#### 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

July 12, 2016

Commission file number: 001-36288

Akari Therapeutics, Plc (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)

(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 has posted an updated investor presentation to its website. 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.

#### **Cautionary Note Regarding Forward-Looking Statements**

The presentation attached hereto as Exhibit 99.1 may contain forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995 and other Federal securities laws. 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: an inability or delay in obtaining required regulatory approvals for Coversin and any other product candidates, which may result in unexpected cost expenditures; 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; 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; 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; our inability to obtain additional capital on acceptable terms, or at all; unexpected cost increases and pricing pressures; uncertainties of cash flows and inability to meet working capital needs; and risks and other risk factors detailed in our public filings with the U.S. Securities and Exchange Commission, including our Annual Report on Form 10-K filed on March 23, 2016. Except as otherwise noted, these forward-looking statements speak only as of the date of the presentation and we undertake no obligation to update or revise any of these statements to reflect events or circumstances occurring after this presentation. We caution investors not to place considerable reliance on the forward-looking statements contained in this presentation.

#### Exhibit No.

99.1 Investor Presentation dated July 2016 of Akari Therapeutics, Plc.

#### **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/ Gur Roshwalb Name: Gur Roshwalb Chief Executive Officer

Date: July 12, 2016



NASDAQ: AKTX

July 2016



# **Cautionary Note Regarding Forward-Looking Statements**



Certain statements in this presentation constitute "forward-looking statements" within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act and are usually identified by the use of words such as "anticipates," "believes," "estimates," "expects," "intends," "may," "plans," "projects," "seeks," "should," "will," and variations of such words or similar expressions. We intend these forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act and Section 21E of the Securities Exchange Act and are making this statement for purposes of complying with those safe harbor provisions. 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. Risks and uncertainties for our company include, but are not limited to: an inability or delay in obtaining required regulatory approvals for Coversin and any other product candidates, which may result in unexpected cost expenditures; 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; 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 products; 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 or other product candidates may not be as large as expected; 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; unexpected cost increases and pricing pressures; and uncertainty of our ability to raise capital and our inability to meet working capital needs. Many of these factors that will determine actual results are beyond our ability to control or predict. For a discussion of the factors that may cause our actual results, performance or achievements to differ materially from any future results, performance or achievements expressed or implied in such forward-looking statements, see the "Risk Factors" section of our most recently filed 10K. 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 press release 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 news release 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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## Coversin: An Evolution in Complement Treatment



#### Definitive Proof of Concept

- Phase 2 PNH patient in successful ongoing treatment—5 months +
- · Significant reduction in LDH and full complement inhibition
- Proven predicate biology
- No placebo effect

#### Competitive Advantages

- Once daily, self-administered, subcutaneous injection- no ISRs
- Once-weekly version in development
- LTB4-independent inhibition may reduce thrombotic risk
- Smaller increased tissue penetration and organ specific therapy

# Expanding Opportunities

- Prioritizing PNH and aHUS \$2.6 billion in 2015 sales
- Unique C5/LTB4 targeting new market opportunities supported by pre-clinical data

#### Driving Value

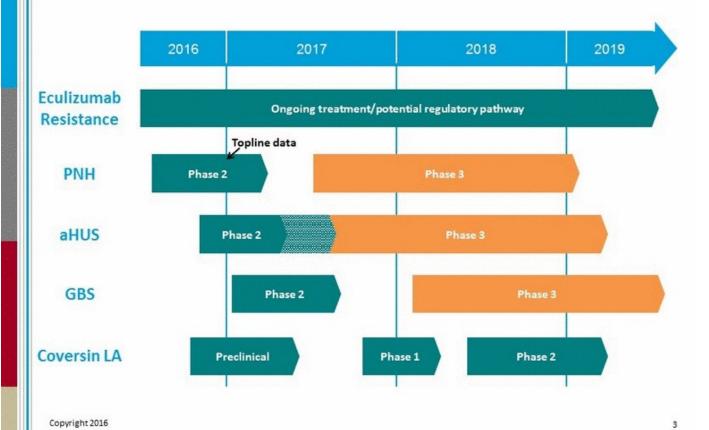
- PNH: Phase 2 top line data expected YE 2016, Phase 3 mid-2017
- aHUS: Phase 2 initiation 4Q 2016GBS: Phase 2 initiation 1Q 2017

