#### 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

October 2018

Commission file number: 001-36288

<u>Akari Therapeutics, Plc</u> (Translation of registrant's name into English)

24 West 40<sup>th</sup> Street, 8<sup>th</sup> Floor New York, NY 10018 (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 October 1, 2018, Akari Therapeutics, Plc updated its corporate presentation that it intends to use in conferences and meetings with investors. A copy of the presentation is furnished with this Report of Foreign Private Issuer on Form 6-K as Exhibit 99.1 and is incorporated herein by reference.

#### Exhibit No.

99.1 Corporate Presentation of Akari Therapeutics, Plc dated October 2018.

#### **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.

<u>Akari Therapeutics, Plc</u> (Registrant)

By: /s/ Clive Richardson

Name: Clive Richardson Interim Chief Executive Officer and Chief Operating Officer

Date: October 1, 2018



### **Investor Presentation**

October 2018

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## Disclaimers

Certain statements in this presentation constitute contains "forward-looking" statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. 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 forwardlooking 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 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 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 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 Coversin may not be as large as expected; risks associate with the departure of our former Chief Executive Officers and other executive officers; risks related to material weaknesses in our internal controls over financial reporting and risks relating to the ineffectiveness of our disclosure controls and procedures; risks associated with the putative shareholder class action and 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 on July 18, 2018. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof.

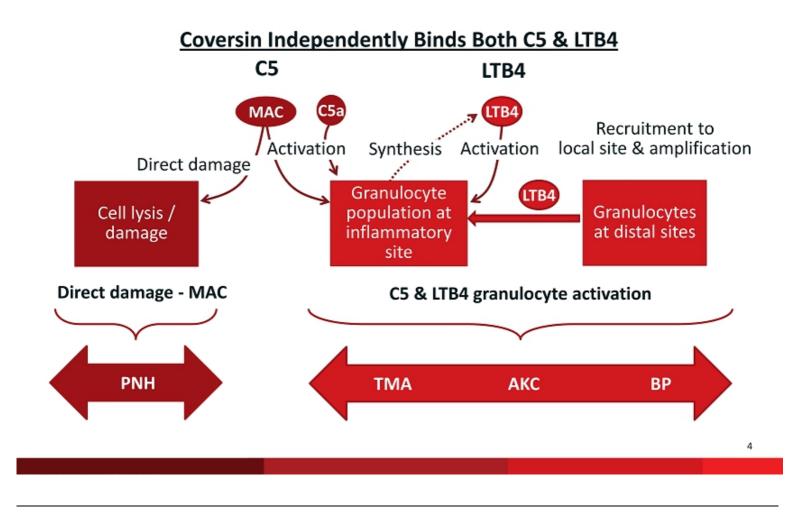
The statements made in this presentation speak only as of the date stated herein, and subsequent events and developments may cause our expectations and beliefs to change. Unless otherwise required by applicable securities laws, we do not intend, nor do we undertake any obligation, to update or revise any forward-looking statements contained in this presentation to reflect subsequent information, events, results or circumstances or otherwise. While we may elect to update these forward-looking statements publicly at some point in the future, we specifically disclaim any obligation to do so, whether as a result of new information, future events or otherwise, except as required by law.

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## Akari Overview

- Creating drugs for acute and chronic orphan inflammatory diseases by modulating complement/C5 <u>and</u> leukotriene/LTB4 pathways
- Lead drug Coversin has unique dual MOA in both C5 & LTB4
- Diversified portfolio : four target orphan inflammatory diseases
  - Bullous pemphigoid (BP)
  - Atopic keratoconjunctivitis (AKC)
  - Severe thrombotic microangiopathy (TMA)
  - Paroxysmal nocturnal haemoglobinuria (PNH)
- Advancing clinical development
  - One Phase I/II, two phase II, and one Phase III clinical trial ongoing
  - AKC and BP initial readout in Q1 2019
- Ongoing development program prioritization
  - Potential to partner one or more active clinical programs
  - Active C5/LTB4 pipeline development for additional indications

## **Coversin: Synchronous C5 and LTB4 Inhibition**



## Growing Clinical Data Set Supports Coversin Development for Range of Inflammatory Conditions

#### Positive safety profile

- Eleven patients on ongoing or completed treatment for between 2 and 32 months; cumulative total of over 13 patient years of treatment
- No SAEs related to Coversin and no neutralizing antibodies

