designations for pediatric HSCT-TMA patients.

PNH - long term data

- § Long-term data from 19 PNH patients treated for over 30 cumulative patient-years showed that self-administered nomacopan:
 - o Is well-tolerated with no reported major adverse vascular events and only a single reported serious adverse event (urinary tract infection) in one patient that was considered possibly related to nomacopan.
 - o Induces transfusion independence (defined as at least six months without transfusion) in 79% (n = 14) PNH patients treated with nomacopan for at least six months, who were transfusion dependent prior to treatment. This compares favorably to the treatment of PNH patients on long-term eculizumab therapy where between 50-60% of transfusion dependent patients become transfusion independent in a 12-month period (Brodsky et al., 2008, SHEPHERD study on eculizumab, Hillmen et al 2013) and supports ongoing studies in other hematological diseases where the role of complement is implicated, such as HSCT-TMA.

EARLY-STAGE PROGRAMS

Ophthalmology program

- § Interim data from a first-in-eye Phase I/II study in atopic keratoconjunctivitis (AKC), a surface of the eye inflammatory disease, showed nomacopan was comfortable and well tolerated. Akari has opened an IND and is looking to expand its program in the surface of the eye.
- § Recently presented data points to the potential role of nomacopan as a treatment for AMD. This includes recent articles in the journal *CELLS* and the *American Journal of Pathology*, which highlights the causative role LTB4 plays in the induction of vascular endothelial growth factor (VEGF) and associated retinal inflammation. Taken together the data supports a potential therapeutic role for long acting PAS-nomacopan, inhibiting both complement and VEGF in sight threatening retinal diseases.
- § In a model of choroidal neo-vascularisation, PAS-nomacopan injected once during the 16-day treatment period was equivalent to Eyelea[®] in reducing neo-vascularization. Work is ongoing to explore the likely human injection frequency for intravitreal (IVT) administration of PAS-nomacopan.
- § Given the specialist nature of the ophthalmology market, Akari is exploring opportunities to collaborate with potential partners to accelerate the development of these ophthalmology programs.

Lung program

- § In the UK, recruitment into the COVID-19 observational study is complete and a publication is in preparation. Initial data has identified elevated levels of LTB4 in COVID patients. In addition, other early disease biomarkers have been analyzed, which may allow for the potential to optimize patient selection for treatment with nomacopan.
- § In the U.S., the FDA has approved a randomized multi-center study in patients hospitalized with COVID-19 pneumonia with a new increased dosing schedule, following experience in Brazil. The clinical study in Brazil, as previously reported has been paused and may potentially now align with the new U.S. program.
- § Akari is exploring opportunities to expand its lung program to include other inflammatory diseases with exacerbations, limited treatment options and where both complement and leukotriene pathways are implicated. In this context an investigator led severe asthma study is being considered in the U.S.

Trauma

- § In March 2021, Akari announced CRADA with the USAISR, working to evaluate the potential for use of nomacopan in battlefield trauma. This follows positive pre-clinical data with nomacopan in a range of pre-clinical models.
- § Trauma is a global burden disease. In the U.S., there are approximately 500,000 trauma hospital discharges a year which are defined as severe and might benefit from early drug intervention to reduce multi-organ dysfunction following trauma. Akari is actively exploring other opportunities in trauma in the civilian population.

New histamine inhibition development program

- § Akari added to its pipeline a novel tick derived histamine inhibitor ‘votucalis’, which has a similar structure to nomacopan. Votucalis uniquely prevents activation of all four histamine G-protein coupled receptors creating new therapeutic opportunities in pain management. As such, votucalis potentially provides the opportunity to expand the Company’s existing dermatology franchise with other modes of administration (local topical delivery) and into other diseases such as atopic dermatitis.
- § The histamine program is supported by positive pre-clinical data in neuropathic pain and itch models.

Full Year 2020 Financial Results

- § As of December 31, 2020, the Company had cash of approximately \$14.1 million, compared to cash of \$5.7 million as of December 31, 2019.
- § In June 2020, Akari entered into a securities purchase agreement (Purchase Agreement) with Aspire Capital Fund, LLC (Aspire Capital) whereby Aspire Capital is committed to purchase up to an aggregate of \$30 million of the Company’s ADSs. During the year ended December 31, 2020, the Company sold to Aspire Capital a total of approximately \$6.0 million of ordinary shares. As of April 15, 2021, approximately \$24.0 million of the original purchase commitment remains available for draw down under the Purchase Agreement.
- § Research and development (R&D) expenses for full year 2020 were approximately \$8.8 million, as compared to approximately \$8.7 million in 2019.
- § General and administrative (G&A) expenses for the full year 2020 were approximately \$9.2 million, as compared to approximately \$8.2 million in 2019. The increase was primarily due to a one-time non-cash financing expense related to the 2020 Purchase Agreement with Aspire Capital.