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# **Clinical Timeline**







# Coversin Nature's Complement Inhibitor



#### **Natural Origins and Development**

- Coversin discovered by Miles Nunn (CSO) in saliva of Ornithodoros moubata tick
- Dampened host immune response allows tick to repeatedly feed without damage from inflammatory substances (300 million years of natural development)
- · Clinical & scientific data emphasizes natural origins
  - Tight independent binding to C5 & LTB4
  - No toxicity signals to date
  - No neutralizing antibodies seen to date

#### **Modern Production**

- Coversin successfully produced in E. coli
- Clinical manufacturing at a leading CMO
- Scale up in 4Q 2016

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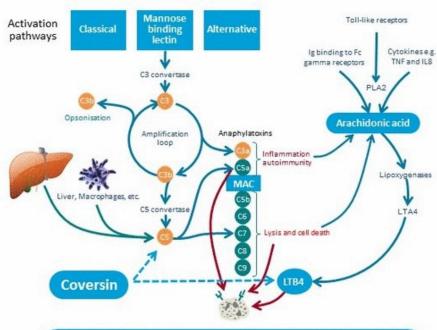


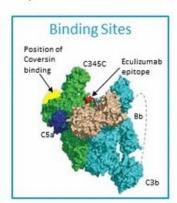
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# **Coversin Active in Range of Diseases**

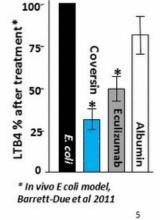
Inhibits C5 – Proven Complement Target Additional LTB4 Anti-inflammatory Activity







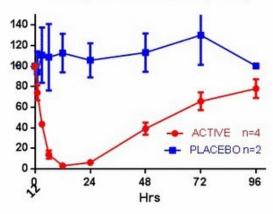
C5a, LTB4 and MAC act jointly on granulocytes, leukocytes and many other immune and tissue cell types - potentially causing inflammation and damage. Activity demonstrated in a range of diseases in animal models



# Single Dose Phase Ia Clinical Trial Demonstrated Full C5 Inhibition



#### 0.57mg/kg Change from baseline (mean)



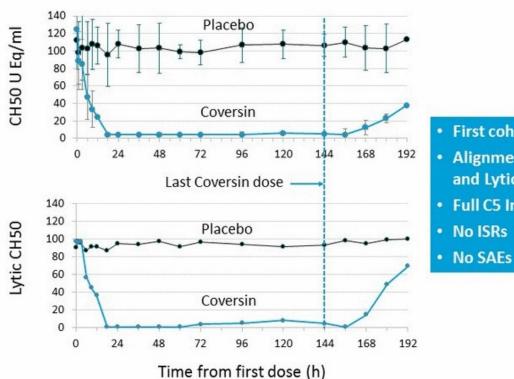
At 3 - 72 hrs p<0.001

- Full complement ablation within 12 hours at 0.57 mg/kg
- Inhibition maintained for 24 hours after single dose
- Good safety profile: no SAEs or injection site reactions
- · 24 normal volunteer subjects (16 active, 8 placebo)
- Only highest dosing cohort (n=6) had CH50 testing done through full 96 hour period
- · Single subcutaneous dose at time 0



# Phase 1b: Full C5 Inhibition in 24 Hours and **Once-Daily** Maintenance Dosing





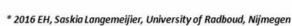
- First cohort (30mg)
- Alignment of Elisa and Lytic results
- Full C5 Inhibition

