
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 2019

Commission file number: 001-36288

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

75/76 Wimpole Street
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 April 23, 2019, Akari Therapeutics, Plc (the “Company”) issued a press release announcing its fourth quarter and full year 2018 financial results and highlights on its clinical development programs. 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 2018 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 April 23, 2019](#)

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
Interim Chief Executive Officer
and Chief Operating Officer

Date: April 23, 2019

Akari Reports Fourth Quarter and Full Year 2018 Financial Results and Business Highlights

- *Treatment with Nomacopan (Coversin) in three patients with mild-to-moderate bullous pemphigoid (BP) resulted in no drug-related adverse events and rapid reduction in BP Disease Area Index (BPDAI) score and blistering in ongoing Phase II clinical trial*
- *Pivotal clinical trial for pediatric hematopoietic stem cell transplant-related thrombotic microangiopathy (HSCT-TMA) expected to start Q4 2019*
- *Initial data on atopic keratoconjunctivitis (AKC) and pre-clinical back of the eye program to be presented at Association for Research in Vision and Ophthalmology (ARVO) 2019*
- *Long-term clinical study with Nomacopan (Coversin) continues to yield encouraging safety data*

NEW YORK and LONDON, April 23, 2019 - Akari Therapeutics, Plc (Nasdaq: AKTX), a biopharmaceutical company focused on innovative therapeutics to treat orphan autoimmune and inflammatory diseases where complement and/or leukotriene systems are implicated, today announced its financial results for the fourth quarter and full year ended December 31, 2018.

“The last several months were an important period in which a number of clinical and preclinical study results validated our focus on poorly treated orphan diseases where the combined inhibition of the complement and leukotriene pathways provides a novel treatment option for Nomacopan (Coversin), our dual action C5 and LTB4 inhibitor,” said Clive Richardson, Interim Chief Executive Officer of Akari Therapeutics. “During the last six months, the Company has broadened its clinical targets with two new ongoing orphan disease programs in **bullous pemphigoid** and **atopic keratoconjunctivitis**, and a third **hematopoietic stem cell transplant-related thrombotic microangiopathy** anticipated to open later this year.”

Full Year 2018 and Recent Business Highlights

- **Phase II clinical trial in patients with bullous pemphigoid (BP).**
 - Initial results recently announced from the ongoing six-week open-label single-arm Phase II clinical trial evaluating Nomacopan (Coversin) in patients with BP showed for the first three patients no drug-related adverse events and a rapid reduction in BPDAI index (*see Company press release issued April 23, 2019*)
- **Phase I/II clinical trial in patients with atopic keratoconjunctivitis (AKC).**
 - AKC is an eye surface inflammatory disease and is one of a larger group of ocular surface inflammatory diseases associated with severe dry-eye including vernal keratoconjunctivitis (VKC), Sjögren’s syndrome and mucous membrane pemphigoid which are currently inadequately treated and may result in permanent loss of vision.
 - An interim update of the Phase I/II AKC clinical trial is planned to coincide with the Association for Research in Vision and Ophthalmology (ARVO) 2019 annual meeting, April 28-May 2, where a poster will also be presented showing Nomacopan’s (Coversin’s) effect in a preclinical model of autoimmune uveitis, a back of the eye orphan disease with significant unmet need. Uveitis is an inflammatory disease affecting the uvea (pigmented layer of the eye).

- **Pediatric hematopoietic stem cell transplant-related thrombotic microangiopathy (HSCT-TMA).**

- In March 2019, Akari announced it had a successful Type B, pre-IND meeting with the Food and Drug Administration (FDA) regarding its proposed pivotal clinical trial program for HSCT-TMA, outlining the clinical development path ahead for this program. In September 2018, Akari announced that in the first two patients treated with Nomacopan (Coversin) as part of a UK named patient program, it had observed a rapid reduction of the markers of complement activation as well as normalization of markers that are elevated in thrombotic microangiopathy (TMA).
- A pivotal clinical trial for pediatric HSCT-TMA patients is expected to start in the fourth quarter of 2019. TMA-HSCT is expected to be the Company's gateway indication into the broader TMA space which includes a large number of related and poorly treated orphan diseases including atypical hemolytic syndrome (aHUS). In order to accommodate the new focus on the broader TMA space, the current aHUS Phase II program is being put on hold and will be reviewed in order to align with the wider TMA program.

