**As filed with the Securities and Exchange Commission on October 16, 2015**

**Registration No. 333-**

**UNITED STATES**
**SECURITIES AND EXCHANGE COMMISSION**
**WASHINGTON, D.C. 20549**

**FORM S-3**

**REGISTRATION STATEMENT**
**UNDER**
**THE SECURITIES ACT OF 1933**

**AKARI THERAPEUTICS, PLC**
(Exact name of registrant as specified in its charter)

| **England and Wales** | **98-1034922** |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (I.R.S. Employer Identification No.) |

**76 Wimpole Street**
**London, W1G 8LY**
**United Kingdom**
**Tel: +44 (0)20 3318 3004**
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

**Gur Roshwalb, M.D.**
**Chief Executive Officer**
**Akari Therapeutics, Plc**
**24 West 40th Street**
**New York, NY 10018**
**Telephone: (646) 350-0702**
(Name, address, including zip code, and telephone number, including area code, of agent for service)

***Copies to*:**
**Kenneth R. Koch, Esq.**
**Jeffrey P. Schultz, Esq.**
**Mintz, Levin, Cohn, Ferris, Glovsky and Popeo P.C.**
**Chrysler Center, 666 Third Avenue**
**New York, NY 10017**
**Tel: (212) 935-3000**

**Approximate date of commencement of proposed sale to the public: From time to time after the effective date of this registration statement as determined by the registrant.**

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box: ☐

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box: ☒

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. ☐

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

| | |
|---|---|
| Large accelerated filer ☐ | Accelerated filer ☐ |
| Non-accelerated filer ☐ (Do not check if a smaller reporting company) | Smaller reporting company ☒ |

**CALCULATION OF REGISTRATION FEE**

| Title of Each Class of Securities to be Registered | Amount to be Registered (2) | Proposed Maximum Offering Price per security (3) | Proposed Maximum Aggregate Offering Price | Amount of Registration Fee |
|---|---|---|---|---|
| Ordinary Shares, par value £0.01 per share (1) | 395,881,100 | $0.1999(3) | $ 79,136,631 | $ 7,969.06 |

(1) American Depositary Shares ("ADSs") issuable on deposit of the ordinary shares registered hereby have been registered under a separate registration statement on Form F-6, as amended (File No. 333-185197). Each ADS represents one hundred (100) Ordinary Shares.

(2) Pursuant to Rule 416(a) of the Securities Act of 1933, as amended, this registration statement shall be deemed to cover additional securities that may be offered or issued to prevent dilution resulting from splits, dividends or similar transactions.

(3) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(c) promulgated under the Securities Act of 1933, as amended, based on the average of the high and low sales prices of the ADSs on the Nasdaq Capital Market on October 9, 2015.

**THE REGISTRANT HEREBY AMENDS THIS REGISTRATION STATEMENT ON SUCH DATE OR DATES AS MAY BE NECESSARY TO DELAY ITS EFFECTIVE DATE UNTIL THE REGISTRANT SHALL FILE A FURTHER AMENDMENT WHICH SPECIFICALLY STATES THAT THIS REGISTRATION STATEMENT SHALL THEREAFTER BECOME EFFECTIVE IN ACCORDANCE WITH SECTION 8(a) OF THE SECURITIES ACT OF 1933, AS AMENDED, OR UNTIL THE REGISTRATION STATEMENT SHALL BECOME EFFECTIVE ON SUCH DATE AS THE SECURITIES AND EXCHANGE COMMISSION, ACTING PURSUANT TO SAID SECTION 8(a), MAY DETERMINE.**

The information in this prospectus is not complete and may be changed. The selling shareholders may not sell these securities under this prospectus until the registration statement of which it is a part and filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

**PRELIMINARY PROSPECTUS, SUBJECT TO COMPLETION, DATED OCTOBER 16, 2015**

# AKARI THERAPEUTICS, PLC

**395,881,100 Ordinary Shares**
**Represented by 3,958,811 American Depositary Shares**

---

This prospectus relates to the resale, by the selling shareholders identified herein (the "Selling Shareholders"), of 395,881,100 of our ordinary shares, par value £0.01 ("Ordinary Shares"), represented by 3,958,811 of our American Depositary Shares ("ADSs"), each representing one hundred (100) of our Ordinary Shares. The Selling Shareholders are identified in the table commencing on page 4 of this prospectus. The Ordinary Shares represented by ADSs held by these Selling Shareholders were acquired pursuant to a previously disclosed securities purchase agreement between each of the Selling Shareholders and us. No Ordinary Shares or ADSs are being registered hereunder for sale by us. We will not receive any proceeds from the sale of the Ordinary Shares or ADSs by the Selling Shareholders.

The Ordinary Shares or ADSs may be sold at fixed prices, at prevailing market prices at the time of sale, at varying prices or at negotiated prices. The Ordinary Shares or ADSs offered by this prospectus may be offered by the Selling Shareholders directly to purchasers or to or through underwriters, brokers or dealers or other agents. See "Plan of Distribution" for additional information.

Our ADSs are listed on the Nasdaq Capital Market under the symbol "AKTX." On October 14, 2015, the closing price of our ADSs on the Nasdaq Capital Market was $18.99 per ADS. Our Ordinary Shares are not currently traded.

---

**Investing in our securities involves a high degree of risk. See "Risk Factors" beginning on page 4 of this prospectus for a discussion of information that should be considered before making a decision to purchase our securities.**

**Neither the Securities and Exchange Commission nor any state commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.**

---

The date of this prospectus is _____, 2015

**TABLE OF CONTENTS**


| | |
|---|---|
| Where You Can Find Additional Information | i |
| Information Incorporated by Reference | i |
| Prospectus Summary | 1 |
| Risk Factors | 4 |
| Cautionary Note Regarding Forward-Looking Statements | 25 |
| Unaudited Pro Forma Consolidated Financial Information | 26 |
| Use of Proceeds | 26 |
| Business | 27 |
| Selling Shareholders | 43 |
| Price Range of our ADSs | 47 |
| Taxation | 48 |
| Plan of Distribution | 54 |
| Experts | 56 |
| Legal Matters | 56 |
| Enforceability of Civil Liabilities | 56 |


This prospectus is part of a registration statement that we have filed with the Securities and Exchange Commission (the "SEC") pursuant to which the selling shareholders named herein may, from time to time, offer and sell or otherwise dispose of the securities covered by this prospectus. You should not assume that the information contained in this prospectus is accurate on any date subsequent to the date set forth on the front cover of this prospectus or that any information we have incorporated by reference is correct on any date subsequent to the date of the document incorporated by reference, even though this prospectus is delivered or securities are sold or otherwise disposed of on a later date. It is important for you to read and consider all information contained in this prospectus, including the Information Incorporated by Reference therein, in making your investment decision. You should also read and consider the information in the documents to which we have referred you under the captions "Where You Can Find Additional Information" and "Information Incorporated by Reference" in this prospectus.

Neither we nor the selling shareholders have authorized any dealer, salesman or other person to give any information or to make any representation other than those contained or incorporated by reference in this prospectus. You must not rely upon any information or representation not contained or incorporated by reference in this prospectus. This prospectus does not constitute an offer to sell or the solicitation of an offer to buy any of our securities other than the securities covered hereby, nor does this prospectus constitute an offer to sell or the solicitation of an offer to buy any securities in any jurisdiction to any person to whom it is unlawful to make such offer or solicitation in such jurisdiction. Persons who come into possession of this prospectus in jurisdictions outside the United States are required to inform themselves about, and to observe, any restrictions as to the offering and the distribution of this prospectus applicable to those jurisdictions.

We have obtained the statistical data, market data and other industry data and forecasts used throughout this prospectus from publicly available information and from reports we commissioned. We have not sought the consent of the sources to refer to the publicly available reports in this prospectus.

In this prospectus, "Akari," the "Company," "we," "us," and "our" refer to Akari Therapeutics, Plc (formerly Celsus Therapeutics Plc) and its subsidiaries, unless the context otherwise requires.

## WHERE YOU CAN FIND ADDITIONAL INFORMATION

We file reports with, and furnish information to, the Securities and Exchange Commission (the "SEC"). You may read and copy the registration statement and any other documents we have filed at the SEC, including any exhibits and schedules, at the SEC's public reference room at 100 F Street N.E., Washington, D.C. 20549. You may call the SEC at 1-800-SEC-0330 for further information on this public reference room. The SEC also maintains web site that contains reports, proxy and information statements and other information regarding issuers like us that file electronically with the SEC. The address of the SEC's web site is http://www.sec.gov.

This prospectus is part of a registration statement on Form S-3 that we filed with the SEC to register the securities offered hereby under the Securities Act of 1933, as amended. This prospectus does not contain all of the information included in the registration statement, including certain exhibits and schedules. You may obtain the registration statement and exhibits to the registration statement from the SEC at the address listed above or from the SEC's web site.

We maintain a corporate website at *www.akaritx.com.* Information contained on, or that can be accessed through, our website does not constitute a part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

## INFORMATION INCORPORATED BY REFERENCE

The SEC allows us to incorporate by reference our publicly filed reports into this prospectus, which means that information included in those reports is considered part of this prospectus. Information that we file with the SEC after the date of this prospectus will automatically update and supersede the information contained in this prospectus. We incorporate by reference the following documents filed with the SEC and any future filings made with the SEC under sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"):

- Annual Report on Form 10-K for the fiscal year ended December 31, 2014, filed with the SEC on February 11, 2015;
- Quarterly Reports on Form 10-Q for the quarters ended March 31, 2015 and June 30, 2015, filed with the SEC on May 12, 2015 and August 12, 2015, respectively;
- Current Reports on Form 8-K and 8-K/A filed on February 17, 2015, April 13, 2015, May 1, 2015, July 13, 2015, July 15, 2015, August 18, 2015, September 1, 2015, September 15, 2015, September 21, 2015, September 22, 2015 and October __, 2015;
- Definitive Proxy Statement on Schedule 14A filed with the SEC on August 3, 2015 (as supplemented);
- The description of the Company's ADSs, which are registered under Section 12 of the Exchange Act, in the Company's registration statement on Form 8-A as filed on January 30, 2014, including any amendment or report filed for the purpose of updating such descriptions.

We will furnish without charge to you, on written or oral request, a copy of any or all of the above documents, other than exhibits to such documents which are not specifically incorporated by reference therein. You should direct any requests for documents to:

Akari Therapeutics, Plc
24 West 40th Street, 8th Floor, New York, NY 10018
Attn: Investor Relations
Telephone: (646) 350-0702

The information relating to us contained in this prospectus is not comprehensive and should be read together with the information contained in the incorporated documents. Descriptions contained in the incorporated documents as to the contents of any contract or other document may not contain all of the information which is of interest to you. You should refer to the copy of such contract or other document filed as an exhibit to our filings.

## PROSPECTUS SUMMARY

*This summary highlights selected information contained elsewhere in this prospectus that we consider important. This summary does not contain all of the information you should consider before investing in our securities. You should read this summary together with the entire prospectus, including "Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements", together with the additional information described under "Information Incorporated By Reference,", before making an investment in our securities.*

**Our Business**

Akari Therapeutics, Plc (formerly Celsus Therapeutics Plc) is a biopharmaceutical company focused on the development and commercialization of life-transforming treatments for a range of rare and orphan autoimmune and inflammatory diseases caused by dysregulation of complement C5, including paroxysmal nocturnal hemoglobinuria (PNH), Guillain Barré syndrome (GBS), and atypical Hemolytic Uremic Syndrome (aHUS).

On July 10, 2015, we entered into a Share Exchange Agreement (the "Acquisition Agreement") with RPC Pharma Limited, a Maltese corporation ("RPC"), the sole shareholder of Volution Immuno Pharmaceuticals SA ("Volution"), a private, Swiss-based, clinical stage biotechnology company that was focused on developing anti-complement and anti-inflammatory molecules as treatments for a wide range of rare and orphan conditions in the autoimmune and inflammatory diseases sectors. Upon the terms and subject to the satisfaction of the conditions described in the Acquisition Agreement, including approval of the transaction by our shareholders on September 16, 2015, we acquired the entire issued share capital of Volution, with Volution becoming our wholly-owned subsidiary on September 18, 2015 (the "Acquisition"). In connection with the closing of the Acquisition, we changed our corporate name to Akari Therapeutics, Plc.

For accounting purposes, the Acquisition is treated as a "reverse acquisition" and Volution is considered the accounting acquirer. Accordingly, our financial statements are the historical financial statements of Voluton as our historical financial statements, except for the legal capital which is Akari's legal capital (Ordinary Shares). Because the Volution securityholders owned approximately 91.68% of the fully-diluted capitalization of the Company immediately following the closing of the Acquisition, Volution is considered to be the acquiring company for accounting purposes, and the transaction will be accounted for by Volution as a reverse acquisition under the acquisition method of accounting for business combinations.

**Our Lead Drug Candidate**

Our lead drug candidate, Coversin, a second-generation and potentially best-in-class complement inhibitor, acts on complement component-C5, preventing release of C5a and formation of C5b – 9 (also known as the membrane attack complex or MAC). Coversin is a recombinant small protein (16,740 Da) derived from a protein discovered in the saliva of the *Ornithodoros moubata* tick, where it modulates the host immune system to allow the parasite to feed without alerting the host to its presence or provoking an immune response.

C5 inhibition is a new form of treatment that was commercially pioneered by Alexion Pharmaceuticals in 2007 (Nasdaq: ALXN) with FDA approval of their drug Soliris® (eculizumab) to treat PNH. Soliris® is currently the only drug approved to treat two complement-related orphan indications, PNH and aHUS, and has annual sales of $2.2 billion. Eculizumab is a humanized monoclonal antibody, administered by twice monthly intravenous infusion (IV).

To date, we have demonstrated: (i) 100% inhibition of complement C5 activity by Coversin within 12 hours in a Phase Ia clinical trial in healthy volunteers; (ii) that Coversin inhibits PNH red blood cell lysis in vitro and (iii) that Coversin can achieve full complement inhibition in the blood of eculizumab-resistant patients tested to date. We believe that the subcutaneous formulation of Coversin will provide considerable patient benefits, accelerating recruitment for trials, and patient uptake if Coversin is approved by regulatory authorities for commercial sale.

Scientific understanding of the role of complement C5 inhibition in the treatment of a range of rare diseases related to uncontrolled activation of the complement arm of the immune system is growing. These rare diseases include conditions such as paroxysmal nocturnal haemoglobinuria (PNH), atypical Hemolytic Uremic Syndrome (aHUS), myasthenia gravis (MG), Guillain Barré syndrome (GBS), and Sjögren's syndrome.

Our initial clinical targets will be PNH, GBS, aHUS, and the treatment of patients with polymorphisms of the C5 molecule which interfere with correct binding of eculizumab, making them resistant to treatment with that drug. The latter are expected to be initially treated under compassionate use and named patient protocols until sufficient safety and efficacy data have been accumulated to allow for regulatory approval.

A Phase Ib clinical trial in healthy volunteers is currently expected to be initiated in the fourth quarter of 2015, and we expect to initiate a Phase II trial in PNH patients in the first quarter of 2016. We expect to begin treating PNH patients resistant to eculizumab on a compassionate basis before year-end 2015, and to start Phase II trials in GBS in the first half of 2016 and in aHUS beginning later in 2016. We expect data from the Phase II trial in PNH to be available by year-end 2016. If Coversin achieves satisfactory results in those Phase II clinical trials, we expect to immediately proceed into Phase III pivotal studies in both Europe and the United States.

**Description of the Private Placement**

On August 17, 2015, we entered into a Securities Purchase Agreement (the "Purchase Agreement") with the investors named therein (the "Investors"), which provided for the sale and issuance, promptly after consummation of the Acquisition, of restricted ADSs, each representing one hundred (100) of our Ordinary Shares, having an aggregate value of $75 million, based on a fully-diluted pre-money valuation of Akari, giving effect to the Acquisition, of $150 million (the "Financing").

Concurrently with the execution of the Purchase Agreement, we entered into a Registration Rights Agreement (the "Registration Rights Agreement"), pursuant to which we agreed to file, no later than 30 days after the completion of the Financing, a registration statement with the Securities and Exchange Commission (the "SEC") covering the resale of the ADSs (and the underlying Ordinary Shares) sold to the Investors in the Financing and will cause the registration statement to be declared effective within 60 days after the completion of the Financing (or 120 days if the registration statement is subject to SEC review). Under the Registration Rights Agreement, we also agreed to maintain the effectiveness of the registration statement until the earlier of (i) the date as of which all of the Investors may sell all of the registrable securities covered by such registration statement pursuant to Rule 144 without limitation, restriction or condition (including any current public information requirement) thereunder, or (ii) the date on which the Investors have sold all of the registrable securities covered by such registration statement in accordance with such registration statement or pursuant to Rule 144. We are required to make certain registration delay payments in the event any registration statement is not filed, declared effective or available for resale in accordance with the terms set forth in the Registration Rights Agreement.