#### Proven C5 binding across disease categories

- Met PNH Phase II primary efficacy reduction in LDH ≤ 1.8X ULN at day 28
- CH50 below limit of quantification (from day 1) in PNH and TMA patients

5

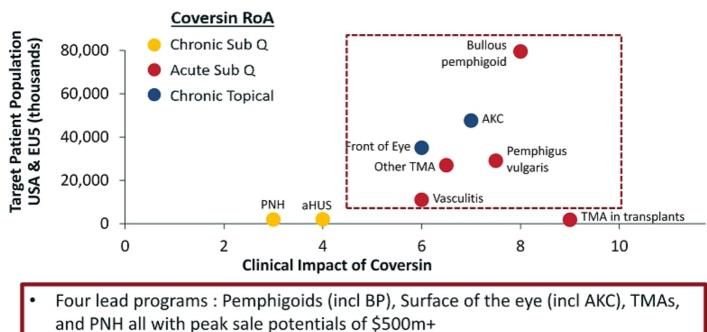
- Resolution of a wide range of clinical markers in TMA patients

#### Proven LTB4 binding in wide range of models

Inhibits LTB4 induced human neutrophil migration

#### ✓ Patients successfully self administering by daily subcutaneous injection

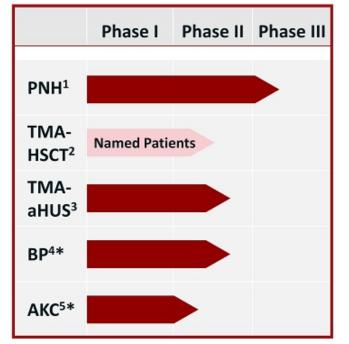
# Focused on Orphan Inflammatory Indications with High Unmet Need



- and Finn all with peak sale potentials of \$50011+
- Most disease target conditions have no approved treatment
- Smaller diseases such as HSCT TMA provide potential gateway into other TMAs

Source: CSM Consulting, LEK

### Portfolio Builds on Coversin PNH Clinical Results Focus on Maximizing Return on Capital

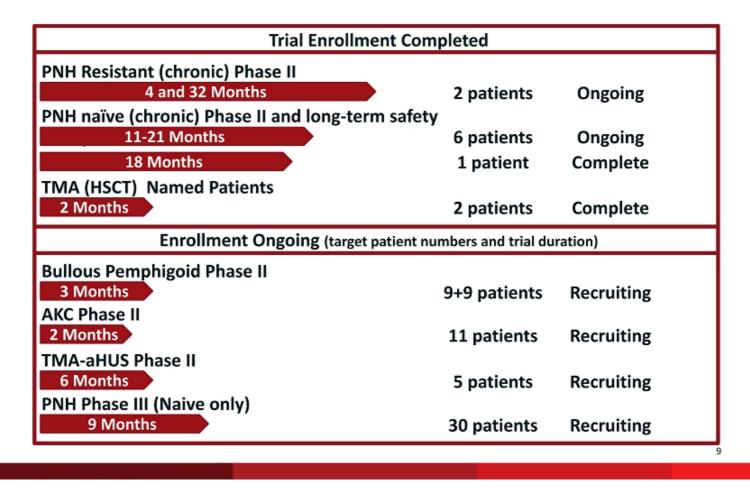


- Initial PNH Phase II and recent TMA patient data provided clinical, safety and dosing validation for Coversin
- \$20m equity facility from Aspire focused on extending Akari's financial runway through completion of ongoing Phase II trials in TMA, BP, and AKC
- Exploring external partnering program in parallel to internal funding

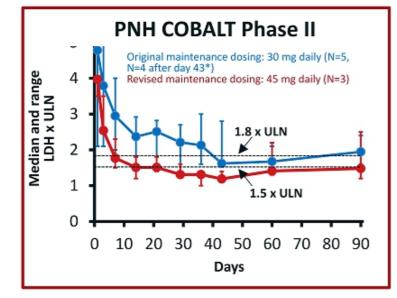
PNH: Paroxysmal nocturnal hemoglobinuria; 2. TMA: Thrombotic Microangiopathy; HSCT Hematopoietic stem cell transplant
 aHUS: Atypical hemolytic-uremic syndrome; 4. BP: Bullous Pemphigoid; 5. AKC: Atopic keratoconjunctivitis; \* Dual action MOA: C5 & LTB4
 7