- **Paroxysmal nocturnal haemoglobinuria (PNH).** Ongoing Phase III, multicenter trial in naïve patients and a Phase II trial in patients who are resistant to eculizumab.

Nomacopan (Coversin) auto-injector pen

- New data in a pig model has shown a similar PK profile for the higher concentrated formulation to be used across the Company's subcutaneous programs. This new highly concentrated formulation with small (0.3mL) volume and water-like viscosity is intended to allow ease of administration and increased patient comfort for use alongside a new auto-injector pen holding a week's dosing stable at room temperature.

Long-term safety study for Nomacopan (Coversin)

- Total cumulative number of patient-years on Nomacopan (Coversin) treatment over 16 years.
- All patients in the long term study have now been treated for more than one year and the first patient has now been treated for over three years.
- No drug related serious adverse events and no neutralizing antibodies reported to date.
- Six PNH patients were transfusion dependent prior to treatment with Nomacopan (Coversin), of which four in the long-term study are now transfusion independent.

Upcoming Events and Milestones

- Update on eye disease program, including initial data from Phase I/II clinical trial in patients with AKC and data from a pre-clinical back of the eye study expected during ARVO Annual Meeting, April 28-May 2, 2019.
- HSCT-TMA pivotal clinical trial expected to start fourth quarter of 2019.
- Expansion of BP Phase II clinical trial into the severe patient population.
- Initiate a Phase I clinical trial with new auto-injector pen formulation in the second half of 2019.

Fourth Quarter and Full Year 2018 Financial Results

- Research and development (R&D) expenses in the fourth quarter of 2018 were \$2.4 million, as compared to \$7.1 million in the same quarter the prior year. This decrease was due primarily to lower manufacturing and clinical costs associated with Nomacopan (Coversin). R&D expenses for full year 2018 were \$11.8 million, as compared to \$23.3 million for the prior year. The decrease was due primarily to lower manufacturing costs for Nomacopan (Coversin) as the Company had previously manufactured clinical trial material for supply through 2019, and an R&D tax credit which offset overall R&D expenses.
- General and administrative (G&A) expenses in the fourth quarter of 2018 were \$2.4 million, as compared to \$3.8 million in the same quarter last year. This decrease was due primarily to lower personnel expenses. G&A expenses for the full year 2018 were \$10.9 million, as compared to \$11.8 million in 2017. This decrease was due primarily to lower personnel, stock-based non-cash compensation and recruiting expenses, offset by higher expenses for professional fees, rent, insurance and other miscellaneous expenses.
- Litigation settlement gain for the year ended December 31, 2018 was \$2,700,000 which was recorded in the consolidated statements of comprehensive loss during the third quarter of 2018. This relates to the receipt of funds from the Company's insurance carrier in 2018 used to settle the Company's securities class action lawsuit which was accrued for in 2017.
- Total other income for the fourth quarter of 2018 was \$1.2 million, as compared to \$1.5 million in the same quarter the prior year, and, for the full year 2018, \$3.5 million as compared to \$2.4 million in 2017. This change was primarily attributed to higher income related to the change in the fair value of the stock option liabilities in 2018 than in 2017, and foreign exchange gains in 2018 as compared to foreign exchange losses in 2017.

- Net loss for the fourth quarter of 2018 was \$3.5 million, compared to a net loss of \$12.1 million for the same period in 2017. Net loss for full year 2018 was \$16.5 million, as compared to \$35.4 million for the prior year. This year over year decrease in net loss was due primarily to the aforementioned \$2.7 million litigation settlement gain, lower R&D expenses and change in fair value of the stock option and warrant liabilities, which were lower in 2018.
- As of December 31, 2018, the Company had cash of \$5.4 million, as compared to cash of \$28.1 million as of December 31, 2017. During the first quarter of 2019 the Company received a research and development cash tax credit of approximately \$4.9 million.
- On September 26, 2018, the Company entered into a securities purchase agreement (the “Purchase Agreement”) with Aspire Capital Fund, LLC (“Aspire Capital”), which provides that, upon the terms, Aspire Capital is committed to purchase up to an aggregate of \$20.0 million of the Company’s ADSs over the 30-month term of the Purchase Agreement. In consideration for entering into the Purchase Agreement, concurrently with the execution of the Purchase Agreement, the Company issued 30,000,000 ordinary shares to Aspire Capital and sold to Aspire Capital 25,000,000 ordinary shares for \$0.02 per share (equivalent to \$2.00 per ADS) for gross proceeds of \$500,000. Subsequently, in March 2019, the Company sold to Aspire Capital 5,000,000 ordinary shares to Aspire Capital 2019 at \$0.0346 per share (equivalent to \$3.46 per ADS) for gross proceeds of \$173,000. Currently, \$19.3 million remains available for draw drawn from this facility.