On September 18, 2015, pursuant to the Purchase Agreement and following the consummation of the Acquisition, we sold to the Investors, in a private placement an aggregate of 3,958,811 restricted ADSs representing 395,881,100 Ordinary Shares at a purchase price of $18.945 per ADS for gross proceeds of $75 million.

The net proceeds from the Financing will provide us with resources to advance Coversin through Phase 2 clinical trials in paroxysmal nocturnal hemoglobinuria (PNH), Guillain Barré syndrome (GBS) atypical, and Hemolytic Uremic Syndrome (aHUS).

The description of the Purchase Agreement and the Registration Rights Agreement are not complete and are qualified in their entirety by reference to the Purchase Agreement and the Registration Rights Agreement, each of which has been filed as an exhibit to the registration statement of which this prospectus is a part. See "Where You Can Find Additional Information" and "Information Incorporated by Reference." The representations, warranties and covenants made by us in such agreements were made solely for the benefit of the parties to such agreements, including, in some cases, for the purpose of allocating risk among the parties thereto, and should not be deemed to be a representation, warranty or covenant to you. Moreover, such representations, warranties or covenants were made as of an earlier date. Accordingly, such representations, warranties and covenants should not be relied on as accurately representing the current state of our affairs.

**Corporate Information**

Akari Therapeutics Plc is organized under the laws of England and Wales. Our corporate headquarters are located at 76 Wimpole Street, London, W1G 8LY, United Kingdom, telephone +44 (0)20 3318 3004 and our US offices are located at 24 West 40$^{th}$ Street, 8$^{th}$ Floor, New York, NY 10018, telephone 646-350-0702.

Our internet address is *www.akaritx.com*. Our website and the information contained on or accessible through our website are not part of this prospectus.

**Implications of Being an Emerging Growth Company**

Pursuant to The Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"), we are classified as an "Emerging Growth Company." Under the JOBS Act, Emerging Growth Companies are exempt from certain reporting requirements, including the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act. Under this exemption, our auditor will not be required to attest to and report on management's assessment of our internal controls over financial reporting during a five-year transition period. We are also exempt from certain other requirements, including the requirement to adopt certain new or revised accounting standards until such time as those standards would apply to private companies.

## THE OFFERING

This prospectus relates to the resale of 395,881,100 of our Ordinary Shares represented by 3,958,811 of our ADSs, each representing one hundred (100) of our Ordinary Shares, by the Selling Shareholders identified in this prospectus, including their transferees, pledgees, donees or successors. See "Selling Shareholders."

The Selling Shareholders may offer to sell the Ordinary Shares represented by ADSs being offered in this prospectus at fixed prices, at prevailing market prices at the time of sale, at varying prices or at negotiated prices. Our ADSs are listed on the NASDAQ Capital Market under the symbol "AKTX".

We have agreed to register the offer and sale of these securities to satisfy registration rights we have granted to the Selling Shareholders. We will not receive any proceeds from the sale of the securities by the Selling Shareholders.

## RISK FACTORS

You should carefully consider the risks described below, together with all of the other information included in or incorporated by reference into this prospectus, before making an investment decision. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we do not currently believe are important to an investor may also harm our business operations. If any of the events, contingencies, circumstances or conditions described in the following risks actually occurs, our business, financial condition or our results of operations could be seriously harmed. If that happens, the trading price of our securities could decline and you may lose part or all of the value of any of our securities held by you.

**Risks Related to our Business**

***We have a limited operating history, have incurred significant operating losses since inception and expect to incur significant losses for the foreseeable future. We may never become profitable or, if achieved, be able to sustain profitability.***

We have incurred significant operating losses since inception and expect to incur significant losses for the foreseeable future as we continue our clinical trial and development programs for Coversin. As of June 30, 2015, Akari Therapeutics, Plc (formerly known as Celsus Therapeutics Plc) had an accumulated deficit of approximately $14.5 million and, on a pro forma basis, $18.3 million as set forth in our Form 8-K/A filed with the SEC on October 16, 2015. Losses have principally resulted from costs incurred in our clinical trials, research and development programs and general and administrative expenses. We have funded our operations primarily through the private placement of equity securities and debt financing. As of September 30, 2015, following the consummation of the Acquisition and the Financing, we had cash and cash equivalents of $76.2 million. We expect to incur significant losses for the foreseeable future as we continue to conduct research and development, clinical testing, regulatory compliance activities and, if Coversin or other future product candidates receive regulatory approval, sales and marketing activities.

We currently generate no revenue from product sales, and may never be able to commercialize Coversin or other future product candidates. Because of the numerous risks and uncertainties associated with developing and commercializing our product candidates, we are unable to predict the extent of any future losses or when we will become profitable, if at all.

***Our business depends on the success of Coversin, which is still under development. If we are unable to obtain regulatory approval for or successfully commercialize Coversin, our business will be materially harmed.***

Coversin has been the sole focus of our product development. Successful continued development and ultimate regulatory approval of Coversin for a wide range of autoimmune diseases including PNH, aHUS, Guillain-Barré Syndrome (GBS) and others, is critical to the future success of our business. We have invested, and will continue to invest, a significant portion of our time and financial resources in the development of Coversin. We will need to raise sufficient funds for, and successfully enroll and complete, our ongoing clinical development program for Coversin in PNH. The future regulatory and commercial success of this product candidate is subject to a number of risks, including the following:

- we may not have sufficient financial and other resources to complete the necessary clinical trials for Coversin;
- we may not be able to obtain adequate evidence of efficacy and safety for Coversin in PNH, aHUS, myasthenia gravis, GBS, keratoconjunctivitis sicca secondary to Sjogren's and in conditions such as antibody mediated transplant rejection or any other indication;
- we do not know the degree to which Coversin will be accepted as a therapy, even if approved;
- in our clinical programs, we may experience variability in patients, adjustments to clinical trial procedures and the need for additional clinical trial sites, which could delay our clinical trial progress;

- the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA, EMA or comparable foreign regulatory bodies for marketing approval;
- patients in our clinical trials may die or suffer other adverse effects for reasons that may or may not be related to Coversin, which could delay or prevent further clinical development;
- the standards implemented by clinical or regulatory agencies may change at any time;
- the FDA, EMA or foreign clinical or regulatory agencies may require efficacy endpoints for a Phase 2 clinical trial for the treatment of PNH, aHUS, GBS and in conditions such as antibody mediated transplant rejection that differ from the endpoints of our planned current or future trials, which may require us to conduct additional clinical trials;
- the mechanism of action of Coversin is complex and we do not know the degree to which it will translate into a medical benefit in certain indications;
- if approved for PNH, aHUS, myasthenia gravis, GBS, keratoconjunctivitis sicca secondary to Sjogren's or antibody mediated transplant rejection, Coversin will likely compete with the off-label use of currently marketed products and other therapies in development;
- our intellectual property rights may not be patentable, valid or enforceable; and
- we may not be able to obtain, maintain or enforce our patents and other intellectual property rights.

Of the large number of drugs in development in the pharmaceutical industry, only a small percentage results in the submission of a new drug application, or NDA, to the FDA and even fewer are approved for commercialization. Furthermore, even if we do receive regulatory approval to market Coversin, any such approval may be subject to limitations on the indicated uses or patient populations for which we may market the product. Accordingly, even if we are able to obtain the requisite financing to continue to fund our development programs, we cannot assure you that Coversin will be successfully developed or commercialized. If we or any of our future development partners are unable to develop, or obtain regulatory approval for, or, if approved, successfully commercialize Coversin, we may not be able to generate sufficient revenue to continue our business.

***If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.***

We may not be able to initiate or continue clinical trials required by the FDA, EMA or other foreign regulatory agencies for Coversin if we are unable to locate and enroll a sufficient number of eligible patients to participate in these clinical trials. We will be required to identify and enroll a sufficient number of patients with PNH, aHUS, GBS, keratoconjunctivitis sicca secondary to Sjogren's or antibody mediated transplant rejection for each of our ongoing and planned clinical trials of Coversin in these indications. Each of these is a rare disease or indication with relatively small patient populations, which could result in slow enrollment of clinical trial participants.

Patient enrollment is affected by other factors, including:

- severity of the disease under investigation;
- design of the clinical trial protocol;
- size and nature of the patient population;
- eligibility criteria for the trial in question;
- perceived risks and benefits of the product candidate under trial;
- proximity and availability of clinical trial sites for prospective patients;
- availability of competing therapies and clinical trials;

- clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians; and
- our ability to monitor patients adequately during and after treatment.

Further, there are only a limited number of specialist physicians that treat patients with these diseases, and major clinical centers are concentrated in a few geographic regions. We also may encounter difficulties in identifying and enrolling such patients with a stage of disease appropriate for our ongoing or future clinical trials. In addition, the process of finding and diagnosing patients may prove costly. Our inability to enroll a sufficient number of patients for any of our clinical trials would result in significant delays or may require us to abandon one or more clinical trials.

***If clinical trials or regulatory approval processes for Coversin are prolonged, delayed or suspended, we may be unable to commercialize Coversin on a timely basis.***

We cannot predict whether we will encounter problems with any of our completed, ongoing or planned clinical trials that will cause us or any regulatory authority to delay or suspend those clinical trials or delay the completion of our ongoing and planned clinical trials and negatively impact our ability to obtain regulatory approval for, and to market and sell, a particular product candidate:

- conditions imposed on us by the FDA, EMA or another foreign regulatory authority regarding the scope or design of our clinical trials;
- insufficient supply of our product candidates or other materials necessary to conduct and complete our clinical trials;
- slow enrollment and retention rate of subjects in our clinical trials; and
- serious and unexpected drug-related side effects related to the product candidate being tested.

Commercialization may be delayed by the imposition of additional conditions on our clinical trials by the FDA, EMA or any other applicable foreign regulatory authority or the requirement of additional supportive studies by the FDA, EMA or such foreign regulatory authority.

We do not know whether our clinical trials will begin as planned, will need to be restructured, or will be completed on schedule, if at all. Delays in our clinical trials will result in increased development costs for our product candidates, and our financial resources may be insufficient to fund any incremental costs. In addition, if our clinical trials are delayed, our competitors may be able to bring products to market before we do and the commercial viability of our product candidates could be limited.

***The efficacy of Coversin may not be known until advanced stages of testing, after we have incurred significant product development costs which may not be recoverable.***

Coversin may fail to show the desired efficacy at any phase in the clinical development program. Good efficacy in animal models of the target indication are no guarantee of success in human clinical trials. Often there is no adequate animal model of a human disease, such as PNH. As a result, the first definitive proof of efficacy may not occur until clinical trials in humans. Until Coversin has completed proof of principal clinical trials in target indications, for example, PNH, aHUS and GBS, there can be no assurance that it will have its expected efficacy in these conditions. If Coversin does not demonstrate adequate efficacy, its development may be delayed or terminated, which could have a material adverse effect on our financial condition and results of operation.

***The route of administration or dose for Coversin may be inadequate.***

Unsatisfactory drug availability due to problems relating to the route of administration or the target tissue availability of the drug is another potential cause of lack of efficacy of Coversin if and when it is commercialized. Complement component C5, the target of Coversin is predominantly found in blood. For PNH, aHUS and GBS, Coversin will be administered subcutaneously. The completed single dose phase 1 study shows that Coversin is able to enter the systemic circulation by absorption from subcutaneous sites in healthy volunteers. However, if daily subcutaneous administration proves to be unfeasible, then we may need to research additional doses or routes of administration, which could delay commercialization of Coversin and result in significant additional costs to us.

***Long-term animal toxicity studies of Coversin could result in adverse results.***

We are currently undertaking long-term animal toxicity studies of Coversin. Such tests may show that Coversin is toxic in certain animals, is not as effective as we expected, or other adverse results. If animal toxicity tests do not yield favorable results, we may be required to abandon our development of Coversin, which could have a material adverse effect on our financial condition and results of operation.

***Chronic dosing of patients with Coversin could lead to an immune response that causes adverse reactions or impairs the activity of the drug.***

There is a risk that chronic dosing of patients with Coversin may lead to an immune response that causes adverse reactions or impairs the activity of the drug. Patients may develop an allergic reaction to the drug and/or develop antibodies directed at the drug. Impaired drug activity could be caused by neutralization of the drug's inhibitory activity or by an increased rate of clearance of the drug from circulation.

One potential toxic side effect of Coversin that has occurred in patients receiving Soliris®, (eculizumab), a humanized antibody against complement component C5, may include the inhibition of the terminal complement system, which can result in an increased incidence of meningitis. As a result, we expect that patients receiving Coversin would also receive meningitis immunization and prophylactic antibiotics as indicated.

Coversin has a secondary binding site that sequesters leukotriene B4 (LTB4). LTB4 synthesis from eicosanoid fatty acids can be induced by a variety of triggers including complement. LTB4 is a pro-inflammatory mediator with potent neutrophil attractant properties. LTB4 inhibition may lead to positive anti-inflammatory benefits, but another potential cause of undesired side effects is that. The reduction of these neutrophil attractant properties may include increased risk of infection, among others.

Any immune response that causes adverse reactions or impairs the activity of the drug could cause a delay in or termination of our development of Coversin, which would have a material adverse effect on our financial condition and results of operation.

***If Coversin is not convenient for patients to use, then potential sales may decrease materially.***

Coversin may be required to be kept refrigerated prior to use and will likely require self-injection. If the drug product is not stable at temperatures of between 4 and 8 degrees Celsius, then the drug product may need to be defrosted before use, which patients could view as inconvenient, causing sales to decrease. In addition, if Coversin shows a lack of long-term stability at low storage temperatures, this may negatively impact our ability to manage the commercial supply chain, which could result in us having to refund customers or replace products that are unstable, which could materially increase our costs and have an adverse effect on our financial condition and results of operation.

***Because Coversin has not yet received regulatory approval, it is difficult to predict the time and cost of development and our ability to successfully complete clinical development and obtain the necessary regulatory approvals for commercialization.***

Coversin has not yet received regulatory approval for the treatment of PNH, or other potential indications, and unexpected problems may arise that could cause us to delay, suspend or terminate our development efforts. Further, Coversin has not yet demonstrated efficacy for PNH in humans, and the long-term safety consequences of inhibition of C5 with Coversin is not known. Regulatory approval of new product candidates such as Coversin can be more expensive and take longer than approval for candidates for the treatment of more well understood diseases with previously approved products.

***We plan to seek orphan drug status for Coversin, but we may be unable to obtain such designation or to maintain the benefits associated with orphan drug status, including market exclusivity.***

We plan to seek orphan drug designation for Coversin in specific orphan indications in which there is a medically plausible basis for its use. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. Although we intend to seek orphan product designation for Coversin, we may never receive such designation.

If a product that has orphan drug designation subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a BLA, to market the same biologic for the same indication for seven years, except in limited circumstances such as a showing of clinical superiority to the product with orphan product exclusivity or if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Even if we were to obtain orphan drug designation for Coversin, we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing pharmaceutical products. If we do obtain exclusive marketing rights in the United States, they may be limited if we seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of the relevant patients. Further, exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve a drug with the same active moiety for the same condition if the FDA concludes that the later drug is safer, more effective, or makes a major contribution to patient care. Furthermore, the FDA can waive orphan exclusivity if we are unable to manufacture sufficient supply of our product.

***We may seek a breakthrough therapy designation from the FDA for Coversin. Such designation or a similar designation from other national or international regulatory agencies, may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that Coversin or any other product candidates will receive marketing approval.***

We may seek a breakthrough therapy designation for Coversin. A breakthrough therapy is defined as a product that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. Designation as a breakthrough therapy is within the discretion of the FDA. Receipt of a breakthrough therapy designation for Coversin may not result in a faster development process, review or approval compared to products considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if Coversin qualifies as a breakthrough therapy, the FDA may later decide that it no longer meet the conditions for qualification.

***Even if we obtain FDA approval of Coversin, we or our partners may never obtain approval or commercialize our products outside of the United States.***

In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding clinical trial design, safety and efficacy. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approvals could result in significant delays, difficulties and costs for us and may require additional preclinical studies or clinical trials which would be costly and time consuming and could delay or prevent introduction of Coversin in those countries. We do not have experience in obtaining regulatory approval in international markets. If we or our partners fail to comply with regulatory requirements or to obtain and maintain required approvals, our target market will be reduced and our ability to realize the full market potential of Coversin will be harmed.

***We currently have no marketing, sales or distribution infrastructure with respect to our product candidates. If we are unable to develop our sales, marketing and distribution capability on our own or through collaborations with marketing partners, we will not be successful in commercializing our product candidates.***

We currently have no marketing, sales or distribution capabilities and have limited sales or marketing experience within our organization. If our product candidate Coversin is approved, we intend either to establish a sales and marketing organization with technical expertise and supporting distribution capabilities to commercialize Coversin, or to outsource this function to a third party. Either of these options would be expensive and time consuming. Some or all of these costs may be incurred in advance of any approval of Coversin. In addition, we may not be able to hire a sales force in the United States or other target market that is sufficient in size or has adequate expertise in the medical markets that we intend to target. Any failure or delay in the development of our or third parties' internal sales, marketing and distribution capabilities would adversely impact the commercialization of Coversin and other future product candidates.