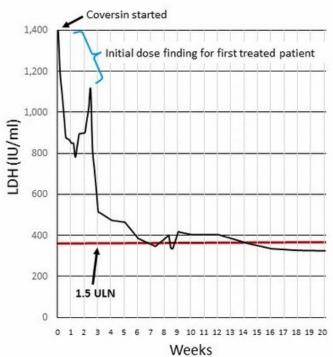


# Positive Ongoing Results In Phase 2 Trial in PNH Patient



- Eculizumab-resistant PNH patient treated since Feb 2016
  - Continues to self-inject
- · Patient has demonstrated:
  - Full complement inhibition (CH50)
  - LDH reduction <1.5X upper limit of normal (ULN)
- "Coversin has proven safe and effective in the first PNH patient treated"\*



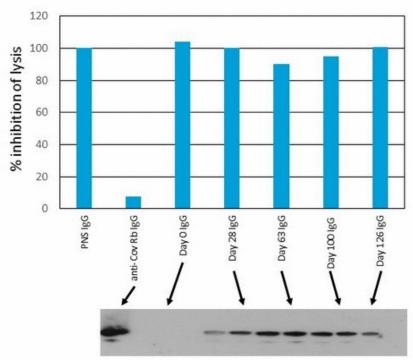


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# Successful Phase 2 Trial in PNH Patient No Neutralizing Antibodies to Date





#### Immunoblot: anti-Cov Rb serum 1:4000; Dutch patient serum 1:200

#### No Neutralizing Antibodies After 4 Months

- Purified IgG from Dutch patient (over 4 months)
- No effect on Coversin C5 inhibition
- Antibody response peak approximately 9 weeks after initial dosing and declines

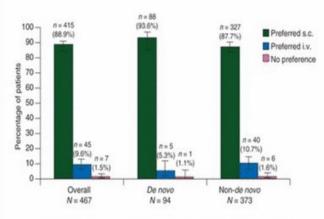
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# Patient Groups Indicate Clear Preference For Subcutaneous Over IV Delivery



#### Study of IV vs SQ Trastuzumab Strong preference for SubQ



"All things considered, which method of administration did you prefer?"

Pivot X. et al. Ann Oncol 2014;25:1979-1987

# Coversin-PNH/aHUS Subcutanous Preference

- Feedback from PNH/aHUS patient groups and KOLs consistently highlights preference for selfadministration
- Coversin small injection volume (< 0.5ml), no ISR</li>
- Auto injector pen planned for commercialisation



## PNH Phase 2 Data Expected By YE 2016



#### 2016 Phase 2

- Leading PNH treatment centers in EU: Leeds & London, UK and Nijmegen, NL
- · Open label trial in patients with PNH
- · Primary efficacy endpoint: LDH at 28 days
- Secondary efficacy endpoints: Hgb, transfusions, hemoglobinuria and QOL

### 2017 Phase 3

- Trial initiation expected summer 2017
- · Working with broad network of leading PNH centres
- Undergoing scientific advice with EMA & FDA



## Developing Once-Weekly Formulation Coversin LA



# Plasma half-life extended > 50X (mouse model)

# 2500 — OmCI — PAS-OmCI — PAS-OmCI — PAS-OmCI — PAS-OmCI — Time post-injection

PK of Coversin and Coversin LA in blood of BALB/c mice post intravenous injection

# Coversin LA fully active (mouse model)

- · Increases MW from 17 to 47kda
  - Effective MW of ~500kda
- Remains fully active; increased C5 binding
- · Highly soluble and fully bioavailable
- · Expected timing
  - 3Q 2016 PK and toxicity studies
  - 2H 2017 Phase 1 POC clinical study



# aHUS Phase 2 Trial Expected Q4 2016



Complement-mediated hemolytic uremic syndrome (aHUS)

Chronic and life-threatening genetic disease characterized by microangiopathic hemolytic anemia, thrombocytopenia, and kidney injury

2016 Phase 2

- Open label clinical trial planned for Q4 2016 in EU
- · Clinical centers identified

2017 Phase 3

- Currently projected clinical protocol allows direct progression into Phase 3 trial
- Expected continuation by mid-2017
- · Approximately 30 total patients