# **Clinical Data**

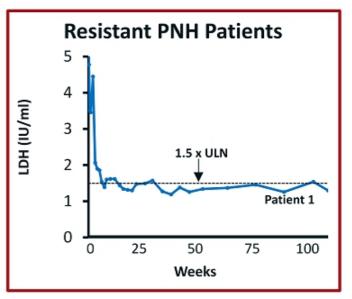
## Patients Being Treated With Coversin Across Four Primary/Lead Indications



# C5 Inhibition Demonstrated in PNH patients treated with Coversin



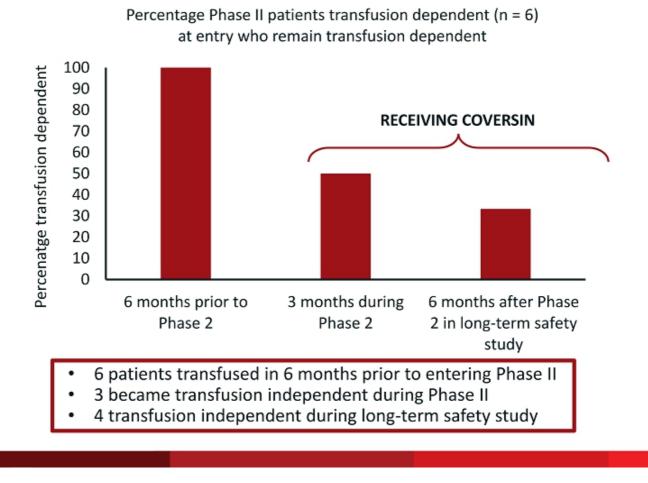
- Naïve patients treated for 90 days
- All completing patients entered long term safety study
- No drug related SAE



- Two patients with C5 polymorphisms resulting in treatment resistance to Eculizumab
- First patient treated for 32 months (graph above)
- Second patient treated for 4 months LDH 1.4X ULN at day 90

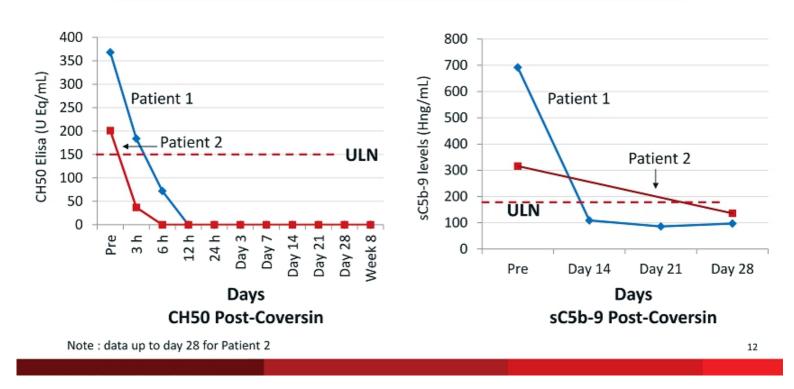
Note : LDH x ULN Day 28 : 1.4, 2.2, 2.3, 1.3, 1.4, 2.7, 1.6, 1.3 :Day 60 : 1.5, 2.1, 1.8, 2.2, 1.5, 1.4, 1.3 Day 90 : 1.6, 2.4, 2.0, 2.5, 1.9, 1.5, 1.2 - \*Patient withdrawn with suspected co-morbidity unrelated to treatment

## Phase II PNH Clinical Endpoint 67% Decline in Transfusion Dependence



#### Pediatric TMA: Post-Bone Marrow Transplant Complement Inhibition demonstrated with Coversin

Complete and rapid C5 inhibition as seen in PNH patients Pediatric dosing regime effective