With respect to our existing and future product candidates, we may choose to collaborate with third parties that have direct sales forces and established distribution systems, either to augment or to serve as an alternative to our own sales force and distribution systems. Our product revenue may be lower than if it directly marketed or sold any approved products. In addition, any revenue we receive will depend in whole or in part upon the efforts of these third parties, which may not be successful and are generally not within our control. If we are unable to enter into these arrangements on acceptable terms or at all, we may not be able to successfully commercialize any approved products. If we are not successful in commercializing any approved products, our future product revenue will suffer and we may incur significant additional losses.

***We only have a limited number of employees to manage and operate our business.***

As of September 30, 2015, we had five full-time employees and a further two full-time equivalent consultants. Our focus on limiting cash utilization requires us to manage and operate our business in a highly efficient manner. We cannot assure you that we will be able to retain adequate staffing levels to run our operations and/or to accomplish all of the objectives that we otherwise would seek to accomplish.

***We depend heavily on our executive officers, directors, and principal consultants and the loss of their services would materially harm our business.***

Our success depends, and will likely continue to depend, upon our ability to retain the services of our current executive officers, directors, principal consultants and others. In addition, we have established relationships with universities and research institutions which have historically provided, and continue to provide, us with access to research laboratories, clinical trials, facilities and patients. The loss of the services of any of these individuals or institutions would have a material adverse effect on our business.

***If we fail to obtain the capital necessary to fund our operations, we will be unable to successfully develop and commercialize Coversin and other future product candidates.***

We will require substantial capital in the future to complete the remaining clinical development for Coversin. In order to initiate our Phase 2 clinical program for Coversin in PNH, we will need to collaborate with a strategic partner or raise significant capital. We expect our spending levels to increase in connection with our clinical trials of Coversin, as well as other corporate activities. The amount and timing of any expenditure needed will depend on numerous factors, including:

- the type, number, scope, progress, expansion costs, results of and timing of our ongoing or future clinical trials or the need for additional clinical trials of Coversin for PNH, aHUS, or any of its other indications or product candidates which we are pursuing or may choose to pursue in the future;
- the costs of obtaining, maintaining and enforcing its patents and other intellectual property rights;
- the costs and timing of obtaining or maintaining manufacturing for Coversin for PNH, aHUS and any of its other indications or product candidates, including commercial manufacturing if any product candidate is approved;
- the costs and timing of establishing sales marketing, and reimbursement capabilities and enhanced internal controls over financial reporting;
- the terms and timing of establishing and maintaining collaborations, license agreements and other partnerships;
- costs associated with any new product candidates that we may develop, in-license or acquire;
- the effect of competing technological and market developments; and
- the costs associated with being a public company.

Some of these factors are outside of our control. We do not expect our existing capital resources together with the net proceeds from the recent Acquisition and Financing to be sufficient to enable us to fund the completion of our clinical trials and commercialization of our product candidates. We expect that we will need to raise additional funds in the future.

We have not sold any products, and we do not expect to sell or derive revenue from any product sales for the foreseeable future. We may seek additional funding through future debt and equity financing, as well as potential additional collaborations or strategic partnerships with other companies or through non-dilutive financings. Additional funding may not be available to us on acceptable terms or at all. In addition, the terms of any financing may adversely affect the holdings or the rights of our shareholders. In addition, the issuance of additional shares by us, or the possibility of such issuance, may cause the market price of our shares to decline.

If we are unable to obtain funding on a timely basis, we will be unable to complete ongoing and planned clinical trials for Coversin and we may be required to significantly curtail some or all of our activities. We also could be required to seek funds through arrangements with collaborative partners or otherwise that may require us to relinquish rights to our product candidates or some of our technologies or otherwise agree to terms unfavorable to us.

***If we or our partners market products in a manner that violates fraud and abuse and other healthcare laws, or if we or they violate government price reporting laws, we or our partners may be subject to administrative civil and/or criminal penalties.***

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal healthcare laws, including those commonly referred to as “fraud and abuse” laws have been applied in recent years to restrict certain marketing practices in the pharmaceutical industry. These laws include, among others, false claims and anti-kickback statutes. At such time, if ever, as we or any of our partners market any of our future approved products, it is possible that some of the business activities of us and/or our partners could be subject to challenge under one or more of these laws.

Federal false claims, false statements and civil monetary penalties laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or to get a false claim paid. The federal healthcare program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Although there are several statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution, they are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor.

In addition, we and/or our partners may be subject to data privacy and security regulation, including the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their respective implementing regulations, which impose specified requirements relating to the privacy, security and transmission of individually identifiable health information.

Most states also have statutes or regulations similar to these federal laws, which may apply to items such as pharmaceutical products and services reimbursed by private insurers. We and/or our partners may be subject to administrative, civil and criminal sanctions for violations of any of these federal and state laws.

***Our success depends on our ability to protect our intellectual property and our proprietary technologies.***

Our commercial success depends in part on our ability to obtain and maintain patent protection and trade secret protection for our product candidates, proprietary technologies, and their uses as well as our ability to operate without infringing upon the proprietary rights of others. We can provide no assurance that our patent applications or those of our licensors will result in additional patents being issued or that issued patents will afford sufficient protection against competitors with similar technologies, nor can there be any assurance that the patents issued will not be infringed, designed around or invalidated by third parties. Even issued patents may later be found unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. The degree of future protection for our proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. Composition-of-matter patents on the biological or chemical active pharmaceutical ingredients are generally considered to offer the strongest protection of intellectual property and provide the broadest scope of patent protection for pharmaceutical products, as such patents provide protection without regard to any method of use or any method of manufacturing. While we have issued composition-of-matter patents in the United States and other countries for Coversin, we cannot be certain that the claims in our issued composition-of-matter patents will not be found invalid or unenforceable if challenged. We cannot be certain that the claims in our patent applications covering composition-of-matter or formulations of our product candidates will be considered patentable by the United States Patent and Trademark Office, or USPTO, and courts in the United States or by the patent offices and courts in foreign countries, nor can we be certain that the claims in our issued composition-of-matter patents will not be found invalid or unenforceable if challenged. Even if our patent applications covering formulations of our product candidates issue as patents, the formulation patents protect a specific formulation of a product and may not be enforced against competitors making and marketing a product that has the same active pharmaceutical ingredient in a different formulation. Method-of-use patents protect the use of a product for the specified method or for treatment of a particular indication. This type of patents may not be enforced against competitors making and marketing a product that has the same active pharmaceutical ingredient but is used for a method not included in the patent. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products "off-label." Although off-label prescriptions may infringe or contribute to the infringement of method-of-use patents, the practice is common and such infringement is difficult to prevent or prosecute.

Our issued composition of matter patents for Coversin are expected to expire in the United States in 2024. Our additional patents and pending patent applications that cover formulations, combination products and use of Coversin to treat various indications are expected to expire at various times that range from 2024 (for issued patents) to potentially 2031 (for pending patent applications if patents were to issue on the pending applications filed thereon).

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our future development partners will be successful in protecting our product candidates by obtaining and defending patents. These risks and uncertainties include the following:

- the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case;

- patent applications may not result in any patents being issued;

- patents that may be issued or in-licensed may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;

- our competitors, many of whom have substantially greater resources and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use, and sell our potential product candidates;

- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and

- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates.

In addition, we rely on the protection of our trade secrets and proprietary know-how. Although we have taken steps to protect our trade secrets and unpatented know-how, including entering into confidentiality agreements with third parties, and confidential information and inventions agreements with employees, consultants and advisors, we cannot provide any assurances that all such agreements have been duly executed, and third parties may still obtain this information or may come upon this or similar information independently. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating its trade secrets. If any of these events occurs or if we otherwise lose protection for our trade secrets or proprietary know-how, our business may be harmed.

***Others may claim an ownership interest in our intellectual property which could expose it to litigation and have a significant adverse effect on its prospects.***

A third party may claim an ownership interest in one or more of our patents or other intellectual property. A third party could bring legal actions against us and seek monetary damages and/or enjoin clinical testing, manufacturing and marketing of the affected product or products. While we believe we own the right, title and interest in the patents for which we have applied and our other intellectual property and are presently unaware of any claims or assertions by third-parties with respect to our patents or other intellectual property, we cannot guarantee that a third-party will not assert a claim or an interest in any of such patents or intellectual property. If we become involved in any litigation, it could consume a substantial portion of our resources, and cause a significant diversion of effort by our technical and management personnel. If any of these actions are successful, in addition to any potential liability for damages, we could be required to obtain a license to continue to manufacture or market the affected product, in which case we may be required to pay substantial royalties or grant cross-licenses to our patents. We cannot, however, assure you that any such license will be available on acceptable terms, if at all. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations as a result of claims of patent infringement or violation of other IP rights, Further, the outcome of IP litigation is subject to uncertainties that cannot be adequately quantified in advance, including the demeanor and credibility of witnesses and the identity of the adverse party. This is especially true in IP cases that may turn on the testimony of experts as to technical facts upon which experts may reasonably disagree.

***Our industry is highly competitive, and our product candidates may become obsolete.***

We are engaged in a rapidly evolving field. Competition from other pharmaceutical companies, biotechnology companies and research and academic institutions is intense and likely to increase. Many of those companies and institutions have substantially greater financial, technical and human resources than us. Those companies and institutions also have substantially greater experience in developing products, conducting clinical trials, obtaining regulatory approval and in manufacturing and marketing pharmaceutical products. Our competitors may succeed in obtaining regulatory approval for their products more rapidly than we do. Competitors have developed or are in the process of developing technologies that are, or in the future may be, the basis for competitive products, such as Alexion Pharmaceuticals' eculizumab. Our competitors may succeed in developing products that are more effective and/or cost competitive than those we are developing, or that would render our product candidates less competitive or even obsolete. In addition, one or more of our competitors may achieve product commercialization or patent protection earlier than us, which could materially adversely affect our business.

***If the FDA or other applicable regulatory authorities approve generic products that compete with any of our or any of our partners' product candidates, the sales of our product candidates would be adversely affected.***

Once an NDA or marketing authorization application outside the United States is approved, the product covered thereby becomes a "listed drug" that can, in turn, be cited by potential competitors in support of approval of an abbreviated new drug application in the United States. Agency regulations and other applicable regulations and policies provide incentives to manufacturers to create modified, non-infringing versions of a drug to facilitate the approval of an abbreviated new drug application or other application for generic substitutes in the United States and in nearly every pharmaceutical market around the world. These generic equivalents, which must meet the same quality standards as branded pharmaceuticals, would be significantly less costly than us to bring to market, and companies that produce generic equivalents are generally able to offer their products at lower prices. Thus, after the introduction of a generic competitor, a significant percentage of the sales of any branded product is typically lost to the generic product. Accordingly, competition from generic equivalents to our or any of our partners' future products, if any, could materially adversely impact our future revenue, profitability and financial condition.

***If physicians and patients do not accept our future products or if the market for indications for which any product candidate is approved is smaller than expected, we may be unable to generate significant revenue, if any.***

Even if any of our product candidates obtain regulatory approval, they may not gain market acceptance among physicians, patients, and third-party payers. Physicians may decide not to recommend its treatments for a variety of reasons including:

- timing of market introduction of competitive products;
- demonstration of clinical safety and efficacy compared to other products;
- cost-effectiveness;
- limited or no coverage by third-party payers;
- convenience and ease of administration;
- prevalence and severity of adverse side effects;
- restrictions in the label of the drug;
- other potential advantages of alternative treatment methods; and
- ineffective marketing and distribution support of our products.

If any of our product candidates are approved, but fail to achieve market acceptance or such market is smaller than anticipated, we may not be able to generate significant revenue and our business would suffer.

***The uncertainty associated with pharmaceutical reimbursement and related matters may adversely affect our business.***

Market acceptance and sales of any one or more of our product candidates will depend on reimbursement policies and may be affected by future healthcare reform measures in the United States and in foreign jurisdictions. Government authorities and third-party payers, such as private health insurers and health maintenance organizations, decide which drugs they will cover and establish payment levels. We cannot be certain that reimbursement will be available for any of our product candidates. Also, we cannot be certain that reimbursement policies will not reduce the demand for, or the price paid for, our products. The insurance coverage and reimbursement status of newly-approved products for orphan diseases is particularly uncertain, and failure to obtain or maintain adequate coverage and reimbursement for Coversin or any other product candidates could limit our ability to generate revenue.

The United States and several foreign jurisdictions are considering, or have already enacted, a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. There is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access to healthcare. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. We expect to experience pricing pressures in connection with the sale of any products that we develop due to the trend toward managed healthcare, increasing influence of health maintenance organizations and additional legislative proposals.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively, ACA, became law in the U.S. While we cannot predict what impact on federal reimbursement policies this legislation will have, the ACA may result in downward pressure on pharmaceutical reimbursement, which could negatively affect market acceptance of, and the price we may charge for, any products we develop that receive regulatory approval.

***If any product liability lawsuits are successfully brought against us or any of our collaborative partners, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.***

We face an inherent risk of product liability lawsuits related to the testing of our product candidates in seriously ill patients and will face an even greater risk if product candidates are approved by regulatory authorities and introduced commercially. Product liability claims may be brought against us or our partners by participants enrolled in our clinical trials, patients, health care providers or others using, administering or selling any of our future approved products. If we cannot successfully defend ourselves against any such claims, we may incur substantial liabilities, which may result in:

- decreased demand for any of our future approved products;
- injury to our reputation;
- withdrawal of clinical trial participants;
- termination of clinical trial sites or entire trial programs;
- significant litigation costs;
- substantial monetary awards to or costly settlements with patients or other claimants;
- product recalls or a change in the indications for which they may be used;
- loss of revenue;
- diversion of management and scientific resources from our business operations; and

- the inability to commercialize our product candidates.

If any of our product candidates are approved for commercial sale, we will be highly dependent upon consumer perceptions of us and the safety and quality of our products. We could be adversely affected if we are subject to negative publicity associated with illness or other adverse effects resulting from patients' use or misuse of our products or any similar products distributed by other companies.

We currently do not have product liability insurance coverage and expect to obtain such coverage initially per clinical trial, which may not be adequate to cover all liabilities that we may incur. We will need to obtain more comprehensive product liability insurance and increase our insurance coverage when we begin the commercialization of our product candidates. Insurance coverage is becoming increasingly expensive. As a result, we may be unable to maintain or obtain sufficient insurance at a reasonable cost to protect us against losses that could have a material adverse effect on our business.

***We enter into various contracts in the normal course of our business in which we indemnify the other party to the contract. In the event we have to perform under these indemnification provisions, it could have a material adverse effect on our business, financial condition and results of operations.***

In the normal course of business, we periodically enter into academic, commercial, service, collaboration, licensing, consulting and other agreements that contain indemnification provisions. With respect to our academic and other research agreements, we typically indemnify the institution and related parties from losses arising from claims relating to the products, processes or services made, used, sold or performed pursuant to the agreements for which we have secured licenses, and from claims arising from our or our sublicensees' exercise of rights under the agreement. With respect to our commercial agreements, we indemnify our vendors from any third-party product liability claims that could result from the production, use or consumption of the product, as well as for alleged infringements of any patent or other intellectual property right by a third party.

Should our obligation under an indemnification provision exceed applicable insurance coverage or if we were denied insurance coverage, our business, financial condition and results of operations could be adversely affected. Similarly, if we are relying on a collaborator to indemnify us and the collaborator is denied insurance coverage or the indemnification obligation exceeds the applicable insurance coverage and does not have other assets available to indemnify us, our business, financial condition and results of operations could be adversely affected.

***Our business and operations would suffer in the event of computer system failures.***

Despite the implementation of security measures, our internal computer systems, and those of our partners and other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, fire, terrorism, war and telecommunication and electrical failures. In addition, our systems safeguard important confidential personal data regarding our subjects. If a disruption event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed, ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of Coversin and other product candidates could be delayed.

***If we fail to develop and commercialize other product candidates, we may be unable to grow our business.***

Although the development and commercialization of Coversin is our primary focus, as part of our longer-term growth strategy, we plan to evaluate the development and commercialization of other therapies related to immune-mediated, inflammatory, orphan and other diseases. We will evaluate internal opportunities from our current product candidates, and also may choose to in-license or acquire other product candidates as well as commercial products to treat patients suffering from immune-mediated or orphan or other disorders with high unmet medical needs and limited treatment options. These other product candidates will require additional, time-consuming development efforts prior to commercial sale, including preclinical studies, clinical trials and approval by the FDA and/or applicable foreign regulatory authorities. All product candidates are prone to the risks of failure that are inherent in pharmaceutical product development, including the possibility that the product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot assure you that any such products that are approved will be manufactured or produced economically, successfully commercialized or widely accepted in the marketplace or be more effective than other commercially available alternatives.