A copy of the Company’s Annual Report on Form 20-F for the year ended December 31, 2018 has been filed with the Securities and Exchange Commission and posted on the Company’s website at <http://investor.akarix.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 Chief Financial Officer of the Company at 75/76 Wimpole Street, London W1G 9RT, United Kingdom or by calling the Company at +44 20 8004 0261.

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 (Coversin), is a C5 complement inhibitor that also independently and specifically inhibits leukotriene B4 (LTB4) activity. Nomacopan (Coversin) 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 (Coversin) 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. 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 (Coversin) 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 (Coversin) 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 (Coversin) 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 (Coversin) may not be as large as expected; risks associated with the departure of our former Chief Executive Officers and other executive officers; 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, 2018</u>	<u>December 31, 2017</u>
Assets		
Current Assets:		
Cash	\$ 5,446,138	\$ 28,106,671
Prepaid expenses and other current assets	1,423,184	706,415
Deferred Financing Costs	585,000	-
Total Current Assets	<u>7,454,322</u>	<u>28,813,086</u>
Restricted cash	521,829	142,235
Property and equipment, net	20,425	55,898
Patent acquisition costs, net	32,978	39,124
Total Assets	<u>\$ 8,029,554</u>	<u>\$ 29,050,343</u>
Liabilities and Shareholders' Equity		
Current Liabilities:		
Accounts payable	\$ 1,586,285	\$ 1,971,161
Accrued expenses	1,489,558	4,795,873
Liabilities related to options and warrants	1,842,424	5,081,335
Total Current Liabilities	<u>4,918,267</u>	<u>11,848,369</u>
Other long-term liability	-	48,003
Total liabilities	<u>4,918,267</u>	<u>11,896,372</u>
Commitments and Contingencies		
Shareholders' Equity:		
Share capital of £0.01 par value		
Authorized: 10,000,000,000 and 5,000,000,000 ordinary shares; issued and outstanding: 1,580,693,413 and 1,525,693,393 at December 31, 2018 and 2017, respectively	23,651,277	22,927,534
Additional paid-in capital	106,616,083	104,799,550
Accumulated other comprehensive loss	(352,426)	(236,246)
Accumulated deficit	(126,803,647)	(110,336,867)
Total Shareholders' Equity	<u>3,111,287</u>	<u>17,153,971</u>
Total Liabilities and Shareholders' Equity	<u>\$ 8,029,554</u>	<u>\$ 29,050,343</u>

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

	Twelve Months Ended		Three Months Ended	
	Dec 31, 2018	Dec 31, 2017	Dec 31, 2018	Dec 31, 2017
Operating Expenses:				
Research and development costs	\$ 11,795,376	\$ 23,285,279	\$ 2,362,358	\$ 7,117,853
General and administrative expenses	10,896,158	11,798,910	2,370,206	3,792,813
Litigation settlement gain	(2,700,000)	2,700,000	-	2,700,000
Total Operating Expenses	19,991,534	37,784,189	4,732,564	13,610,666
Loss from Operations	(19,991,534)	(37,784,189)	(4,732,564)	(13,610,666)
Other Income (Expense):				
Interest income	222,256	175,393	24,110	51,036
Changes in fair value of option and warrant liabilities - gain	3,238,911	2,581,473	1,161,783	1,571,468
Foreign currency exchange gain (loss)	81,501	(358,540)	39,020	(127,213)
Other expenses	(17,914)	(13,394)	(5,103)	(2,779)
Total Other Income (Expenses)	3,524,754	2,384,932	1,219,810	1,492,512
Net Loss	(16,466,780)	(35,399,257)	(3,512,754)	(12,118,154)
Foreign Currency Translation Adjustment	(116,180)	43,851	(55,943)	52,153
Comprehensive Loss	\$ (16,582,960)	\$ (35,355,406)	\$ (3,568,697)	\$ (12,066,001)
Loss per ordinary share (basic and diluted)	\$ (0.01)	\$ (0.03)	\$ (0.00)	\$ (0.01)
Weighted average ordinary shares (basic and diluted)	1,540,309,840	1,247,293,388	1,580,693,413	1,453,823,828

For more information

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