
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

May 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 May 16, 2022, Akari Therapeutics, Plc (the “Company”) issued a press release announcing its financial results for the full year ended December 31, 2021, 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 2021 and Recent Clinical Highlights”, 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 May 16, 2022](#)

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: May 17, 2022

Akari Therapeutics Reports Full Year 2021 Financial Results and Highlights Clinical Progress

- Clinical trial sites open and enrolling patients in FDA and EMA registration-directed Phase III Part A study of nomacopan in pediatric hematopoietic stem cell transplant-related thrombotic microangiopathy (HSCT-TMA)
- FDA and EMA registration-directed Phase III Part A study of nomacopan in bullous pemphigoid (BP) is open for enrollment
- Advanced the development of long-acting PAS-nomacopan for geographic atrophy/dry age-related macular degeneration (GA/dAMD); preclinical data showed PAS-nomacopan effective in the inhibition of choroidal neovascularization (CNV) and suggested a clinical dose interval of three months may be possible
- Increased the total manufacturing yield of investigational nomacopan more than five-fold
- Appointment of industry veteran Rachele Jacques as President and CEO

NEW YORK and LONDON, May 16, 2022 (GLOBE NEWSWIRE) -- Akari Therapeutics, Plc (Nasdaq: AKTX), a late-stage biotechnology company focused on advanced therapies for autoimmune and inflammatory diseases, today announced financial results for the full year ended December 31, 2021, as well as recent pipeline progress.

“During the last twelve months, Akari has advanced nomacopan pre-clinical and clinical development programs, including three focus areas of autoimmune skin diseases, thrombotic microangiopathies, and progressive retinal diseases,” said Rachele Jacques, President and CEO of Akari Therapeutics. “Broad and deep research and development work is producing compelling science in diseases with complex pathologies and is providing the foundation for next steps in the development of bispecific recombinant nomacopan. Late-stage programs in pediatric HSCT-TMA and BP are active and advancing in Part A clinical studies, which will inform the pivotal Part B studies that will be the basis for potential regulatory submissions in the U.S. and Europe.”

Full Year 2021 and Recent Clinical Highlights

Late-Stage Program Studying Investigational Nomacopan in Pediatric HSCT-TMA

- Phase III Part A clinical trial sites are open and recruiting in the U.S. and Europe for investigation of nomacopan in pediatric HSCT-TMA.
 - o Urgent unmet need exists in pediatric HSCT-TMA with no approved treatment options in the U.S. or Europe; currently the subset of patients Akari is studying are facing a mortality rate of ~80%
 - o Nomacopan was granted Orphan Drug and Fast Track designations from the U.S. Food and Drug Administration (FDA) for pediatric HSCT-TMA
 - o Patient dosing is underway in the Part A study that has a recruitment goal of approximately seven patients, with a minimum of two patients in each of three age cohorts

Late-Stage Program Studying Investigational Nomacopan in Bullous Pemphigoid (BP)

- FDA and European Medicines Agency (EMA) registration-directed Phase III Part A study of nomacopan in moderate and severe BP patients is open for enrollment following resolution of third-party supply chain partner issues that resulted in delays. Data from the Part A study will inform the pivotal Part B study that will be the basis for potential regulatory submissions in the U.S. and Europe
 - o There are no approved therapies; superpotent topical steroid and high dose oral corticosteroid (OCS) are the current standards of care
 - o The mortality rate in BP is approximately three-fold higher than the general population due to the disease itself, and infections and cardiovascular conditions that are more common in older patients and are exacerbated by treatment with high dose OCS.¹
 - o There is significant unmet need for an effective steroid-sparing therapy.
 - o Nomacopan was granted Orphan Drug and Fast Track designations by the FDA and Orphan Drug designation from the EMA for the treatment of BP
- Results from the completed Phase II study of subcutaneous nomacopan in patients with mild to moderate BP were published online in JAMA Dermatology in May 2022
 - o The Phase II study advanced understanding of the nomacopan safety profile and informed duration of treatment in the ARREST-BP Phase III Part A clinical trial, which is currently open for enrollment
 - o The multi-center, single arm nonrandomized controlled Phase II study included nine patients newly diagnosed or recurrent patients with mild to moderate active BP
 - o Patients received subcutaneous nomacopan (30 mg once daily) with lesional mometasone from Day 1 to 21 of treatment and nomacopan only from Day 21 to Day 42
 - o Seven of nine patients responded to nomacopan with three, regarded as complete responders, showing >80% reduction in BPDAI (BP disease activity index) activity and four patients showing >70% reduction in pruritis by day 42; two of nine patients were non-responders
 - o None of the nine patients reported Common Terminology Criteria for Adverse Events (CTCAE) grade three, four or five treatment-related adverse events
- A poster outlining the design of the Phase III study of nomacopan in patients with moderate to severe BP was presented at the 2021 International Pemphigus & Pemphigoid Foundation (IPPF) Scientific Symposium