**Risks Related to Our Reliance on Third Parties**

***If the third parties on which we rely on for our clinical trials and results do not perform our clinical trial activities in accordance with good clinical practices and related regulatory requirements, we may be unable to obtain regulatory approval for or commercialize our product candidates.***

We use and heavily rely on third-party service providers to conduct and/or oversee the clinical trials of our product candidates and expect to continue to do so for the foreseeable future. Nonetheless, we are responsible for confirming that each of our clinical trials is conducted in accordance with the FDAs and/or EMA's requirements and its general investigational plan and protocol.

The FDA and EMA require us and our third-party service providers to comply with regulations and standards, commonly referred to as good clinical practices, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the trial participants are adequately protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. Third parties may not complete activities on schedule or conduct our clinical trials in accordance with regulatory requirements or the respective trial plans and protocols. In addition, third parties may not be able to repeat their past successes in clinical trials. The third parties' failure to carry out their obligations could delay or prevent the development, approval and commercialization of our product candidates or result in enforcement action against us.

***Use of third parties to manufacture our product candidates may increase the risk that we will not have sufficient quantities of our product candidates, products, or necessary quantities at an acceptable cost.***

We do not own or operate manufacturing facilities for the production of clinical or commercial quantities of its product candidates, and we lack the resources and the capabilities to do so. As a result, we currently rely on third parties for supply of the active pharmaceutical ingredients, or API, in our product candidates. Our strategy is to outsource all manufacturing of our product candidates and products to third parties.

We currently engage a third-party manufacturer to provide clinical material of the API and fill and finish services for the final drug product formulation of Coversin that is being used in our clinical trials. Although we believe that there are several potential alternative manufacturers who could manufacture Coversin, we may incur added costs and delays in identifying and qualifying any such replacement. In addition, we have not yet concluded a commercial supply contract with any commercial manufacturer. There is no assurance that we will be able to timely secure needed supply arrangements on satisfactory terms, or at all. Our failure to secure these arrangements as needed could have a material adverse effect on our ability to complete the development of our product candidates or, to commercialize them. We may be unable to conclude agreements for commercial supply with third-party manufacturers, or may be unable to do so on acceptable terms. There may be difficulties in scaling up to commercial quantities and formulation of Coversin and the costs of manufacturing could be prohibitive.

Even if we are able to establish and maintain arrangements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- reliance on third-parties for manufacturing process development, regulatory compliance and quality assurance;

- limitations on supply availability resulting from capacity and scheduling constraints of third-parties;
- the possible breach of manufacturing agreements by third-parties because of factors beyond our control; and
- the possible termination or non-renewal of the manufacturing agreements by the third-party, at a time that is costly or inconvenient to us.

If we do not maintain our key manufacturing relationships, we may fail to find replacement manufacturers or develop our own manufacturing capabilities, which could delay or impair our ability to obtain regulatory approval for our products. If we do find replacement manufacturers, we may not be able to enter into agreements with them on terms and conditions favorable to us and there could be a substantial delay before new facilities could be qualified and registered with the FDA and other foreign regulatory authorities.

The FDA and other foreign regulatory authorities require manufacturers to register manufacturing facilities. The FDA and corresponding foreign regulators also inspect these facilities to confirm compliance with current good manufacturing practices, or cGMPs. Contract manufacturers may face manufacturing or quality control problems causing drug substance production and shipment delays or a situation where the contractor may not be able to maintain compliance with the applicable cGMP requirements. Any failure to comply with cGMP requirements or other FDA, EMA and comparable foreign regulatory requirements could adversely affect our clinical research activities and our ability to develop our product candidates and market our products following approval.

***If our third-party manufacturer of Coversin is unable to increase the scale of its production of Coversin, and/or increase the product yield of its manufacturing, then our costs to manufacture the product may increase and commercialization may be delayed.***

In order to produce sufficient quantities of Coversin to meet the demand for clinical trials and subsequent commercialization, our third party manufacturer of Coversin will be required to increase its production and optimize its manufacturing processes while maintaining the quality of the product. The transition to larger scale production could prove difficult. In addition, if our third party manufacturer is not able to optimize its manufacturing process to increase the product yield for Coversin, or if it is unable to produce increased amounts of Coversin while maintaining the quality of the product, then we may not be able to meet the demands of clinical trials or market demands, which could decrease our ability to generate profits and have a material adverse impact on our business and results of operation.

**Risks Related to our ADSs and Ordinary Shares**

***Ownership of our ADSs and/or Ordinary Shares involves a high degree of risk.***

Investing in and owning our ADSs and Ordinary Shares involves a high degree of risk. Shareholders should read carefully the risk factors provided within this section, as well as our public documents filed with the SEC, including the financial statements therein.

***If we are deemed or become a passive foreign investment company, or PFIC, for U.S. federal income tax purposes in 2015 or in any prior or subsequent years, there may be negative tax consequences for U.S. taxpayers that are holders of our ADSs.***

We will be treated as a passive foreign investment company, or PFIC, for U.S. federal income tax purposes in any taxable year in which either (i) at least 75% of our gross income is "passive income" or (ii) on average at least 50% of our assets by value produce passive income or are held for the production of passive income. Passive income for this purpose generally includes, among other things, certain dividends, interest, royalties, rents and gains from commodities and securities transactions and from the sale or exchange of property that gives rise to passive income. Passive income also includes amounts derived by reason of the temporary investment of funds, including those raised in a public offering. In determining whether a non-U.S. corporation is a PFIC, a proportionate share of the income and assets of each corporation in which it owns, directly or indirectly, at least a 25% interest (by value) is taken into account.

We were not treated as a PFIC for 2014 but may be treated as a PFIC for the current taxable year and future taxable years. If we are deemed a PFIC for any taxable year, and a U.S. Holder does not make an election to treat us as a "qualified electing fund," or QEF, or make a "mark-to-market" election, then "excess distributions" to a U.S. shareholder, and any gain realized on the sale or other disposition of our ADSs will be subject to special rules. Under these rules: (i) the excess distribution or gain would be allocated ratably over the U.S. Holder's holding period for ADSs; (ii) the amount allocated to the current taxable year and any period prior to the first day of the first taxable year in which we were a PFIC would be taxed as ordinary income; and (iii) the amount allocated to each of the other taxable years would be subject to tax at the highest rate of tax in effect for the applicable class of taxpayer for that year, and an interest charge for the deemed deferral benefit would be imposed with respect to the resulting tax attributable to each such other taxable year. In addition, if the U.S. Internal Revenue Service determines that we are a PFIC for a year with respect to which we have determined that we were not a PFIC, it may be too late for a U.S. shareholder to make a timely QEF or mark-to-market election. U.S. Holders who hold our ADSs during a period when we are a PFIC will be subject to the foregoing rules, even if we cease to be a PFIC in subsequent years, subject to exceptions for U.S. shareholders who made a timely QEF or mark-to-market election. A U.S. shareholder can make a QEF election by completing the relevant portions of and filing IRS Form 8621 in accordance with the instructions thereto. A QEF election generally may not be revoked without the consent of the IRS. Upon request of any shareholder or pursuant to an agreement with any shareholder, we will annually furnish U.S. shareholders with information needed in order to complete IRS Form 8621 (which form would be required to be filed with the IRS on an annual basis by the U.S. shareholder) and to make and maintain a valid QEF election for any year in which we or any of our subsidiaries are a PFIC.

***A limited public market exists for our securities and we cannot assure you that our securities will continue to be listed on the NASDAQ Capital Market or any other securities exchange or that an active trading market will ever develop for any of our securities.***

Our ADSs were approved for listing and began trading on the NASDAQ Capital Market under the symbol "CLTX" on January 31, 2014 and commenced trading under the symbol "AKTX" commencing on September 21, 2015. We cannot assure you that we will be successful in meeting the continuing listing standards of the NASDAQ Capital Market. Consequently, the trading liquidity of our ADSs may not improve. We may not be successful in maintaining the listing of our ADSs on the NASDAQ Capital Market and cannot assure you that our ADSs will be listed on a national securities exchange. There is no assurance that an active trading market in our ADSs will develop, or if such a market develops, that it will be sustained.

***The market price of our ADSs may be volatile and may fluctuate in a way that is disproportionate to our operating performance.***

Even if an active trading market develops for our ADSs, our stock price may experience substantial volatility as a result of a number of factors. The market prices for securities of biotechnology companies in general have been highly volatile and may continue to be so in the future. The following factors, in addition to other risk factors described in this section, may have a significant impact on the market price of our ADSs:

- sales or potential sales of substantial amounts of our Ordinary Shares or ADSs;
- delay or failure in initiating, enrolling, or completing pre-clinical or clinical trials or unsatisfactory results of these trials or events reported in any of our current or future clinical trials;
- announcements about us or about our competitors, including clinical trial results, regulatory approvals or new product introductions;
- developments concerning our licensors or product manufacturers;
- litigation and other developments relating to our patents or other proprietary rights or those of our competitors;
- conditions in the pharmaceutical or biotechnology industries;
- governmental regulation and legislation;
- variations in our anticipated or actual operating results;
- change in securities analysts' estimates of our performance, or our failure to meet analysts' expectations;
- whether, to what extent and under what conditions the FDA will permit us to continue developing our product candidates, if at all, and if development is continued, any reports of safety issues or other adverse events observed in any potential future studies of these product candidates;

- adverse publicity relating to the aHUS, myasthenia gravis, Guillain Barré syndrome, keratoconjunctivitis sicca secondary to Sjogren's or in conditions such as antibody mediated transplant rejection markets, including with respect to other products and potential products in such markets;
- our ability to enter into new collaborative arrangements with respect to our product candidates;
- the terms and timing of any future collaborative, licensing or other arrangements that we may establish;
- our ability to raise additional capital to carry through with our clinical development plans and current and future operations and the terms of any related financing arrangements;
- the timing of achievement of, or failure to achieve, our and any potential future collaborators' clinical, regulatory and other milestones, such as the commencement of clinical development, the completion of a clinical trial or the receipt of regulatory approval;
- announcement of FDA approval or non-approval of our product candidates or delays in or adverse events during the FDA review process;
- actions taken by regulatory agencies with respect to our product candidates or products, our clinical trials or our sales and marketing activities, including regulatory actions requiring or leading to restrictions, limitations and/or warnings in the label of an approved product candidate;
- uncontemplated problems in the supply of the raw materials used to produce our product candidates;
- the commercial success of any product approved by the FDA or its foreign counterparts;
- introductions or announcements of technological innovations or new products by us, our potential future collaborators, or our competitors, and the timing of these introductions or announcements;
- market conditions for equity investments in general, or the biotechnology or pharmaceutical industries in particular;
- we may have limited or very low trading volume that may increase the volatility of the market price of our ADSs;
- regulatory developments in the United States and foreign countries;
- changes in the structure or reimbursement policies of health care payment systems;
- any intellectual property infringement lawsuit involving us;
- actual or anticipated fluctuations in our results of operations;
- changes in financial estimates or recommendations by securities analysts;
- hedging or arbitrage trading activity that may develop regarding our ADSs;
- regional or worldwide recession;
- sales of large blocks of our Ordinary Shares or ADSs;
- sales of our Ordinary Shares or ADSs by our executive officers, directors and significant shareholders;
- managerial costs and expenses;
- changes in accounting principles; and
- the loss of any of our key scientific or management personnel.

The stock markets in general, and the markets for biotechnology stocks in particular, have experienced significant volatility that has often been unrelated to the operating performance of particular companies. The financial markets continue to face significant uncertainty, resulting in a decline in investor confidence and concerns about the proper functioning of the securities markets, which decline in general investor confidence has resulted in depressed stock prices for many companies notwithstanding the lack of a fundamental change in their underlying business models or prospects. These broad market fluctuations may adversely affect the trading price of our Ordinary Shares or ADSs.

In the past, class action litigation has often been instituted against companies whose securities have experienced periods of volatility in market price. Any such litigation brought against us could result in substantial costs, which would hurt our financial condition and results of operations and divert management's attention and resources, which could result in delays of our clinical trials or commercialization efforts.

***Insiders have control over us which could delay or prevent a change in corporate control or result in the entrenchment of management and/or the board of directors.***

As of September 30, 2015, our directors and executive officers, together with their affiliates and related persons, beneficially own, in the aggregate, approximately 61.7% of our outstanding Ordinary Shares. RPC, which is controlled by our chairman Ray Prudo, beneficially owns approximately 61.3% of our outstanding Ordinary Shares. Accordingly, these shareholders, if acting together, or Ray Prudo, individually, may have the ability to impact the outcome of matters submitted to our shareholders for approval, including the election and removal of directors and any merger, consolidation, or sale of all or substantially all of our assets. In addition, these persons may have the ability to influence the management and affairs of our company. Accordingly, this concentration of ownership may harm the market price of our ADSs by:

- delaying, deferring, or preventing a change in control;
- entrenching our management and/or the board of directors;
- impeding a merger, consolidation, takeover, or other business combination involving us; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

***Your investment may be diluted by exercises of outstanding options and warrants.***

As of September 30, 2015, we had outstanding options to purchase an aggregate of 56,345,315 of our Ordinary Shares at a weighted average exercise price of $0.37 per share and warrants to purchase an aggregate of 7,588,526 shares of our Ordinary Shares at a weighted average exercise price of $0.90 per share. The exercise of such outstanding options and warrants will result in dilution of your investment. In addition, as described below, you may experience additional dilution if we issue Ordinary Shares in the future. As a result of this dilution, you may receive significantly less than the full purchase price you paid for the shares in the event of liquidation.

***Future sales and issuances of our Ordinary Shares or rights to purchase Ordinary Shares pursuant to our equity incentive plans could result in additional dilution of the percentage ownership of our shareholders and could cause our share price to fall.***

We expect that significant additional capital will be needed in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our shareholders may experience substantial dilution. We may sell Ordinary Shares (which may be represented by ADSs), convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell Ordinary Shares, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing shareholders, and new investors could gain rights superior to our existing shareholders.

***Sales of a substantial number of our Ordinary Shares by our existing shareholders in the public market could cause our stock price to fall.***

Sales of a substantial number of our Ordinary Shares in the public market or the perception that these sales might occur, could significantly reduce the market price of our Ordinary Shares and impair our ability to raise adequate capital through the sale of additional equity securities.

***Anti-takeover provisions in our charter documents and under English law could make an acquisition of our company more difficult and may prevent attempts by our shareholders to replace or remove our organization management.***

Provisions in our articles of incorporation may delay or prevent an acquisition or a change in management. These provisions include a classified board of directors and a prohibition on actions by written consent of the our shareholders. Although we believe these provisions collectively will provide for an opportunity to receive higher bids by requiring potential acquirors to negotiate with our board of directors, they would apply even if the offer may be considered beneficial by some shareholders. In addition, these provisions may frustrate or prevent any attempts by our shareholders to replace or remove then current management by making it more difficult for shareholders to replace members of the board of directors, which is responsible for appointing the members of management.

***We do not anticipate paying cash dividends, and accordingly, shareholders must rely on the appreciation in our ADSs for any return on their investment.***

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Therefore, the success of an investment in our ADSs will depend upon any future appreciation in their value. There is no guarantee that our ADSs will appreciate in value or even maintain the price at which our shareholders have purchased their shares.

***We were and are required to evaluate our internal control over financial reporting under Section 404 of the Sarbanes-Oxley Act of 2002, and any adverse results from such evaluation could result in a loss of investor confidence in our financial reports and have an adverse effect on the price of our ADSs.***

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, we were required to furnish a report by our management on our internal control over financial reporting for fiscal 2014 (included in our Annual Report on Form 20-F), which was the year following our first annual report required to be filed with the SEC and are required to furnish a report by our management on our internal control over financial reporting for fiscal 2015. Such reports contain, among other matters, an assessment of the effectiveness of our internal control over financial reporting as of the end of our fiscal year, including a statement as to whether or not our internal control over financial reporting is effective. These assessments must include disclosure of any material weaknesses in our internal control over financial reporting identified by management. If we are unable to assert that our internal control over financial reporting is effective, we could lose investor confidence in the accuracy and completeness of our financial reports, which could have an adverse effect on the price of our stock ADSs.

Our independent registered public accounting firm is not required to formally attest to the effectiveness of our internal control over financial reporting until the later of the year following our first annual report required to be filed with the SEC, or the date we are no longer an "emerging growth company." At such time, our independent registered public accounting firm may issue a report that is adverse in the event it is not satisfied with the level at which our controls are documented, designed or operating. Our remediation efforts may not enable us to avoid a material weakness in the future. We will remain an "emerging growth company" for up to five years, although if the market value of our ADSs that is held by non-affiliates exceeds $700 million as of any June 30 before that time, we would cease to be an "emerging growth company" as of the following December 31. Furthermore, as a result of the extended time period afforded us as an "emerging growth company," the effectiveness of our internal control over financial reporting may not be as transparent to our investors as they may otherwise expect of a public reporting company, which could further impact investor confidence in the accuracy and completeness of our financial reports.