# **GBS Phase 2 Trial Expected 1Q 2017**



#### Guillain Barré syndrome (GBS)

Immune-mediated polyneuropathy leading to destruction of myelin sheath GBS patients: 2–12% die; 10–35% have permanent impairment Growing worldwide annual incidence (15K in US/EU) + Zika-driven increases

2017 Phase 2

- · Attractive clinical trial duration: 28 days + 6 month follow up
- · Primary endpoint: improvement in GBS Disability Rating Scale
- 1 point = difference between wheelchair-bound or ambulatory
- · Sites and lead investigator identified



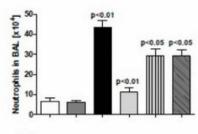
# Coversin: C5 + LTB4 Combination Targeting

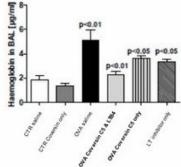


## **Emerging Differentiation**

#### Complex-mediated acute lung injury model

Significant decline in inflammation markers Complement and LTB4 - equal & additive roles





Roversi P et al. J Biol Chem 288: 18789; 2013

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#### LTB4 Binding Adds to Coversin

- Existing LTB4 long term treatment inhibition with Zileuton\* (small molecule approved in EU)
- · LTB4 acts as signal relay molecule
- Coversin LTB4 binding may reduce non-complement-mediated recruitment & activation of granulocytes and platelets to sites of inflammation and thrombosis
- LTB4 plays a role is neutrophil attraction in thrombosis

<sup>\*</sup> Removed from US due to off target effects



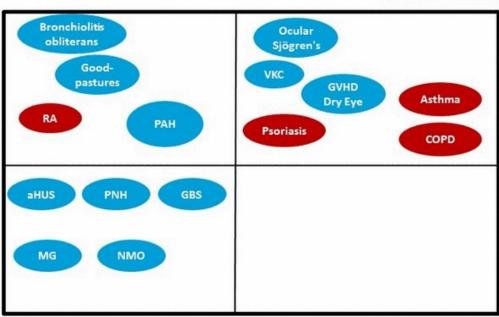
# Dual C5/LTB4 Activity May Lead To Enhanced Market Opportunities





Complement & LTB4

Primarily Complement



Systemic

Local

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\*Coversin activity demonstrated in over 10 animal models



# **Financial Summary**



• \$75m PIPE September 2015

ADS outstanding 11,776,934

ADS Fully Diluted 12,667,441

Cash as of March 31 \$56m (no debt)

Funding through Early 2018



## Proven Management Team



Ray Prudo MD **Executive Chairman** 

• Lead investor (RPC); entrepreneur; founder Volution/Akari and TDL

Gur Roshwalb MD, MBA Chief Executive Officer

· Celsus; Venrock; Piper Jaffray; Internist

Clive Richardson

**Chief Operating Officer** 

LEK Consulting; Head of Research - Investec; RPC

Wynne Weston-Davies, MD Medical Director

• European Medical Director, BMS; 25 years development exp.

Miles Nunn PhD Chief Scientific Officer

Coversin inventor; expert on parasite:host interactions

**Dov Elefant** 

Chief Financial Officer

• Lev Pharmaceuticals; EpiCept; Synvista; Tetragenix

Robert Shaw JD General Counsel

• KV Pharmaceuticals; Savient Pharmaceuticals; Pliva Inc.

Michael King MBA **Corporate Development** 

Aprecia Pharmaceuticals; McKinsey Consulting; Sandoz GmbH

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# Milestones Historic and Anticipated



## 2H 2015 -1H 2016

- Merger / \$75MM PIPE
  3-month NHP toxicity study
- Phase 2 (resistant) trials-PNH patient treated (>5 months)

2H 2016

- · Phase 2 PNH and aHUS trial initiations
- US IND Submission
- CMC scale up 4Q 2016
- Phase 2 PNH topline data YE 2016

1H 2017

- Phase 2 GBS trial data
- Phase 2 aHUS trial data

2H 2017

- Phase 3 PNH trial initiation
- Phase 3 aHUS trial initiation
- Phase 1 Coversin LA trial initiation



NASDAQ: AKTX

July 2016