- § For the full year 2020, total other income was approximately \$899,000 as compared to approximately \$117,000 in 2019. This change was primarily due to higher income related to the change in the fair value of warrant liabilities in 2020 than in 2019, and foreign exchange gains in 2020 as compared to foreign exchange losses in 2019.
- § Net loss for full year 2020 was approximately \$17.1 million, as compared to approximately \$16.8 million for the prior year. The slight decrease in net income was primarily due to the aforementioned one-time non-cash financing expense related to the 2020 Purchase Agreement with Aspire Capital.
- § As part of the 2020 audit, the Company discovered an error in its accounting treatment of certain options (RPC options) from 2015 that should have been accounted for as an equity instrument as opposed to a liability. Accordingly, the Company concluded that the financial statements contained in the Company's Annual Reports on Form 20-F for the years ended December 31, 2015 through 2019, as well as the interim condensed consolidated financial statements contained in the quarterly reports on Form 6-K for each quarter within these years, as well as the quarterly periods ended March 31, 2020, June 2020 and September 2020, should be restated and therefore not relied upon. This is a non cash re-statement and the RPC options do not constitute a legal liability to the Company and will not affect the Company's financial statements upon settlement. The Company has included restated financial statements and notes thereto and any other appropriate revisions in its Annual Report on Form 20-F for the year ended December 31, 2020 and for more information please refer to Note 3 of our Annual Report on Form 20-F for the year ended December 31, 2020.

A copy of the Company's Annual Report on Form 20-F for the year ended December 31, 2020 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>.

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 particularly 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. 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; 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 departure of our former Chief Executive Officers and other executive officers; 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
As of December 31, 2020 and 2019
(in U.S. Dollars, except share data)

	<u>December 31, 2020</u>	<u>December 31, 2019</u> As Restated
Assets		
Current Assets:		
Cash	\$ 14,055,777	\$ 5,731,691
Prepaid expenses and other current assets	521,880	712,975
Total Current Assets	<u>14,577,657</u>	<u>6,444,666</u>
Property and equipment, net	-	5,013
Patent acquisition costs, net	27,150	30,163
Total Assets	<u>\$ 14,604,807</u>	<u>\$ 6,479,842</u>
Liabilities and Shareholders' Equity		
Current Liabilities:		
Accounts payable	3,380,782	1,228,772
Accrued expenses	1,839,706	4,228,604
Liability related to warrants	-	1,014,868
Total Liabilities	<u>\$ 5,220,488</u>	<u>\$ 6,472,244</u>
Commitments and Contingencies		
Shareholders' Equity:		
Share capital of \$0.0001 par value		
Authorized: 10,000,000,000 ordinary shares; issued and outstanding: 3,847,331,923 and 2,245,865,913 at December 31, 2020 and December 31, 2019, respectively	384,733	31,987,016
Additional paid-in capital	139,734,651	133,568,636
Capital redemption reserve	52,193,811	-
Accumulated other comprehensive loss	(648,065)	(348,860)
Accumulated deficit	(182,280,811)	(165,199,194)
Total Shareholders' Equity	<u>9,384,319</u>	<u>7,598</u>
Total Liabilities and Shareholders' Equity	<u>\$ 14,604,807</u>	<u>\$ 6,479,842</u>

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
For the Years Ended December 31, 2020, 2019 and 2018
(in U.S. Dollars, except share data)

	Years Ended December 31,		
	2020	2019	2018
		As Restated	As Restated
Operating Expenses:			
Research and development expenses	\$ 8,820,204	\$ 8,739,420	\$ 11,795,376
General and administrative expenses	9,160,770	8,223,700	11,689,926
Litigation settlement gain	-	-	(2,700,000)
Total Operating Expenses	<u>17,980,974</u>	<u>16,963,120</u>	<u>20,785,302</u>
Loss from Operations	<u>(17,980,974)</u>	<u>(16,963,120)</u>	<u>(20,785,302)</u>
Other Income:			
Interest income	13,615	5,531	222,256
Changes in fair value of warrant liabilities - gain	556,810	198,948	-
Foreign currency exchange gains (losses)	350,939	(67,256)	81,501
Other expenses	(22,007)	(20,306)	(17,914)
Total Other Income	<u>899,357</u>	<u>116,917</u>	<u>285,843</u>
Net Loss	<u>(17,081,617)</u>	<u>(16,846,203)</u>	<u>(20,499,459)</u>
Other Comprehensive Income:			
Foreign Currency Translation Adjustment	(299,205)	3,566	(116,180)
Comprehensive Loss	<u>\$ (17,380,822)</u>	<u>\$ (16,842,637)</u>	<u>\$ (20,615,639)</u>
Loss per ordinary share (basic and diluted)	<u>\$ (0.01)</u>	<u>\$ (0.01)</u>	<u>\$ (0.01)</u>
Weighted average ordinary shares (basic and diluted)	<u>3,159,037,588</u>	<u>1,830,998,609</u>	<u>1,540,309,840</u>

For more information

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