***We incur significant costs and demands upon management as a result of complying with the laws and regulations affecting public companies, which could harm our operating results.***

As a public company, we incur significant legal, accounting and other expenses, including costs associated with public company reporting requirements. We also incur costs associated with current corporate governance requirements, including requirements under Section 404 and other provisions of SOX, as well as rules implemented by the SEC and The NASDAQ Stock Market. The expenses incurred by public companies for reporting and corporate governance purposes have increased dramatically in recent years. We estimate these costs to be approximately $1,000,000 over the next fiscal year and on an annual basis thereafter.

However, for as long as we remain an "emerging growth company" as defined in the JOBS Act, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a non-binding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We intend to take advantage of these reporting exemptions until we are no longer an "emerging growth company."

Under the JOBS Act, "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. In other words, an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We are choosing to "opt out" of the extended transition period related to the exemption from new or revised accounting standards, and as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies. This election is irrevocable. We will remain an "emerging growth company" for up to five years, although if the market value of our ADSs that are held by non-affiliates exceeds $700 million as of any June 30 before that time, we would cease to be an "emerging growth company" as of the following December 31. After we are no longer an "emerging growth company," we expect to incur significantly higher expenses and devote substantially more management effort toward ensuring compliance with the requirements of Section 404 of the Sarbanes-Oxley Act of 2002, when applicable to us.

***We are an "emerging growth company" and as a result of this and other reduced disclosure requirements applicable to emerging growth companies, our ADSs may be less attractive to investors.***

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. In addition, Section 107 of the JOBS Act also provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. In other words, an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We are choosing to "opt out" of the extended transition period related to the exemption from new or revised accounting standards, and as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies. This election is irrevocable. We cannot predict if investors will find our Ordinary Shares less attractive because of our reduced disclosure requirements. If some investors find our Ordinary Shares less attractive as a result, there may be a less active trading market for our ADSs and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an "emerging growth company." We will remain an "emerging growth company" for up to five years, although if the market value of our Ordinary Shares that is held by non-affiliates exceeds $700 million as of any June 30 before that time, we would cease to be an "emerging growth company" as of the following December 31.

***U.S. investors may not be able to enforce their civil liabilities against our company or certain of our directors, controlling persons and officers.***

It may be difficult for U.S. investors to bring and/or effectively enforce suits against our company outside of the United States. We are a public limited company incorporated in England and Wales under the Companies Act 2006, as amended. Several of our directors are not residents of the United States, and all or substantial portions of their assets are located outside of the United States. As a result, it may be difficult for U.S. holders of our Ordinary Shares or ADSs to effect service of process on these persons within the United States or to make effective recovery in the United States by enforcing any judgments rendered against them. In addition, if a judgment is obtained in the U.S. courts based on civil liability provisions of the U.S. federal securities laws against us or our directors or officers, it may, depending on the jurisdiction, be difficult to enforce the judgment in the non-U.S. courts against us and any of our non-U.S. resident executive officers or directors. Accordingly, U.S. shareholders may be forced to bring legal proceedings against us and our respective directors and officers under English law and in the English courts in order to enforce any claims that they may have against us or our directors and officers. The enforceability of a U.S. judgment in the United Kingdom will depend on the particular facts of the case as well as the laws and treaties in effect at the time. The United States and the United Kingdom do not currently have a treaty providing for reciprocal recognition and enforcement of judgments (other than arbitration awards) in civil and commercial matters. Nevertheless, it may be difficult for U.S. shareholders to bring an original action in the English courts to enforce liabilities based on the U.S. federal securities laws against us and any of our non-U.S. resident executive officers or directors.

***Holders of ADSs must act through the depositary to exercise their rights as shareholders of our company.***

Holders of our ADSs do not have the same rights of our shareholders and may only exercise the voting rights with respect to the underlying Ordinary Shares in accordance with the provisions of the deposit agreement for the ADSs. Under our amended and restated memorandum and articles of association, the minimum notice period required to convene an Annual General Meeting is no less than 21 clear days' notice and 14 clear days' notice for a general meeting (unless, in the case of an annual general meeting all members entitled to attend and vote at the meeting, or in the case of a general meeting, a majority of the members entitled to attend and vote who hold not less than 95% of the voting shares (excluding treasury shares), agree to shorter notice). When a general meeting is convened, holders of our ADSs may not receive sufficient notice of a shareholders' meeting to permit them to withdraw their Ordinary Shares to allow them to cast their vote with respect to any specific matter. In addition, the depositary and its agents may not be able to send voting instructions to holders of our ADSs or carry out their voting instructions in a timely manner. We will make all reasonable efforts to cause the depositary to extend voting rights to holders of our ADSs in a timely manner, but we cannot assure them that they will receive the voting materials in time to ensure that they can instruct the depositary to vote their ADSs. Furthermore, the depositary and its agents will not be responsible for any failure to carry out any instructions to vote, for the manner in which any vote is cast or for the effect of any such vote. As a result, holders of our ADSs may not be able to exercise their right to vote and they may lack recourse if their ADSs are not voted as they requested. In addition, in the capacity as an ADS holder, they will not be able to call a shareholders' meeting.

***The depositary for our ADSs will give us a discretionary proxy to vote our Ordinary Shares underlying ADSs if a holder of our ADSs does not vote at shareholders' meetings, except in limited circumstances, which could adversely affect their interests.***

Under the deposit agreement for the ADSs, the depositary will give us a discretionary proxy to vote our Ordinary Shares underlying ADSs at shareholders' meetings if a holder of our ADSs does not vote, unless:

- we have failed to timely provide the depositary with our notice of meeting and related voting materials;
- we have instructed the depositary that we do not wish a discretionary proxy to be given;
- we have informed the depositary that there is substantial opposition as to a matter to be voted on at the meeting; or
- a matter to be voted on at the meeting would have a material adverse impact on shareholders.

The effect of this discretionary proxy is that a holder of our ADSs cannot prevent our Ordinary Shares underlying such ADSs from being voted, absent the situations described above, and it may make it more difficult for shareholders to influence the management of our company. Holders of our Ordinary Shares are not subject to this discretionary proxy.

***Holders of our ADSs may be subject to limitations on transfers of ADSs.***

ADSs are transferable on the books of the depositary. However, the depositary may close its transfer books at any time or from time to time when it deems expedient in connection with the performance of its duties. In addition, the depositary may refuse to deliver, transfer or register transfers of ADSs generally when our books or the books of the depositary are closed, or at any time if we or the depositary deems it advisable to do so because of any requirement of law or of any government or governmental body, or under any provision of the deposit agreement, or for any other reason.

***The rights of holders of our ADSs to participate in any future rights offerings may be limited, which may cause dilution to their holdings and they may not receive cash dividends if it is impractical to make them available to them.***

We may from time to time distribute rights to our shareholders, including rights to acquire our securities. However, we cannot make rights available to holders of our ADSs in the United States unless we register the rights and the securities to which the rights relate under the Securities Act or an exemption from the registration requirements is available. Also, under the deposit agreement, the depositary will not make rights available to holders of our ADSs unless either both the rights and any related securities are registered under the Securities Act, or the distribution of them to ADS holders is exempted from registration under the Securities Act. We are under no obligation to file a registration statement with respect to any such rights or securities or to endeavor to cause such a registration statement to be declared effective. Moreover, we may not be able to establish an exemption from registration under the Securities Act. Accordingly, holders of our ADSs may be unable to participate in our rights offerings and may experience dilution in their holdings.

In addition, the depositary has agreed to pay to holders of our ADSs the cash dividends or other distributions it or the custodian receives on our Ordinary Shares or other deposited securities after deducting its fees and expenses. Holders of our ADSs will receive these distributions in proportion to the number of Ordinary Shares their ADSs represent. However, the depositary may, at its discretion, decide that it is inequitable or impractical to make a distribution available to any holders of ADSs. For example, the depositary may determine that it is not practicable to distribute certain property through the mail, or that the value of certain distributions may be less than the cost of mailing them. In these cases, the depositary may decide not to distribute such property and holders of our ADSs will not receive any such distribution.

**Risks Relating to the Acquisition**

***The integration of Akari and Volution will require significant resources and may not be successful.***

There is no history of Akari (formerly known as "Celsus Therapeutics, Plc") and Volution as a combined company. Additionally, various decisions regarding management restructuring, operational staffing and reporting systems have not yet been finalized. As a result, there can be no guarantee that the two companies will operate together successfully as a combined company. Integration of the companies and consolidation of their operations will require considerable management time, which could result in the diversion of management resources from other important matters.

***The failure to integrate successfully the acquired business in the expected timeframe could adversely affect the combined company's future results.***

The failure to integrate successfully and to manage successfully the challenges presented by the integration process may result in the combined company's failure to achieve some or all of the anticipated benefits of the Acquisition.

Potential difficulties that may be encountered in the integration process include the following:

- using the combined company's cash and other assets efficiently to develop the business of the combined company;
- appropriately managing the liabilities of the combined company;
- potential unknown or currently unquantifiable liabilities associated with the Acquisition and the operations of the combined company; and
- performance shortfalls at one or both of the companies as a result of the diversion of management's attention caused by integrating the companies' operations.

***The operations of the combined company may be adversely affected by the integration.***

The combined company will be subject to various risks following the consummation of the Acquisition, including:

- interruption of the operations of the combined companies; and
- anticipated and unanticipated costs relating to additional administrative or operating expenses of each business.

These and other factors could adversely affect the combined business and operating results.

## FORWARD-LOOKING STATEMENTS

This prospectus and the Information Incorporated by Reference into this prospectus contain forward-looking statements. These forward-looking statements are based on current expectations and beliefs and involve numerous risks and uncertainties that could cause actual results to differ materially from expectations. These forward-looking statements should not be relied upon as predictions of future events as we cannot assure you that the events or circumstances reflected in these statements will be achieved or will occur. You can identify forward-looking statements by the use of forward-looking terminology including "believes," "expects," "may," "will," "should," "seeks," "intends," "plans," "pro forma," "estimates," or "anticipates" or the negative of these words and phrases or other variations of these words and phrases or comparable terminology. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. For example, forward-looking statements include, but are not limited to statements about:

- the timing and success of preclinical studies and clinical trials conducted by us and our development partners;
- the ability to obtain and maintain regulatory approval of Coversin and any other our product candidates, and the labeling for any approved products;
- the scope, progress, expansion, and costs of developing and commercializing Coversin or other future product candidates;
- the size and growth of the potential markets for Coversin or other future product candidates and the ability to serve those markets;
- our expectations regarding our expenses and revenue, the sufficiency of our cash resources and needs for additional financing;
- the rate and degree of market acceptance of any of Coversin or other future product candidates;
- our expectations regarding competition;
- our anticipated growth strategies;
- our ability to attract or retain key personnel;
- our ability to establish and maintain development partnerships;
- our expectations regarding federal, state and foreign regulatory requirements;
- regulatory developments in the United States and foreign countries;
- our ability to obtain and maintain intellectual property protection for Coversin and other future product candidates;
- the anticipated trends and challenges in our business and the market in which we operate; and
- statements of belief and any statement of assumptions underlying any of the foregoing.

Additional factors that could cause actual results to differ materially from those expressed in the forward-looking statements are discussed in reports filed with the SEC by Akari. We encourage you to read these filings as they are made. See "Where You Can Find Additional Information" beginning on page i of this prospectus.

**If any of these risks or uncertainties materializes or any of these assumptions proves incorrect, our results could differ materially from the forward-looking statements. All forward-looking statements in this prospectus are current only as of the date on which the statements were made. We do not undertake any obligation to publicly update any forward-looking statement to reflect events or circumstances after the date on which any statement is made or to reflect the occurrence of unanticipated events.**

## UNAUDITED PRO FORMA CONSOLIDATED FINANCIAL INFORMATION

Incorporated by reference herein is the unaudited pro forma consolidated financial information reflecting the consummation of the Acquisition and the Financing in a transaction to be accounted for as a reverse acquisition with Volution Immuno Pharmaceuticals SA treated as the accounting acquirer. This financial information is included in Exhibit 99.3 to our Current Report on Form 8-K/A, filed with the Commission on October 16, 2015 and consists of (i) the unaudited pro forma consolidated statement of operation for the six month period ended June 30, 2015, (ii) the unaudited pro forma consolidated balance sheets, as of June 30, 2015 and (iii) the unaudited pro forma consolidated statement of operation, for the period from January 1, 2014 through December 31, 2014. The unaudited pro forma consolidated financial information should be read in conjunction with the historical consolidated financial statements and the related notes of Akari, included in Akari's periodic reports filed with the Commission, and of Volution, included in Exhibits 99.1 and 99.2 to our Current Report on Form 8-K/A, filed with the Commission on October 16, 2015 and incorporated by reference herein. See "Incorporation of Information by Reference."

## USE OF PROCEEDS

This prospectus relates ADSs representing our Ordinary Shares that may be offered and sold from time to time by the Selling Shareholders. We will not receive any of the proceeds resulting from the sale of the ADSs representing Ordinary Shares by the Selling Shareholders.

## BUSINESS

### Overview

We are a clinical-stage biopharmaceutical company focused on the development and commercialization of innovative therapeutics to treat rare and orphan autoimmune and inflammatory diseases. Our lead drug, Coversin, a second-generation and potentially best-in-class complement inhibitor, acts on complement component-C5, preventing release of C5a and formation of C5b – 9 (also known as the membrane attack complex or MAC). Coversin is a recombinant small protein (16,740 Da) derived from a protein discovered in the saliva of the *Ornithodoros moubata* tick, where it modulates the host immune system to allow the parasite to feed without alerting the host to its presence or provoking an immune response.

C5 inhibition is a new form of treatment that was commercially pioneered by Alexion Pharmaceuticals in 2007 (Nasdaq: ALXN) with FDA approval of their drug Soliris® (eculizumab) to treat PNH. Soliris® is currently the only drug approved to treat two complement-related orphan indications, PNH and aHUS, and has annual sales of $2.2 billion. Eculizumab is a humanized monoclonal antibody, administered by twice monthly intravenous infusion (IV).

To date, we have demonstrated: (i) 100% inhibition of complement C5 activity by Coversin within 12 hours in a Phase Ia clinical trial in healthy volunteers; (ii) that Coversin inhibits PNH red blood cell lysis in vitro and (iii) that Coversin can achieve full complement inhibition in the blood of eculizumab-resistant patients tested to date. We believe that the subcutaneous formulation of Coversin will provide considerable patient benefits, accelerating recruitment for trials, and patient uptake if Coversin is approved by regulatory authorities for commercial sale.

Scientific understanding of the role of complement C5 inhibition in the treatment of a range of rare diseases related to uncontrolled activation of the complement arm of the immune system is growing. These rare diseases include conditions such as paroxysmal nocturnal haemoglobinuria (PNH), atypical Hemolytic Uremic Syndrome (aHUS), myasthenia gravis (MG), Guillain Barré syndrome (GBS), and Sjögren's syndrome.

### The Complement System

In mammals, including humans, the immune system exists primarily to protect the body from invasion by harmful microbes and parasites. In humans, it is divided into the innate immune system, nonspecific defense mechanisms that come into play immediately or within hours of an antigen's appearance in the body, and the adaptive immune system, which develops after birth in response to exposure to foreign antigens. The adaptive immune system mounts attacks against organisms to which the host has previously been exposed, principally through production of antibodies and T-cells. The complement system (see figure 1, below), in evolutionary terms one of the oldest parts of the immune system, is considered to bridge the divide between innate and adaptive immunity, working with the immune system to disable and clear out foreign invaders and unwanted cells. It acts by triggering one or all of three processes: inflammation, thrombosis or cell destruction by lysis. Together with white blood cells and antibodies, it marks organisms recognized as pathogenic for destruction, and then assists in this process by signalling for the appropriate white cells and mounting a direct lytic (destructive) attack on foreign cells.

Another important function of the complement system is the recognition of dead and dying host cells, marking them for removal by phagocytes. When activated, the complement system produces a cascade of proteins. C5, near the end of the complement cascade, is then split into the anaphylatoxin C5a, a powerful inflammatory substance in its own right, and into C5b, necessary for the formation of the membrane attack complex (MAC), which is responsible for much of the tissue damage in many autoimmune diseases. Although both C5a and the MAC provide useful protection against microbial infection when produced in appropriate circumstances, their unregulated release may lead to life-threatening inflammatory and autoimmune conditions. Coversin binds to the complement C5 molecule to prevent it splitting into complement C5a and C5b. The coversin molecule also has a binding site for the pro-inflammatory cytokine leukotriene B4 (LTB4). This confers additional anti-leukocyte properties and may contribute to additional efficacy in conditions in which trafficking of neutrophils and eosinophils play a role. Although not immediate targets for the Company such diseases include asthma, COPD and other respiratory inflammatory diseases.