## Coversin Activity Demonstrated in HSCT–TMA Across a Range of Outcome Measures (2 Patients)

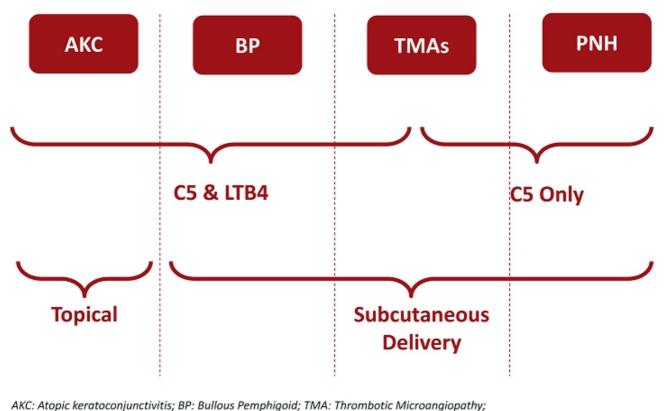
TMA Marker	Patient	Baseline	Day 7	Day 14	Day 28	Day 60
Hemolytic anaemia	1	Yes			<b>├</b> ───→	Resolved
	2	No				
Red blood cell	1	Yes			<b>├</b>	Resolved
fragments	2	Yes —		<b>├</b>	Resolved	
Thrombocytopenia	1	Yes			<b>├</b> ──→	Resolved
	2	Yes —		Resolved		
Increased LDH	1	Yes —			Resolved	
	2	Yes —		Resolved		
Proteinuria and/or	1	Yes —			Resolved	
increased creatinine	2	Yes				→ N/A
Hypertension	1	Yes —			<b>├</b> ───→	Resolved
	2	Yes —		Resolved		
Neurology	1	Yes —		Resolved		
	2	No				
GI bleed	1	No				
	2	Yes			Resolved	

Patient 1 : treated at GOSH made a complete recovery and Coversin was discontinued after seven weeks.

Patient 2 : despite resolution of the TMA markers, patient died at day 63 of lung damage considered unrelated to treatment with Coversin. Note - data for patient 2 is up to day 28

# **Clinical Programs**

## Clinical Programs focused on C5 & C5/LTB4 Targets And Both SQ and Topical Delivery

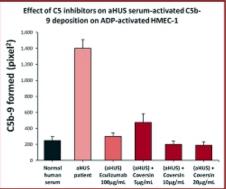


PNH: Paroxysmal nocturnal hemoglobinuria

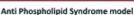
## Thrombotic Microangiopathies (TMA) Several Diseases With Unmet Need

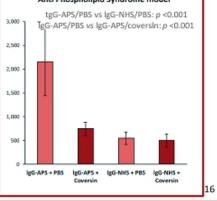
- Thrombotic Microangiopathies
  - Range of orphan disease, in most cases no approved therapy
  - Numerous conditions considered complement driven with LTB4 implicated in several
- Atypical hemolytic-uremic syndrome (aHUS)
   Ongoing Phase II program in naïve patients
- Hematopoietic stem cell transplant (HSCT TMA)
  - Named patient program; 2 patients to date
  - Gateway condition
- Other TMAs
  - Preclinical data in anti-phospholipid syndrome
  - Potential for treatment with Coversin

#### aHUS – *ex vivo* endothelial cell surface model



#### Antiphospholipid model area of induced thrombi





## Thrombotic Microangiopathy (TMA) After Transplant: Significant Unmet Need

- Orphan condition in which there is evidence that both terminal complement activation and possibly LTB4 have a role in driving disease
- Complications following bone marrow transplantation (BMT) in up to 30% of patients
- In severe cases, mortality in excess of 80%
- Use of eculizumab in TMA, post bone marrow transplant appears to offer better outcomes compared to SoC
- Coversin used on a named patient basis for Pediatric HSCT-TMA

#### TMA offers opportunity to expand into related conditions



## **Bullous Pemphigoid (BP)**

- Orphan condition in which there is evidence that both terminal complement activation (C5) and LTB4 have a role in driving disease
- TPP moderate to severe patients, newly presenting or relapsing
- Other biologicals with different MOA are also in Phase II development for BP (e.g. – Taltz<sup>®</sup> (anti-IL17a) and Bertillumab<sup>®</sup> (anti-eotaxin))
- · Focus of biologicals is steroid sparing and rapid reduction symptoms
- Elevated C5/LTB4 in ex-vivo study of BP patients

#### BP offers opportunity to expand into related conditions



# Bullous Pemphigoid Phase II Trial Design in Patients with Mild-to-Moderate Disease

- Trial approved Netherlands (2 sites) and expected soon in Germany (6 sites)
- · Amendment planned to increase trial size with 9 additional moderate-severe patients

#### Study design

- Phase II Open label single arm (n = 9); 42 days treatment
- Test role of C5 & LTB4 dual inhibition in improving BP outcomes
- Active; newly diagnosed or recurrent, mild to moderate treated with topical mometasone

#### Treatment

- Coversin
- <u>Day 1</u>: 60 mg and 30 mg 12 hours later, <u>Day 2-42</u>: 30 mg od

