
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

November 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
(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

Akari Therapeutics, Plc (the “Company”) is attaching to this Report on Form 6-K a press release with revised third quarter 2019 financial results to reflect liability treatment of the warrants issued in connection with the July 3, 2019 registered direct offering, as well as the related fair market valuation as of September 30, 2019. The warrants were previously reflected using equity treatment in the Company’s press release dated November 4, 2019. There is no impact on net cash or operating expenses. A copy of the revised press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

The information contained in the statements under “Third Quarter 2019 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 Revised Press Release dated November 27, 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
Chief Executive Officer and Chief Operating Officer

Date: November 27, 2019

Akari Therapeutics Reports Revised Third Quarter 2019 Financial Results And Highlights Recent Clinical Progress

- *New data demonstrate dual role of C5 and LTB4 in both bullous pemphigoid (BP) and atopic keratoconjunctivitis (AKC). There are no U.S. Food and Drug Administration (FDA)-approved treatments for either disease.*
- *Clinical progress across our target conditions*
 - o *Phase II BP data demonstrated 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 in patients with moderate BP*
 - o *Part A of AKC Phase I/II study completed with a rapid mean 55% improvement in the composite clinical score at day 56*
- *Continued advancement of clinical programs*
 - o *Pivotal clinical trial for pediatric hematopoietic stem cell transplant-related thrombotic microangiopathy (HSCT-TMA) expected to start Q4 2019*
 - o *Fast Track designation for HSCT-TMA and orphan drug designation for BP and HSCT-TMA granted by the FDA*
- *Over 20 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, November 27, 2019 - 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 revised financial results for the third quarter ended September 30, 2019 and recent clinical progress.

“We are excited about the positive clinical data we are accumulating in patients treated with nomacopan across our target rare disease indications. The rapid and sustained clinical improvement combined with the positive long-term safety profile we have observed in patients, helps to offer further validation of nomacopan’s unique method of action as an inhibitor of both the complement and leukotriene pathways,” said Clive Richardson, Chief Executive Officer of Akari Therapeutics. “We look forward to further progress across both our topical and subcutaneous clinical programs in 2020 as we look to drive nomacopan through the clinic and towards helping patients afflicted by these rare and debilitating inflammatory conditions. In addition, we seek to partner those programs in which a joint development approach can produce a faster outcome.”

Third Quarter 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.

Further evidence for potential therapeutic benefits of inhibition of C5 and LTB4 by nomacopan

In the last three months, the Company has announced preclinical data in both BP and AKC demonstrating the likely combined role of C5 and LTB4 in these two severe inflammatory conditions:

- § In BP, an orphan condition with no approved treatment, the Company announced new data demonstrating synergistic benefits of nomacopan's dual C5 and LTB4 inhibitory activity. This new study was undertaken by Dr. Christian Sadik's team at University of Lubeck, Germany. These data were published in the August 2019 edition of JCI Insight [link].
- § In AKC, a surface of the eye disease with no approved treatment, the Company announced new data from the conjunctival tissue of patients showing for the first time the presence of both the C5a receptor and the leukotriene LTB4 receptor on the conjunctival surface of the eye.

Pediatric HSCT-TMA

- § A pivotal trial for HSCT-TMA with nomacopan is expected to start in the fourth quarter of 2019. This devastating condition has an estimated 80% mortality rate in children and has no approved treatments. In August 2019, the FDA granted Fast Track designation to nomacopan for the treatment of HSCT-TMA as well as orphan drug designation for treatment of pediatric patients.

Phase II clinical trial in patients with BP

- § Phase II trial results with nomacopan were presented at the 28th European Academy of Dermatology and Venereology (EADV) Congress on October 10, 2019. 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 Bullous Pemphigoid Disease Area Index (BPDAI) score and mean 68% decline in blister score by day 42, with either no or minimal early steroid treatment. The data showed nomacopan's potential as monotherapy with the additional potential benefit of reducing steroid use which has multiple adverse effects.
- § During the third quarter of 2019, the FDA granted orphan drug designation for nomacopan for the treatment of BP. The company is now exploring pivotal trial designs.

Phase I/II clinical trial in patients with AKC

- § 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. Enrollment in the Part B placebo-controlled efficacy arm of the study in 16 patients continues, with a data read out expected in the first quarter of 2020.

Paroxysmal nocturnal hemoglobinuria (PNH) program

- § The Company continues to accumulate positive long-term treatment data, which includes over 20 cumulative patient-years of data with no reported drug related serious adverse events. Our ongoing Phase III PNH study in naïve patients is expected to have an interim data readout in mid 2020 with the next stage subject to our pen injector program which aims to hold one week's supply of nomacopan stable at room temperature with a daily 0.3ml injection.

Third Quarter 2019 Financial Results

The following selected financial data has been revised to reflect liability treatment of the warrants issued in connection with the July 3, 2019 registered direct offering, as well as the related fair market valuation as of September 30, 2019. The warrants were previously reflected using equity treatment in the company's press release dated November 4, 2019. There is no impact on net cash or operating expenses.