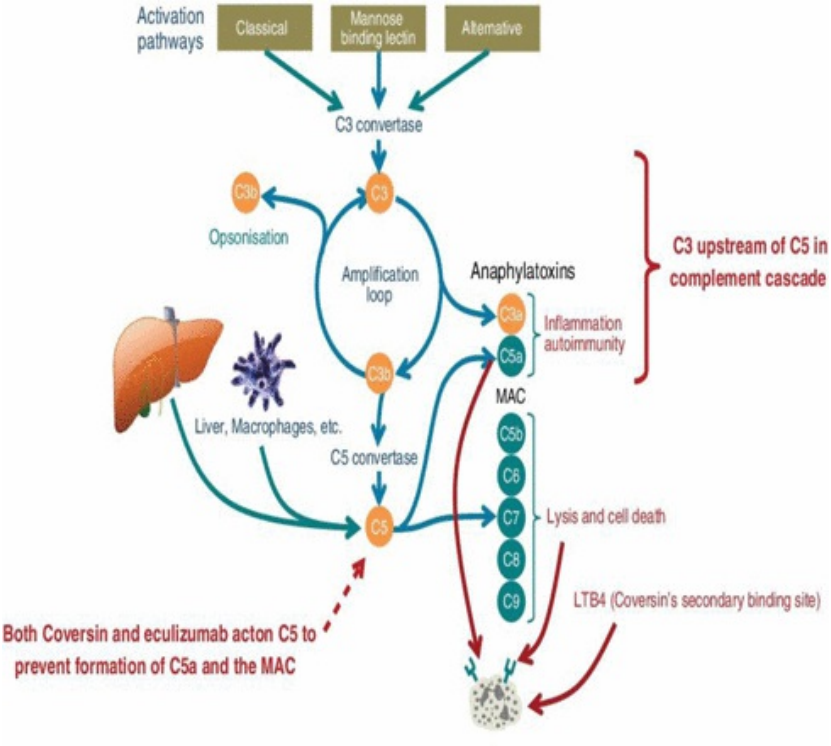



Figure 1

Complement C3 and C5 are produced continuously by organs such as the liver and by cells such as macrophages to act as raw material to "prime the pump" should the complement system be called into action. Once activated, the whole complement cascade runs automatically until the potential threat is eliminated by one of the immune mechanisms. To prevent it running out of control, the complement system also includes a number of regulator, or inhibitor, proteins and it is usually when these proteins are deficient for genetic or other reasons that the complement system becomes dysregulated, and may start to directly attack the body's own healthy organs and tissues. In other circumstances, the complement system may run out of control in response to a relatively mild infection which results in a "cytokine storm" in which an uncontrolled inflammatory reaction or thrombotic event endangers the body's own survival. Until the relatively recent discovery and regulatory approval of clinical complement inhibitors (such as eculizumab), doctors were able to offer little effective treatment for such life-threatening events.

There are known pathological consequences of total terminal complement inhibition. These are well-understood both through study of people with a congenital genetic total C5 deficiency, and via careful follow-up of patients receiving eculizumab, some of whom have been terminally complement suppressed for more than nine years. It has been found that the most serious consequence of terminal complement inhibition is an increased tendency to meningitis caused by the *Neisseria meningitidis* bacterium. As a result of this discovery, all patients receiving eculizumab are carefully monitored and given either or both meningitis immunisation and prophylactic antibiotics. We expect that this precaution will also apply to patients treated with Coversin.

While it is possible to target other components of the complement system, like C3, it remains unclear if these targets will be safe or effective. C3, for example, plays a larger role in the complement system than C5, in that it not only leads eventually to the activation of C5, but is also involved in opsonization and removal of senescent cells as well as other immune functions. Unlike patients with inherited C5 deficiency, where the greatest risk is from *Neisseria* infections, which can be guarded against with a meningitis vaccine, C3 inhibition may carry a more significant risk since individuals with congenital C3 deficiencies suffer from generalised infections and other developmental abnormalities, rarely surviving beyond early childhood if untreated.

**Lead Drug Candidate — Coversin**

Our lead drug, Coversin, a second-generation and potentially best-in-class complement inhibitor, acts on complement C5, preventing release of C5a and formation of C5b-9 (also known as the membrane attack complex or MAC). Coversin is a recombinant small protein (16,740 Da) derived from a native protein discovered in the saliva of the *Ornithodoros moubata* tick, where it modulates the host immune system to allow the parasite to feed without alerting the host to its presence or provoking an immune response.

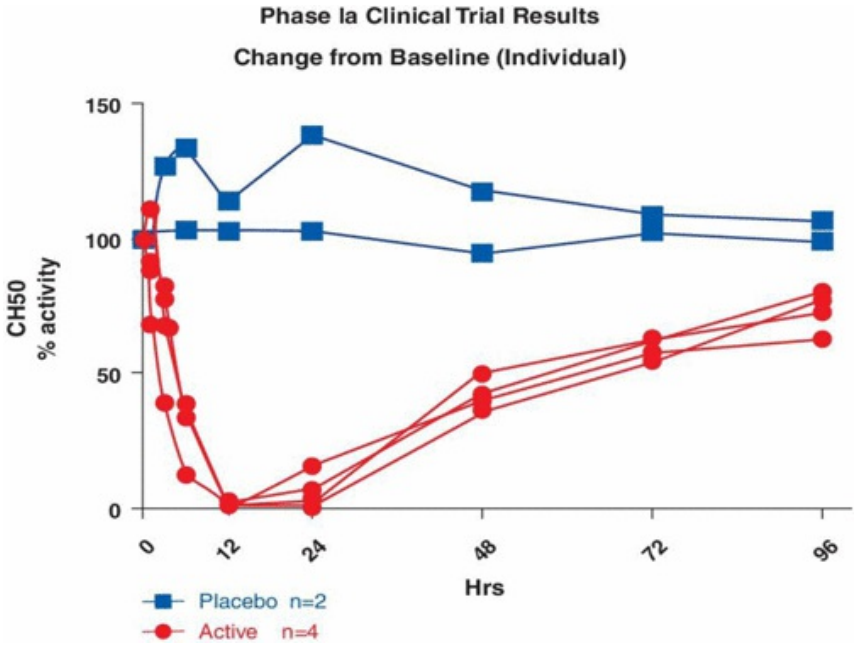
To date, we have demonstrated: (i) 100% inhibition of complement C5 activity by Coversin within 12 hours in a Phase Ia clinical trial in healthy volunteers; (ii) that Coversin inhibits PNH red blood cell lysis in vitro and (iii) that Coversin can achieve full complement inhibition in the blood of eculizumab-resistant patients tested to date. We believe that the subcutaneous formulation of Coversin will provide considerable patient benefits, accelerating recruitment for trials, and patient uptake if Coversin is approved by regulatory authorities for commercial sale.

Although the precise binding site is different, Coversin acts on C5 in broadly the same way as eculizumab, inhibiting C5 activation and release of C5a and the formation of the membrane attack complex (MAC). As Coversin is active across mammalian species, We have been able to carry out numerous pre-clinical experiments, demonstrating activity in a broad range of complement mediated diseases.

**Clinical Development Program — Past and Future**

The role of complement dysregulation in inflammatory and autoimmune diseases is becoming increasingly recognized. From a handful of diseases known to be associated with disorders of the complement system thirty years ago, there are now more than 80 described in medical literature. Our future development strategy for Coversin will likely be dependent on a number of factors, including commercial considerations, availability of clinical material, support from key opinion leaders for development targeting specific indications, and human and other resources. It is likely that our chief focus will be on rare and orphan diseases, including disease states spanning hematology, nephrology, transplantation, neurology and ophthalmology.

Coversin entered clinical development in 2013 when a Phase Ia clinical trial was initiated under a Clinical Trials Authorisation (CTA) issued by the Medicines and Healthcare products Regulatory Agency (MHRA), an executive agency of the Department of Health in the United Kingdom. The primary objective of this single ascending dose, first-in-man study was to explore the safety profile of Coversin. The drug was well tolerated, and no serious or dose-related adverse events were reported. The secondary objective of this Phase Ia clinical trial was to examine the effect of Coversin on complement activity at the highest, therapeutic dose. This showed that the peak onset of action was about nine hours after injection, and that the effect of a single dose persisted for more than 96 hours. The effects were consistent between all subjects and showed 100% inhibition of the complement system (see Phase Ia trial results, at right) within 12 hours. This trial suggested that Coversin is suitable for once daily subcutaneous injection. Confirmation of this and of the optimal repeat dose are expected to be obtained in a Phase Ib repeat dose study to be initiated in the fourth quarter of 2015.




Our initial clinical targets will be PNH, GBS, aHUS, and the treatment of patients with polymorphisms of the C5 molecule which interfere with correct binding of eculizumab, making them resistant to treatment with that drug. The latter are expected to be initially treated under compassionate use and named patient protocols until sufficient safety and efficacy data have been accumulated to allow for regulatory approval.

A Phase Ib clinical trial in healthy volunteers is currently expected to be initiated in the fourth quarter of 2015, and we expect to initiate a Phase II trial in PNH patients in the first quarter of 2016. We expect to begin treating PNH patients resistant to eculizumab on a compassionate basis before year-end 2015, and to start Phase II trials in GBS in the first half of 2016 and in aHUS beginning later in 2016. We expect data from the Phase II trial in PNH to be available by year-end 2016. If Coversin achieves satisfactory results in those Phase II clinical trials, we expect to immediately proceed into Phase III pivotal studies in both Europe and the United States.

Throughout 2016, we expect to present data on eculizumab resistant compassionate use patients as they become available.

Coversin, at 17 kDa, is much smaller than typical antibodies currently used in therapeutic treatment. Coversin can be self-administered by subcutaneous injection, much like an insulin injection, which the Company believes will provide considerable benefits in terms of patient convenience. Use of fixed dose regimens and a dry powder formulation will further increase patient comfort and convenience, and patient surveys suggest that a majority of patients would prefer to self-inject daily than undergo intravenous infusions. Coversin's small physical size allows it to be potentially used in a variety of formulations, some of which may enable therapeutic use via topical or inhaled routes of administration.

***Toxicology***

We successfully completed short-term toxicology trials of Coversin in rats and cynomolgus monkeys at doses of up to 100 times the highest expected human dose. No evidence of any harmful reaction or laboratory findings outside the generally-accepted normal range was found. These toxicology studies were used as a basis to gain regulatory authorization for Coversin's Phase 1a clinical trial in 2014, and will also support the five day repeat-dose Phase Ib clinical trial to be initiated in 2015.

We have initiated longer term (one month) toxicology studies in mice and cynomolgus monkeys and, if these do not show any unexpected toxicity, we expect the UK regulatory authorities (MHRA) to require only a single animal species (mouse) sufficient for long term toxicology studies of up to six months to support eventual marketing authorization in humans.

Certain specialized forms of toxicology studies, including both carcinogenicity and reproductive toxicology studies, will also be necessary before marketing authorization. These are normally performed in mice, and we expect to complete these additional toxicology studies concurrently with planned Phase II and Phase III clinical trials.

***Immunogenicity***

We successfully completed a chronic (28 day) dosing experiment in mice to investigate whether daily subcutaneous administration of the expected therapeutic dose of Coversin induces an antibody response, and whether the antibodies neutralise complement inhibition by Coversin. The data from this chronic dosing experiment showed Coversin was well tolerated with no injection site allergic reactions or behavioral changes. Coversin can induce formation of low titre anti-drug IgG antibodies in mice after four weeks of daily inoculation, which is not uncommon, but these antibodies were not neutralising and had no effect on Coversin's ability to inhibit complement.

We believe this data supports the development of Coversin for chronic use in humans. During the upcoming Phase Ib and Phase II clinical trials and chronic toxicology studies, we plan to concurrently investigate whether any antibodies arise to Coversin, and if they do, whether these antibodies affect the drug's activity or clearance rates and consequently drug tolerance and efficacy of the drug.

***Metabolic studies***

Metabolic studies, also known as ADME (administration, distribution, metabolism and excretion), are routinely undertaken in the development of any new drug. We have carried out a comprehensive program of such studies with Coversin in animals and as part of its Phase Ia trial and has gained a good insight into the behavior of the molecule.

When administered intravenously, Coversin is immediately available to bind complement C5, which circulates continuously in the bloodstream. Any Coversin that remains unbound is rapidly filtered and excreted by the kidney with a circulating half-life of approximately 30 minutes. Coversin is uniformly distributed through most blood-perfused tissues of the body, but does not cross the intact blood brain barrier into the central nervous system. If given in excess, Coversin will ablate all circulating C5, as was demonstrated in the Company's Phase Ia trial. Complete ablation results in reduction of terminal complement activity to zero until it is replenished by natural production, chiefly by the liver and macrophages. In our Phase Ia trial, 100% C5 inhibition was achieved in 12 hours, and did not return to baseline for four days.

**Target Indications**

***Paroxysmal nocturnal haemoglobinuria***

PNH is an ultra-rare, life-threatening and debilitating disease of the blood with an estimated 8,000 – 10,000 patients across North America and Europe. Due to an acquired genetic deficiency, uncontrolled complement activation in PNH patients allows their own complement system to attack and destroy blood cells, leading to life-threatening complications.

Patients with PNH suffer from chronic complement activation and destruction of some of their blood cells, known as hemolysis, caused by the C5 cleavage product C5b-9 (the membrane attack complex). This hemolysis is associated with further clinical symptoms and negative outcomes, including kidney disease, thrombosis (blood clots), liver dysfunction, fatigue, impaired quality of life, recurring pain, shortness of breath, pulmonary hypertension, intermittent episodes of dark-colored urine (hemoglobinuria), and anemia. When the destruction of red blood cells is sufficiently large, recurrent blood transfusions may be necessary.

Before the introduction of eculizumab, PNH patients, many of whom were in young adulthood, faced a life of repeated blood transfusions, thromboembolic complications and typical life expectancies of only 8 – 10 years from diagnosis. There are no animal models of the autoimmune hematological condition paroxysmal nocturnal haemoglobinuria (PNH). The advent of eculizumab, the first effective complement C5 inhibitor, transformed this bleak outlook, and most of these patients now enjoy a more normal life expectancy.

***Eculizumab resistance***

Coversin and eculizumab both prevent the splitting of complement C5 into its active components, but they each accomplish this effect by binding to specific and different sites on the molecule. It has recently been discovered that a small but identifiable subgroup of eculizumab-treated patients have a C5 polymorphism affecting the eculizumab binding site which prevents correct binding and makes these patients resistant to treatment — but does not appear to affect binding by Coversin in those patients tested to date. While this polymorphism has been identified in 3.5% of the Japanese population, the prevalence of this and other potential mutations that may interfere with eculizumab binding activity in non-Japanese patients remains unknown.

A currently available blood test enables some of these eculizumab-resistant patients to be identified, we are in discussions with regulatory authorities to allow treatment of patients with Coversin under compassionate or named-patient protocols, as there are no alternate treatments currently available. We have identified several non-Japanese patients to date and has demonstrated that Coversin fully inhibits complement activity in the blood of these patients by blocking C5.

***Guillain Barré syndrome***

Guillain Barré syndrome is an acute immune-mediated polyneuropathy where the immune system is triggered into attacking the myelin sheath surrounding nerves, leading to progressive, fairly symmetric muscle weakness accompanied by absent or depressed deep tendon reflexes. Patients usually present a few days to a week after onset of symptoms. The weakness can vary from mild difficulty with walking to nearly complete paralysis of all extremities, facial, respiratory, and bulbar muscles.

Guillain-Barré syndrome occurs worldwide, with an overall incidence of one to two per 100,000 per year. According to the U.S. Department of Health and Human Services, Agency for Healthcare Research and Quality, there are over 6,000 patients admitted to US hospitals with a primary diagnosis of GBS every year. While all age groups are affected, the incidence increases by approximately 20% with every ten-year increase in age beyond the first decade of life. Patients are treated with supportive care, plasma exchange or Intravenous Immunoglobulin (IVIG).

The proportion of patients with GBS who walk independently at six months and one year after diagnosis is approximately 80 and 84 percent, respectively. At one year, full recovery of motor strength occurs in about 60 percent of patients, while severe motor problems persist in about 14 percent. Approximately five to ten percent of patients with GBS have a prolonged course with several months of ventilator dependency and very delayed and incomplete recovery. Within one year of diagnosis, approximately 4 to 5 percent of patients with GBS die despite intensive care. Of patients who become ventilator dependent, about 20 percent will die.