**Primary endpoint** 

Safety

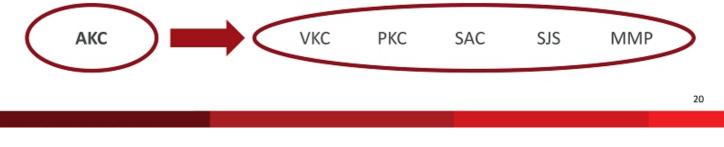
#### Secondary endpoints

Efficacy evaluated by BPDAI (BP disease activity index) and QoL at day 42

## Atopic Keratoconjunctivitis (AKC)

- Severe eye surface inflammation causing infiltration of immune cells (neutrophils & T cells) – a major cause of blindness
- Topical drugs, such as steroids or cyclosporin, often not effective or cannot be given chronically
- · Progresses to affect cornea; may lead to vision loss
- Both complement and LTB4 known to be involved
- Preclinical model demonstrated greater inflammatory reduction than typically achieved by cyclosporin

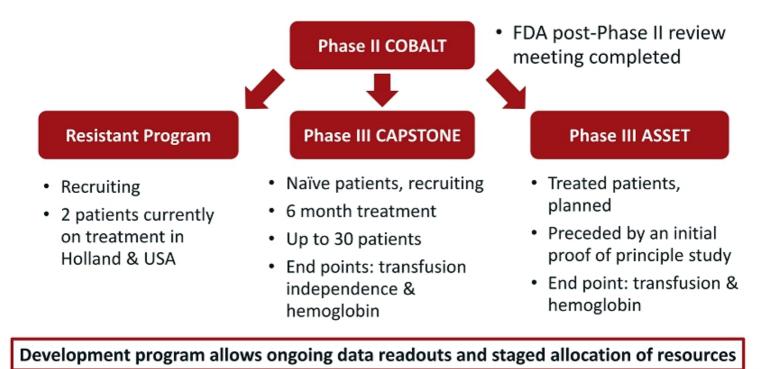
#### AKC offers opportunity to expand into related conditions



## Planned AKC Phase I/II Proof-of-Principle Trial Design

<ul> <li>Study design</li> <li>Phase I/II randomized, double blind, placebo-controlled, safety and dose finding study – 11 active 8 placebo</li> </ul>					
<ul> <li>Treatment</li> <li>Coversin topical eye drops three times daily for 2 months <ul> <li>High (0.25%), medium (0.125%) and low (0.063%) doses</li> </ul> </li> <li>Placebo eye drops</li> </ul>					
Primary endpoint	Secondary endpoints				
<ul> <li>Safety, comfort</li> </ul>	<ul> <li>Clinical signs and symptoms</li> <li>Reduction in inflammatory markers (MMP-9)</li> <li>Cytology</li> </ul>				

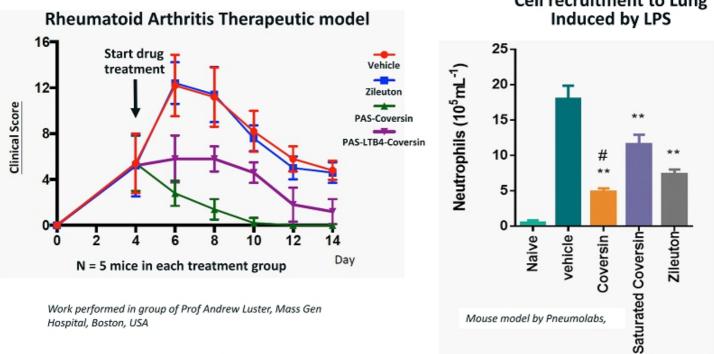
## PNH Clinical Programs: Staged Phase III Commitment Focus on PNH Patient Convenience



Focus on patient convenience : SQ, highly soluble, stable at room temp, New formulation in development for Auto injector pen with 1 week dosing

## **Expanding Pipeline Focused on Indications** Where C5 and LTB4 Both Involved





## Cell recruitment to Lung

# Akari Summary

- Unique mode of action inhibiting both C5 and LTB4
- Diversified pipeline :
  - AKC and BP initial readouts Q1 2019
  - TMAs ongoing readouts in aHUS and TMA post HSCT H1 2019
  - PNH staged readouts in 2019
  - Preclinical ongoing programs in lung, RA, trauma
- \$20 million financing facility with Aspire Capital
- \$15 million in cash at June 30, 2018



## **Investor Presentation**

October 2018

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