- § As of September 30, 2019, the Company had cash of \$6.3 million. In addition, the Company received in October 2019 \$2.9 million in research and development tax credits from the UK tax authorities. This compares to cash of \$5.4 million as of December 31, 2018.

- § During the third quarter of 2019, the Company sold to Aspire Capital Fund, LLC (Aspire Capital) a total of \$4.6 million of ordinary shares. As of September 30, 2019, approximately \$13.4 million of the original \$20 million remains available for draw down under the equity purchase agreement entered into with Aspire Capital.
- § Research and development (R&D) expenses in the third quarter of 2019 were \$1.8 million, as compared to R&D expenses of \$3.3 million in the same quarter the prior year. This decrease was primarily due to the recognition of the aforementioned R&D tax credit of \$2.9 million in the third quarter of 2019, proceeds of which were received in October 2019.
- § General and administrative (G&A) expenses in the third quarter of 2019 were \$1.4 million, as compared to \$2.4 million in the same quarter last year. This decrease was primarily due to lower expenses associated with professional fees and rent.
- § Total other income for the third quarter of 2019 was \$0.6 million, as compared to total other expense of \$0.6 million in the same period the prior year.
- § Net loss for the third quarter of 2019 was \$2.6 million, compared to a net loss of \$3.6 million for the same period in 2018. The decrease in net loss in the third quarter of 2019 was due primarily to lower net R&D and G&A expenses, as well as change in the fair value of the option liabilities, offset by the one-time litigation settlement gain that was recorded in the third quarter of 2018.

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 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

CONDENSED CONSOLIDATED BALANCE SHEETS

As of September 30, 2019 and December 31, 2018

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

	<u>September 30,</u> <u>2019</u>	<u>December 31,</u> <u>2018</u>
	<u>(Unaudited)</u>	
Assets		
Current Assets:		
Cash	\$ 6,268,667	\$ 5,446,138
Tax Credit Receivable	2,902,987	-
Prepaid expenses and other current assets	1,058,527	1,423,184
Deferred financing costs	402,042	585,000
Total Current Assets	<u>10,632,223</u>	<u>7,454,322</u>
Restricted cash	-	521,829
Property and equipment, net	8,388	20,425
Patent acquisition costs, net	29,147	32,978
Total Assets	<u>\$ 10,669,758</u>	<u>\$ 8,029,554</u>
Liabilities and Shareholders' Equity		
Current Liabilities:		
Accounts payable	\$ 1,315,411	\$ 1,586,285
Accrued expenses	3,035,056	1,489,558
Liability related to options and warrants	3,068,834	1,842,424
Total Liabilities	<u>7,419,301</u>	<u>4,918,267</u>
Shareholders' Equity:		
Share capital of £0.01 par value		
Authorized: 10,000,000,000 ordinary shares; issued and outstanding: 2,100,865,913 and 1,580,693,413 at September 30, 2019 and December 31, 2018, respectively	30,123,701	23,651,277
Additional paid-in capital	109,560,217	106,616,083
Accumulated other comprehensive loss	(402,093)	(352,426)
Accumulated deficit	(136,031,368)	(126,803,647)
Total Shareholders' Equity	<u>3,250,457</u>	<u>3,111,287</u>
Total Liabilities and Shareholders' Equity	<u>\$ 10,669,758</u>	<u>\$ 8,029,554</u>

AKARI THERAPEUTICS, Plc

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS - UNAUDITED

For the Three and Nine Months Ended September 30, 2019 and September 30, 2018

(in U.S. Dollars)

	Three Months Ended		Nine Months Ended	
	September 30,	September 30,	September 30,	September 30,
	2019	2018	2019	2018
Operating Expenses:				
Research and development expenses	\$ 1,763,057	\$ 3,303,790	\$ 3,038,038	\$ 9,433,018
General and administrative expenses	1,354,263	2,382,153	6,098,767	8,537,191
Litigation settlement gain	-	(2,700,000)	-	(2,700,000)
Total Operating Expenses	3,117,320	2,985,943	9,136,805	15,270,209
Loss from Operations	(3,117,320)	(2,985,943)	(9,136,805)	(15,270,209)
Other Income (Expenses):				
Interest income	2,057	66,073	3,792	198,146
Changes in fair value of option and warrant liabilities – gain/(loss)	515,489	(715,846)	(12,594)	2,077,128
Foreign currency exchange gains (losses)	37,209	36,036	(71,989)	42,481
Other expenses	(2,788)	6,425	(10,124)	(1,572)
Total Other Income (Expenses)	551,967	(607,312)	(90,915)	2,316,183
Net Loss	(2,565,353)	(3,593,255)	(9,227,720)	(12,954,026)
Other Comprehensive (Loss) Income:				
Foreign Currency Translation Adjustment	3,281	(65,848)	(49,667)	(60,237)
Comprehensive Loss	\$ (2,562,072)	\$ (3,659,103)	\$ (9,277,387)	\$ (13,014,263)
Loss per ordinary share (basic and diluted)	\$ (0.00)	\$ (0.00)	\$ (0.01)	\$ (0.01)
Weighted average ordinary shares outstanding (basic and diluted)	1,971,025,222	1,528,682,540	1,721,098,272	1,526,700,724

For more information

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