Causes of death include acute respiratory distress syndrome, sepsis, pulmonary emboli, and unexplained cardiac arrest. In an *in vitro* model of GBS, Coversin was shown to prevent the development of the characteristic pathological markers of disease activity, and *in vivo* protected mice from developing respiratory paralysis, the most serious consequence of GBS in humans.

Coversin has been successfully tested in animal models of Guillain Barré syndrome (GBS). In GBS, complement-mediated damage is provoked by the deposition of auto-antibodies, against the neuromuscular junction in the myelin sheath. This in turn triggers systemic complement activation and local tissue destruction, with often devastating neurological consequences.

***Atypical Hemolytic Uremic Syndrome (aHUS)***

Complement-mediated ‘atypical’ hemolytic uremic syndrome (aHUS) is a chronic and life-threatening ultra-rare genetic disease with an estimated prevalence of seven per one million individuals in which uncontrolled complement activation causes blood clots in small blood vessels throughout the body, or thrombotic microangiopathy (TMA), leading to kidney failure, stroke, heart attack and death.

The prognosis for patients with aHUS is generally poor. Approximately 70% of patients with the most common mutation experience chronic renal insufficiency, chronic dialysis, or death by one year after the first clinical symptoms. aHUS commonly recurs in patients who undergo renal transplantation for the kidney injury and kidney failure suffered due to the uncontrolled complement activity. Approximately 50% of patients with aHUS have been identified to have genetic mutations in at least one of the complement control proteins or neutralizing autoantibodies to complement regulatory factors, which can lead to uncontrolled complement activation. Eculizumab received accelerated FDA approval in 2011 based on data from both prospective and retrospective trials in a cumulative total of 67 adult and pediatric patients.

Eculizumab remains the first and only therapy approved for the treatment of pediatric and adult patients with aHUS. Alexion, the maker of eculizumab, has noted that the opportunity for eculizumab in aHUS is at least as large as PNH, with more patients in the United States receiving eculizumab for aHUS than PNH at a similar timeframe from launch since its approval in aHUS. Given that eculizumab and Coversin have the same mode of action, it is anticipated that Coversin will be effective in treating aHUS patients.

***Sjogren's-related dry eye syndrome***

Sjögren's syndrome is a chronic multisystem inflammatory autoimmune disorder characterized by a combination of dry eyes and dry mouth. According to medical literature, it is estimated that the annual incidence of Sjogren's may range between four to as high as 43 per 100,000 people, with approximately five percent of these patients having severe dry eye. Severe dry eye is a painful and debilitating symptom that can lead to blindness. There is evidence that Coversin has activity against eye surface inflammation. Delivery by the topical ocular route, made possible by Coversin's small molecular size, has considerable advantages both in reducing the total quantity of drug needed and, because the very small topical dose, virtually abolishes the effects of systemic complement inhibition, in reducing the risk of meningitis infection or need for prophylaxis of potential *Neisseria* infections.

Sjögren's syndrome, a complement driven autoimmune disease affects multiple organs including the eye where it is responsible for a very severe form of dry eye which can be sight threatening. It is estimated that dry eye disease generally affects approximately 8% of the population, mainly women, and in 11% of these it is a co-morbidity of Sjögren's syndrome. Thus approximately 2.5m people in the United States suffer from ocular Sjögren's syndrome. The only approved drug for dry eye (but not Sjögren's syndrome), cyclosporine, is of limited efficacy against ocular Sjögren's syndrome.

Coversin's special physical characteristics make it an attractive candidate drug for the treatment of ocular Sjögren's syndrome which is not accessible by this route to antibodies like eculizumab or gene therapies which require systemic complement inhibition. Relative to systemic diseases such as PNH and aHUS, ocular drug development is potentially rapid and new drugs typically gain marketing approval much sooner than their systemic counterparts. Coversin has already successfully completed a 60 day topical eye toxicology study and is in a position to enter eye clinical trials in the near future.

**Market Opportunity in Complement Mediated Diseases**

The NIH estimates that approximately 23.5 million Americans may suffer from an autoimmune disorder, although this number may underestimate actual prevalence as it includes only 24 diseases for which good epidemiology studies were available. Researchers have identified 80 – 100 different autoimmune diseases and suspect at least 40 additional diseases of having an autoimmune basis. These diseases are chronic and can be life-threatening. Autoimmune disease is one of the top 10 leading causes of death in female children and women in all age groups up to 64 years of age. The NIH estimates annual direct health care costs for autoimmune diseases to be in the range of $100 billion. As noted earlier, the complement system works with the immune system to disable and clear out foreign invaders and unwanted cells, and as such, plays an important role in the pathology of many autoimmune diseases. The term "Complement Mediated Diseases" applies to diseases and conditions where a patient's immune system attacks and destroys healthy body tissue by mistake, causing damage through its complement component and through mediators induced by complement activation. These diseases and conditions are often very rare, and include such diseases as PNH, aHUS, Myasthenia Gravis, GBS, transplant mediated organ rejection, glomerulopathies (kidney diseases), as well as numerous other disorders. While not all complement mediated diseases will respond to a direct C5 inhibitor, like Coversin, there is a large market opportunity as demonstrated by eculizumab with $2.2 billion in sales in 2014, with expectation of continued growth to its two approved indications of PNH and aHUS due to many other additional indications in current preclinical and clinical development.

**Competition**

The development and commercialization of new drugs is highly competitive. We will face competition with respect to all product candidates that we may develop or commercialize in the future from pharmaceutical and biotechnology companies worldwide. The key factors affecting the success of any approved product will be its efficacy, safety profile, drug interactions, method of administration, pricing, reimbursement and level of promotional activity relative to those of competing drugs.

Our potential competitors may have substantially greater financial, technical, and personnel resources than we do. In addition, many of these competitors have significantly greater commercial infrastructures. Our ability to compete successfully will depend largely on its ability to leverage its collective experience in drug discovery, development and commercialization to:

- discover and develop medicines that are differentiated from other products in the market, including eculizumab;
- obtain patent and/or proprietary protection for our medicines and technologies;
- obtain required regulatory approvals;
- obtain a commercial partner;
- commercialize its drugs, if approved; and
- attract and retain high-quality research, development and commercial personnel.

*Coversin*. If approved, we would expect Coversin to compete in the market for PNH and aHUS treatment with eculizumab, which was developed by Alexion Pharmaceuticals. Eculizumab is the first and only therapy approved for PNH, is marketed by Alexion and had sales of approximately $2.2 billion in 2014. Clinicians, nurses and patient groups contacted by the Company believe that the ability to self-administer Coversin as a fixed-dose daily subcutaneous injection will be an attractive alternative therapy.

There has been a broad research effort in complement based therapy to date, with eculizumab being the first and only therapy approved that directly inhibits C5. We believe that Coversin is amongst the most advanced in clinical development of next generation C5 inhibitors. However, we are aware of certain other companies and academic institutions that are continuing their efforts to discover and develop alternate complement and/or C5 inhibitors, including Alexion, Alnylam, Swedish Orphan Biovitrum and RA Pharmaceuticals.

We are aware of certain other companies that are focused on developing therapies targeting other aspects of the complement system, including Appelis, Amyndus, Achillion, Omeros, Chemocentryx and True North Therapeutics.

**Sales and Marketing**

Because we are focused on discovery and development of drugs, it currently has no sales, marketing or distribution capabilities in order to commercialize Coversin or any approved drug candidates. If our product candidate Coversin is approved, we intend either to establish a sales and marketing organization with technical expertise and supporting distribution capabilities to commercialize Coversin, or to outsource this function to a third party.

**Manufacturing**

We currently rely on a third-party contract manufacturer (CMO), which complies with FDA's current good manufacturing practice requirements, for all of our clinical supplies, including active pharmaceutical ingredients, or APIs, drug substances and finished drug products for our preclinical research and clinical trials, including the Phase I/II trials for Coversin. Analytical methods that define activity, identity, purity, sterility, endotoxin, and host cell related impurities have been established and qualified for release testing of drug substance. We to complete scale-up to commercial fermentation batch sizes and yields with this CMO by the end of 2016.

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We currently rely, and expect to continue to rely, on third-party contract manufacturers, or CMOs, for the manufacture of Coversin and any other drug candidates that it may develop for larger scale preclinical and clinical testing, as well as for commercial quantities of any drug candidates that are approved.

We currently expect initial commercial supplies of Coversin to be supplied as a dry powder together with syringes prefilled with sterile water for injection. This will enable the drug to be stored for long periods at room temperature and simplify distribution and storage by hospitals and pharmacies. Further evaluation activities are ongoing regarding potential future alternate drug delivery and device options and/or improvements.

We plan to expand our relationship with the current CMO for commercial supplies of Coversin if and when it nears potential approval, and plans to examine alternate CMOs for secondary commercial supplies of Coversin.

**Employees**

As of September 30, 2015, we had five full-time employees and two full-time equivalent consultants.

**Properties**

We currently lease 4,900 square feet of office space in New York, New York, for approximately $24,000 per month. The lease for this property expires in August 2019. We also lease office and laboratory space in London, England. The lease for this property expires in March 2019 and either party may terminate this lease upon three months' advance notice.

**Intellectual Property**

We will be able to protect our technology and products from unauthorized use by third parties only to the extent it is covered by valid and enforceable patents or is effectively maintained as trade secrets. Patents and other proprietary rights are thus an essential element of our business.

Our success will depend in part on our ability to obtain and maintain proprietary protection for our product candidates, technology, and know-how, to operate without infringing on the proprietary rights of others, and to prevent others from infringing it proprietary rights. Our policy is to seek to protect its proprietary position by, among other methods, filing U.S. and foreign patent applications related to its proprietary technology, inventions, and improvements that are important to the development of its business. We also rely on trade secrets, know-how, continuing technological innovation, and in-licensing opportunities to develop and maintain is proprietary position.

We own or have exclusive rights to two United States and 16 foreign issued patents and allowed patent applications, and five United States and 14 foreign pending patent applications, relating to the complement C5 inhibitor protein Coversin and its use in the treatment of key disease indications. Our current patent portfolio covers the jurisdictions of United States, Canada, major European countries, Japan, China, Australia and New Zealand.

Issued United States patents which cover our product candidate Coversin will expire between 2024 and 2025, excluding any patent term extensions that might be available following the grant of marketing authorizations. Issued patents outside of the United States directed to our product candidate Coversin and its uses will expire between 2024 and 2031. We have pending patent applications for our product candidate Coversin that, if issued, would expire in the United States and in countries outside of the United States between 2024 and 2035, excluding any patent term adjustment that might be available following the grant of the patent and any patent term extensions that might be available following the grant of marketing authorizations. These pending patent applications relate to the following specific compositions and methods: complement inhibitor molecule; methods for treating myasthenia gravis; methods for treating peripheral nerve disorders; methods for treating respiratory disorders; and methods for treating viral infections of the respiratory tract. In addition, we have a pending patent application on C5 polymorphisms that, if issued, would expire in the United States and in countries outside of the United States in 2035, excluding any patent term adjustment that might be available following the grant of the patent and any patent term extensions that might be available following the grant of marketing authorizations.

**Orphan Drug Designation**

Most of Coversin's target disease indications are rare diseases, and therefore our plans to pursue orphan drug designation where possible. If granted, each such designation might provide for regulatory exclusivity for seven years in the United States and ten years in the European Union from the date of product approval for individual indications.

Eculizumab has been granted Orphan Status for some of the same disease indications that we propose to treat with Coversin. However, Coversin is not considered structurally similar to eculizumab, and so these preceding Orphan designations should not pose a barrier to market entry for Coversin. There is also a possibility for us to obtain additional Orphan Designation(s) for Coversin beyond those already granted to eculizumab, based on the substantial medical benefits that it may offer in terms of its efficacy in certain clinical populations and dosage forms.

**Government Regulation**

*Government Regulation and Product Approval*

Government authorities in the U.S., at the federal, state and local level, and other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing and export and import of products such as those that the Company is developing. A new drug must be approved by the FDA through the new drug application, or NDA, process and a new biologic must be approved by the FDA through the biologics license application, or BLA, process before it may be legally marketed in the U.S. The animal and other non-clinical data and the results of human clinical trials performed under an Investigational New Drug application, or IND, and under similar foreign applications will become part of the NDA or BLA.

*U.S. Drug Development Process*

In the U.S., the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and in the case of biologics, also under the Public Health Service Act, or PHSA, and implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local, and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, requesting product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement, or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us. The process required by the FDA before a drug or biologic may be marketed in the U.S. generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies according to Good Laboratory Practices or other applicable regulations;
- submission to the FDA of an IND which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials according to Good Clinical Practices to establish the safety and efficacy of the proposed drug for its intended use;
- submission to the FDA of an NDA or BLA;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with current good manufacturing practice, or cGMP, to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity; and
- FDA review and approval of the NDA or BLA.

Once a pharmaceutical candidate is identified for development, it enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information and analytical data, to the FDA as part of the IND. The sponsor will also include a protocol detailing, among other things, the objectives of the first phase of the clinical trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated, if the first phase lends itself to an efficacy evaluation. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Clinical holds also may be imposed by the FDA at any time before or during studies due to safety concerns or non-compliance.

All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with good clinical practice regulations. They must be conducted under protocols detailing the objectives of the trial, dosing procedures, subject selection and exclusion criteria and the safety and effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND, and progress reports detailing the results of the clinical trials must be submitted at least annually. In addition, timely safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse events. An institutional review board, or IRB, at each institution participating in the clinical trial must review and approve each protocol before a clinical trial commences at that institution and must also approve the information regarding the trial and the consent form that must be provided to each trial subject or his or her legal representative, monitor the study until completed and otherwise comply with IRB regulations.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- ***Phase I:*** The product candidate is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case of some products for severe or life-threatening diseases, such as cancer, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.
- ***Phase II:*** This phase involves studies in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.
- ***Phase III:*** Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical study sites. These studies are intended to establish the overall risk-benefit ratio of the product candidate and provide, if appropriate, an adequate basis for product labeling.

The FDA or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. Phase I, Phase II, and Phase III testing may not be completed successfully within any specified period, if at all.

During the development of a new drug, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase II, and before an NDA or BLA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and FDA to reach agreement on the next phase of development. Sponsors typically use the end of Phase II meeting to discuss their Phase II clinical results and present their plans for the pivotal Phase III clinical trial that they believe will support approval of the new drug.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

*U.S. Review and Approval Processes*

The results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling, and other relevant information are submitted to the FDA as part of an NDA or BLA requesting approval to market the product. The submission of an NDA or BLA is subject to the payment of user fees; a waiver of such fees may be obtained under certain limited circumstances. The FDA reviews all NDAs and BLAs submitted to ensure that they are sufficiently complete for substantive review before it accepts them for filing. The FDA may request additional information rather than accept a NDA or BLA for filing. In this event, the NDA or BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. FDA may refer the NDA or BLA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. The approval process is lengthy and often difficult, and the FDA may refuse to approve an NDA or BLA if the applicable regulatory criteria are not satisfied or may require additional clinical or other data and information. Even if such data and information is submitted, the FDA may ultimately decide that the NDA or BLA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. The FDA may issue a complete response letter, which may require additional clinical or other data or impose other conditions that must be met in order to secure final approval of the NDA or BLA, or an approval letter following satisfactory completion of all aspects of the review process. The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant to assure and preserve the product's identity, strength, quality and purity. The FDA reviews a BLA to determine, among other things whether the product is safe, pure and potent and the facility in which it is manufactured, processed, packed or held meets standards designed to assure the product's continued safety, purity and potency. Before approving an NDA or BLA, the FDA will inspect the facility or facilities where the product is manufactured.

NDAs or BLAs receive either standard or priority review. A drug representing a significant improvement in treatment, prevention or diagnosis of disease may receive priority review. Priority review for an NDA for a new molecular entity and original BLAs will be six months from the date that the NDA or BLA is filed. In addition, products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval and may be approved on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on the basis of an effect on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, or IMM, that is reasonably likely to predict an effect on IMM or other clinical benefit. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. Priority review and accelerated approval do not change the standards for approval, but may expedite the approval process.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. In addition, the FDA may require a sponsor to conduct Phase IV testing which involves clinical trials designed to further assess a drug's safety and effectiveness after NDA or BLA approval, and may require testing and surveillance programs to monitor the safety of approved products which have been commercialized.

The Food and Drug Administration Safety and Innovation Act, or FDASIA, which was enacted in 2012, made permanent the Pediatric Research Equity Act, or PREA, which requires a sponsor to conduct pediatric studies for most drugs and biologics, for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under PREA, original NDAs, BLAs and supplements thereto, must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The sponsor or FDA may request a deferral of pediatric studies for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug or biologic is ready for approval for use in adults before pediatric studies are complete or that additional safety or effectiveness data needs to be collected before the pediatric studies begin. After April 2013, the FDA must send a non-compliance letter to any sponsor that fails to submit the required assessment, keep a deferral current or fails to submit a request for approval of a pediatric formulation.