Pre-Clinical Program Studying Investigational Long-Acting PAS-Nomacopan for Geographic Atrophy/Dry Age-Related Macular Degeneration (GA/dAMD)

- Akari has conducted pre-clinical studies that explore the importance of the leukotriene B4 (LTB4)-VEGF axis and the potential role of nomacopan's bispecific inhibition of both C5 and LTB4 in treating GA/dAMD
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- Studies have indicated that while certain complement inhibitors slow the progression of GA, they may also promote choroidal neovascularisation (CNV), which can harm the macula, damage vision,^{2,3} and require VEGF rescue therapy
- LTB4 is a potent leukotactic agent that can increase retinal vascular endothelial growth factor (VEGF) a key driver of CNV. Inhibition of LTB4 may decrease the risk of CNV.⁴
- Akari has conducted pre-clinical studies that explore the importance of the LTB4-VEGF axis and the potential role of nomacopan's bispecific inhibition of both C5 and LTB4 in treating GA/dAMD
 - o In a non-infectious allergic uveitis animal model, PAS-nomacopan reduced VEGF by more than 50% compared to saline control, equivalent to the inhibition caused by an anti-VEGF antibody. In addition, PAS-nomacopan was significantly more effective in reducing retinal inflammation than the anti-VEGF antibody.
 - o A pre-clinical study presented at ARVO 2022 used an industry standard model of laser induced CNV. Intravitreal (IVT) PAS-nomacopan injected once during a 16-day treatment period was compared to an FDA-approved VEGF inhibitor for impact on neo-vascularization. The IVT single dose of 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.) Single IVT injection of PAS-nomacopan showed a trend towards reduced leakage on Day 14 (p = 0.097).
- Currently approved therapies for retinal diseases injected directly into the vitreous cavity are typically administered monthly. Studies have shown that due to adverse effects (such as an increase in intraocular pressure [IOP]), discomfort and anxiety, IVT injection presents a heavy burden on patients
 - o PASylation of nomacopan has the potential to make it long-lasting in the back of the eye and may provide a dosing interval that is more attractive to patients
- Akari is continuing pharmacokinetic (PK) and pharmacodynamic (PD) work to optimize PAS-nomacopan with the aim of achieving safety and efficacy in GA, and meeting patient preferences for less frequent injections

Studies of Investigational Nomacopan in Inflammation-Implicated Lung Conditions

- Advanced the study of investigational nomacopan in the treatment of inflammation-implicated lung conditions
 - o The CORONET study evaluated compassionate use of investigational nomacopan in the treatment of hospitalized COVID-19 pneumonia patients in the U.S.
 - o The CASCADE study in the U.K. explored correlations between biomarkers and risk stratification categories to help predict the subsets of COVID-19 pneumonia patients who have a higher propensity to deteriorate clinically to more severe disease

Nomacopan Manufacturing

- Significantly increased the total yield of nomacopan (more than five-fold) with a new manufacturing process

References:

1. *Tedbirt B, et al., JAMA Dermatol. 2021 Apr 1;157(4)*
 2. *Liao DS, et al. Ophthalmology. 2020 Feb;127(2)*
 3. *Jaffe GJ et al. Ophthalmology. 2021 Apr;128(4)*
 4. *Sasaki F et al. JCI Insight. 2018 Sep 20;3(18)*
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Full Year 2021 Financial Results

- At December 31, 2021, the Company had cash of approximately \$9.4 million, compared to cash of approximately \$14.1 million at December 31, 2020.
- In March 2022, Akari entered into an agreement with Paulson Investment Company, LLC to serve as placement agent in connection with a registered direct offering and sold approximately 7.4 million of the Company's ADSs for gross proceeds of approximately \$8.9 million.
- In December 2021, Akari entered into an agreement with Paulson Investment Company, LLC to serve as placement agent in connection with a registered direct offering and sold approximately 4.3 million of the Company's ADSs for gross proceeds of approximately \$6.0 million.
- In July 2021, Akari closed a private placement of approximately \$12.3 million in gross proceeds by issuing approximately 7.9 million of the Company's ADSs.
- Research and development (R&D) expenses for full year 2021 were approximately \$9.1 million, as compared to approximately \$8.8 million for full year 2020.
- General and administrative expenses for full year 2021 were approximately \$8.1 million, as compared to approximately \$9.2 million for full year 2020. This decrease was primarily due to a one-time non-cash financing expense of approximately \$900,000 in 2020 related to the 2020 Purchase Agreement with Aspire Capital.
- For full year 2021, total other loss was approximately \$210,000 as compared to total other income of approximately \$899,000 for full year 2020. This change was primarily due to the accounting reclassification of warrant liabilities to shareholders' equity as of December 2020.
- Net loss for the full year 2021 was approximately \$17.4 million, as compared to net loss of approximately \$17.1 million for full year 2020.

A copy of the Company's Annual Report on Form 20-F for the year ended December 31, 2021 will be 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 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. The Akari pipeline includes two late-stage programs for bullous pemphigoid (BP) and thrombotic microangiopathy (TMA), as well as earlier stage research and development programs in eye and lung diseases with significant unmet need. For more information about Akari, please visit akaritx.com.

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.

Consolidated Statements

AKARI THERAPEUTICS, Plc

CONSOLIDATED BALANCE SHEETS

As of December 31, 2021 and 2020

(in U.S. Dollars, except share data)

	December 31,	December 31,
	2021	2020
Assets		
Current Assets:		
Cash	\$ 9,361,270	\$ 14,055,777
Prepaid expenses	2,173,528	292,680
Other current assets	90,301	229,200
Total Current Assets	11,625,099	14,577,657
Patent acquisition costs, net	22,929	27,150
Total Assets	\$ 11,648,028	\$ 14,604,807
Liabilities and Shareholders' Equity		
Current Liabilities:		
Accounts payable	1,788,563	3,380,782
Accrued expenses	3,184,883	1,839,706
Liability related to deposits received for share subscriptions	1,120,000	—
Total Liabilities	\$ 6,093,446	\$ 5,220,488
Commitments and Contingencies		
Shareholders' Equity:		
Share capital of \$0.0001 par value		
Authorized: 15,000,000,000 ordinary shares; issued and outstanding: 4,759,731,923 and 3,847,331,923 at December 31, 2021 and December 31, 2020, respectively	475,973	384,733
Additional paid-in capital	153,130,813	139,734,651
Capital redemption reserve	52,193,811	52,193,811
Accumulated other comprehensive loss	(540,967)	(648,065)
Accumulated deficit	(199,705,048)	(182,280,811)
Total Shareholders' Equity	5,554,582	9,384,319
Total Liabilities and Shareholders' Equity	\$ 11,648,028	\$ 14,604,807

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
For the Years Ended December 31, 2021, 2020 and 2019
(in U.S. Dollars, except share data)

	Years Ended December 31,		
	2021	2020	2019
Operating Expenses:			
Research and development expenses	\$ 9,133,455	\$ 8,820,204	\$ 8,739,420
General and administrative expenses	8,080,681	9,160,770	8,223,700
Total Operating Expenses	17,214,136	17,980,974	16,963,120
Loss from Operations	(17,214,136)	(17,980,974)	(16,963,120)
Other Income:			
Interest income	10,600	13,615	5,531
Changes in fair value of warrant liabilities - gain	—	556,810	198,948
Foreign currency exchange losses	(193,219)	(350,939)	(67,256)
Other expenses	(27,482)	(22,007)	(20,306)
Total Other (Loss) Income	(210,101)	899,357	116,917
Net Loss	(17,424,237)	(17,081,617)	(16,846,203)
Other Comprehensive Income:			
Foreign Currency Translation Adjustment	107,098	(299,205)	3,566
Comprehensive Loss	\$ (17,317,139)	\$ (17,380,822)	\$ (16,842,637)
Loss per ordinary share (basic and diluted)	\$ (0.00)	\$ (0.01)	\$ (0.01)
Weighted average ordinary shares (basic and diluted)	4,292,112,667	3,159,037,588	1,830,998,609

For more information

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