*Patent Term Restoration and Marketing Exclusivity*

Depending upon the timing, duration and specifics of FDA approval of our drugs, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND, and the submission date of an NDA or BLA, plus the time between the submission date of an NDA or BLA and the approval of that application, except that the period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved drug is eligible for the extension, and the extension must be applied for prior to expiration of the patent. The United States Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration.

Pediatric exclusivity is another type of marketing exclusivity available in the U.S. The FDASIA made permanent the Best Pharmaceuticals for Children Act, or BPCA, which provides for an additional six months of marketing exclusivity if a sponsor conducts clinical trials in children in response to a written request from the FDA, or a Written Request. If the Written Request does not include studies in neonates, the FDA is required to include its rationale for not requesting those studies. The FDA may request studies on approved or unapproved indications in separate Written Requests. The issuance of a Written Request does not require the sponsor to undertake the described studies.

*Biologics Price Competition and Innovation Act of 2009*

On March 23, 2010, President Obama signed into law the Patient Protection and Affordable Care Act which included the Biologics Price Competition and Innovation Act of 2009, or BPCIA. The BPCIA amended the PHSA to create an abbreviated approval pathway for two types of "generic" biologics — biosimilars and interchangeable biologic products, and provides for a twelve-year exclusivity period for the first approved biological product, or reference product, against which a biosimilar or interchangeable application is evaluated; however if pediatric studies are performed and accepted by the FDA, the twelve-year exclusivity period will be extended for an additional six months A biosimilar product is defined as one that is highly similar to a reference product notwithstanding minor differences in clinically inactive components and for which there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity and potency of the product. An interchangeable product is a biosimilar product that may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.

The biosimilar applicant must demonstrate that the product is biosimilar based on data from (1) analytical studies showing that the biosimilar product is highly similar to the reference product; (2) animal studies (including toxicity); and (3) one or more clinical studies to demonstrate safety, purity and potency in one or more appropriate conditions of use for which the reference product is approved. In addition, the applicant must show that the biosimilar and reference products have the same mechanism of action for the conditions of use on the label, route of administration, dosage and strength, and the production facility must meet standards designed to assure product safety, purity and potency.

An application for a biosimilar product may not be submitted until four years after the date on which the reference product was first approved. The first approved interchangeable biologic product will be granted an exclusivity period of up to one year after it is first commercially marketed, but the exclusivity period may be shortened under certain circumstances.

The FDA has issued a number of final and draft guidances in order to implement the law. On April 28, 2015, the FDA issued the following three final guidances: "Scientific Considerations in Demonstrating Biosimilarity to a Reference Product," "Quality Considerations in Demonstrating Biosimilarity of a Therapeutic Protein Product to a Reference Product," and "Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009 Guidance for Industry." The draft guidances include "Formal Meetings between the FDA and Biosimilar Biological Product Sponsors or Applicants" issued March 29, 2013, "Clinical Pharmacology Data to Support a Demonstration of Biosimilarity to a Reference Product" issued May 13, 2014, "Reference Product Exclusivity for Biological Products Filed Under Section 351(a) of the PHS Act" issued August 4, 2014, and "Biosimilars: Additional Questions and Answers Regarding Implementation of the Price Competition and Innovation Act of 2009," issued May 12, 2015. The guidance documents provide FDA's current thinking on approaches to demonstrating that a proposed biological product is biosimilar to a reference product. The FDA intends to issue additional guidance documents in the future. Nevertheless, the absence of final guidance documents covering all biosimilars issues does not prevent a sponsor for seeking licensure of a biosimilar under the BPCIA, and the FDA recently approved the first biosimilar application in the United States.

*Orphan Drug Designation*

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the U.S., or more than 200,000 individuals in the U.S. and for which there is no reasonable expectation that the cost of developing and making available in the U.S. a drug for this type of disease or condition will be recovered from sales in the U.S. for that drug. Orphan drug designation must be requested before submitting an NDA or BLA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process. If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication, except in very limited circumstances, for seven years. Orphan drug exclusivity, however, also could block the approval of one of our products for seven years if a competitor obtains approval of the same drug as defined by the FDA or if our product candidate is determined to be contained within the competitor's product for the same indication or disease.

The FDA also administers a clinical research grants program, whereby researchers may compete for funding to conduct clinical trials to support the approval of drugs, biologics, medical devices, and medical foods for rare diseases and conditions. A product does not have to be designated as an orphan drug to be eligible for the grant program. An application for an orphan grant should propose one discrete clinical study to facilitate FDA approval of the product for a rare disease or condition. The study may address an unapproved new product or an unapproved new use for a product already on the market.

*Fast Track Designation and Accelerated Approval*

FDA is required to facilitate the development, and expedite the review, of drugs that are intended for the treatment of a serious or life-threatening disease or condition for which there is no effective treatment and which demonstrate the potential to address unmet medical needs for the condition. Under the fast track program, the sponsor of a new drug candidate may request that FDA designate the drug candidate for a specific indication as a fast track drug concurrent with, or after, the filing of the IND for the drug candidate. FDA must ermine if the drug candidate qualifies for fast track designation within 60 days of receipt of the sponsor's request.

Under the fast track program, FDA may designate a drug for fast-track status if it is intended to treat a serious or life-threatening illness and nonclinical or clinical data demonstrate the potential to address an unmet medical need. Similarly, the agency may designate a drug for accelerated approval if it treats a serious condition and generally provides meaningful therapeutic benefit to patients over existing treatments based upon a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments.

In clinical trials, a surrogate endpoint is a measurement of laboratory or clinical signs of a disease or condition that substitutes for a direct measurement of how a patient feels, functions, or survives. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. A drug candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, will allow FDA to withdraw the drug from the market on an expedited basis. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by FDA.

In addition to other benefits such as the ability to use surrogate endpoints and engage in more frequent interactions with FDA, FDA may initiate review of sections of a fast track drug's BLA before the application is complete. This rolling review is available if the applicant provides, and FDA approves, a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, FDA's time period goal for reviewing an application does not begin until the last section of the BLA is submitted. Additionally, the fast track designation may be withdrawn by FDA if FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

In FDASIA, Congress encouraged the FDA to utilize innovative and flexible approaches to the assessment of products under accelerated approval. The law required the FDA to issue related draft guidance within a year after the law's enactment and also promulgate confirming regulatory changes. In May 2014, the FDA published a Guidance for Industry entitled, "Expedited Programs for Serious Conditions-Drugs and Biologics" which provides guidance on FDA programs that are intended to facilitate and expedite development and review of new drugs as well as threshold criteria generally applicable to concluding that a drug is a candidate for these expedited development and review programs. In addition to the Fast Track, accelerated approval and priority review programs discussed above, the FDA also provided guidance on a new program for Breakthrough Therapy designation. A request for Breakthrough Therapy designation should be submitted concurrently with, or as an amendment to an IND. FDA has already granted this designation to over 30 new drugs and has approved several.

*Post-Approval Requirements*

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further FDA review and approval. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws and regulations. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products. Future inspections by the FDA and other regulatory agencies may identify compliance issues at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct.

Any drug products manufactured or distributed by us pursuant to FDA approvals are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the drug, providing the FDA with updated safety and efficacy information, drug sampling and distribution requirements, complying with certain electronic records and signature requirements, and complying with FDA promotion and advertising requirements. FDA strictly regulates labeling, advertising, promotion and other types of information on products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label.

From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. It is impossible to predict whether further legislative changes will be enacted, or FDA regulations, guidance or interpretations changed or what the impact of such changes, if any, may be.

*Foreign Regulation*

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we must obtain approval by the comparable regulatory authorities of foreign countries or economic areas, such as the 28-member European Union, before we may commence clinical trials or market products in those countries or areas. The approval process and requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from place to place, and the time may be longer or shorter than that required for FDA approval.

Under European Union regulatory systems, a company may submit marketing authorization applications either under a centralized or decentralized procedure. The centralized procedure, which is compulsory for medicinal products produced by biotechnology or those medicinal products containing new active substances for specific indications such as the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, viral diseases and designated orphan medicines, and optional for other medicines which are highly innovative. Under the centralized procedure, a marketing application is submitted to the European Medicines Agency (EMA) where it will be evaluated by the Committee for Medicinal Products for Human Use and a favorable opinion typically results in the grant by the European Commission of a single marketing authorization that is valid for all European Union member states within 67 days of receipt of the opinion. The initial marketing authorization is valid for five years, but once renewed is usually valid for an unlimited period. The decentralized procedure provides for approval by one or more "concerned" member states based on an assessment of an application performed by one member state, known as the "reference" member state. Under the decentralized approval procedure, an applicant submits an application, or dossier, and related materials to the reference member state and concerned member states. The reference member state prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. Within 90 days of receiving the reference member state's assessment report, each concerned member state must decide whether to approve the assessment report and related materials. If a member state does not recognize the marketing authorization, the disputed points are eventually referred to the European Commission, whose decision is binding on all member states.

When conducting clinical trials in the EU, we must adhere to the provisions of the EU Clinical Trials Directive and the laws and regulations of the EU Member States implementing them. These provisions require, among other things, that the prior authorization of an Ethics Committee and the submission and approval of a clinical trial authorization application be obtained in each Member State be obtained before commencing a clinical trial in that Member State.

As in the United States, it may be possible in foreign countries to obtain a period of market and/or data exclusivity that would have the effect of postponing the entry into the marketplace of a competitor's generic product. For example, in the EU, if any of our products receive marketing approval in the European Economic Area, or EEA which is comprised of the 28 member states of the EU plus Norway, Iceland and Liechtenstein, we expect they will benefit from 8 years of data exclusivity and an additional 2 years of marketing exclusivity. An additional one-year extension of marketing exclusivity is possible if during the data exclusivity period, we obtain an authorization for one or more new therapeutic indications that is deemed to bring a significant clinical benefit compared to existing therapies. The data exclusivity period begins on the date of the product's first marketing authorization in the EU and prevents biosimilars from relying on the holder of the marketing authorization for the reference biological medicine's pharmacological, toxicological and clinical data for a period of 8 years. After 8 years, a biosimilar product application may be submitted and the sponsoring companies may rely on the marketing authorization holder's data. However, a biosimilar medicine cannot launch until 2 years later (or a total of 10 years after the first marketing authorization in the EU of the innovator product), or 3 years later (or a total of 11 years after the first marketing authorization in the EU of the innovator product) if the marketing authorization holder obtains marketing authorization for a new indication with significant clinical benefit within the 8 year data exclusivity period.

As in the United States, a sponsor may apply for designation of a product as an orphan drug for the treatment of a specific indication in the EU before the application for marketing authorization is made. Orphan drugs in Europe enjoy economic and marketing benefits, including up to 10 years of market exclusivity for the approved indication unless another applicant can show that its product is safer, more effective or otherwise clinically superior to the orphan-designated product.

*Reimbursement*

Sales of pharmaceutical products depend in significant part on the availability of third-party reimbursement. Third-party payors include government healthcare programs, managed care providers, private health insurers and other organizations. These third-party payors are increasingly challenging the price and examining the cost-effectiveness of medical products and services. In addition, significant uncertainty exists as to the reimbursement status of newly approved healthcare products. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of our products. Our drug candidates may not be considered cost-effective. It is time consuming and expensive to seek reimbursement from third-party payors. Reimbursement may not be available or sufficient to allow us to sell our products on a competitive and profitable basis.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the United States and generally tend to by significantly lower.

## SELLING SHAREHOLDERS

This prospectus relates to the resale of 395,881,100 Ordinary Shares represented by 3,958,811 of our ADSs by the Selling Shareholders.

The following table sets forth as of September 30, 2015, based on information provided to us by the Selling Shareholders or otherwise known to us, the name of the Selling Shareholders, the nature of any position, office or other material relationship, if any, which the Selling Shareholders have had, within the past three years, with us or with any of our predecessors or affiliates, and the number of Ordinary Shares beneficially owned by the Selling Shareholders before this offering. The number of Ordinary Shares owned are those beneficially owned, as determined under the rules of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under these rules, beneficial ownership includes any Ordinary Shares as to which a person has sole or shared voting power or investment power and any Ordinary Shares which the person has the right to acquire within 60 days through the exercise of any option, warrant or right, through conversion of any security or pursuant to the automatic termination of a power of attorney or revocation of a trust, discretionary account or similar arrangement. No Selling Shareholder is a broker-dealer or an affiliate of a broker-dealer. If any Selling Shareholder identified below transfers some or all of its securities to a pledgee, donee, transferee or other successor-in-interest, we may be required to file a prospectus supplement or a post-effective amendment to the registration statement of which this prospectus is a part.

The fourth column assumes the sale of all of the Ordinary Shares offered by the Selling Shareholders pursuant to this prospectus. However, because the Selling Shareholders may sell all or some of their shares under this prospectus from time to time, or in another permitted manner, we cannot assure you as to the actual number of shares that will be sold by the Selling Shareholders. The percentage of Ordinary Shares owned after the offering is based on 1,177,693,383 Ordinary Shares issued and outstanding as of September 30, 2015. On September 18, 2015, pursuant to the Purchase Agreement, we sold to the Selling Shareholders in a private placement an aggregate of 3,958,811 restricted ADSs representing 395,881,100 Ordinary Shares at a purchase price of $18.945 per ADS. See “Prospectus Summary — Description of the Private Placement.”

| Selling Shareholder | Number of Ordinary Shares Beneficially Owned Before Offering | Number of Ordinary Shares Offered | Number of ADSs Representing Ordinary Shares Offered | Number of Ordinary Shares Beneficially Owned After Offering | Percentage of Ordinary Shares Beneficially Owned After Offering |
|---|---|---|---|---|---|
| Deerfield Private Design Fund III, L.P. (1) | 57,535,000 | 57,535,000 | 575,350 | 0 | 0% |
| Deerfield Special Situations Fund, L.P. (2) | 57,535,000 | 57,535,000 | 575,350 | 0 | 0% |
| 667, L.P. (3) | 3,004,900 | 3,004,900 | 30,049 | 0 | 0% |
| Baker Brothers Life Sciences, L.P. (3) | 36,583,300 | 36,583,300 | 365,833 | 0 | 0% |
| CVI Investments, Inc. (4) | 2,639,100 | 2,639,100 | 26,391 | 0 | 0% |
| Mark Cohen (5) | 3,298,473 | 1,055,600 | 10,556 | 2,242,873(6) | 0.19% |
| Dafna Lifescience LP (7) | 1,504,300 | 1,504,300 | 15,043 | 0 | 0% |
| Dafna Lifescience Market Neutral LP (7) | 105.500 | 105.500 | 1,055 | 0 | 0% |
| Dafna Lifescience Select LP (7) | 1,029,200 | 1,029,200 | 10,292 | 0 | 0% |
| ECOR1 Capital Fund, L.P. (8) | 2,932,400 | 2,932,400 | 29,324 | 0 | 0% |
| ECOR1 Capital Fund Qualified, L.P. (8) | 7,096,500 | 7,096,500 | 70,965 | 0 | 0% |
| Foresite Capital Fund III, L.P. (9) | 26,392,100 | 26,392,100 | 263,921 | 0 | 0% |
| Ghost Tree Master Fund, LP (10) | 2,639,100 | 2,639,100 | 26,391 | 0 | 0% |
| Growth Equity Opportunities Fund IV, LLC (11) | 26,392,100 | 26,392,100 | 263,921 | 0 | 0% |
| JFL Partners Fund LP (12) | 527,700 | 527,700 | 5,277 | 0 | 0% |
| QVT Fund IV LP (13) | 4,355,400 | 4,355,400 | 43,554 | 0 | 0% |
| QVT Fund V LP (13) | 19,635,800 | 19,635,800 | 196,358 | 0 | 0% |
| Quintessence Fund L.P. (13) | 2,400,900 | 2,400,900 | 24,009 | 0 | 0% |
| RA Capital Healthcare Fund, L.P. (14) | 21,852,700 | 21,852,700 | 218,527 | 0 | 0% |
| Blackwell Partners LLC-Series A (14) | 4,539,400 | 4,539,400 | 45,394 | 0 | 0% |
| Boxer Capital, LLC (15) | 14,501,100 | 9,501,100 | 95,011 | 5,000,000 | 0.42% |
| MVA Investors, LLC (15) | 1,055,600 | 1,055,600 | 10,556 | 0 | 0% |
| Venrock Healthcare Capital Partners II, L.P. (16) | 26,289,200 | 26,289,200 | 262,892 | 0 | 0% |
| VHCP Co-Investment Holdings II, LLC (16) | 10,659,800 | 10,659,800 | 106,598 | 0 | 0% |
| Venrock Healthcare Capital Partners, L.P. (16) | 13,387,100 | 13,387,100 | 133,871 | 0 | 0% |
| VHCP Co-Investment Holdings, LLC (16) | 2,448,100 | 2,448,100 | 24,481 | 0 | 0% |
| Vivo Capital Fund VIII, L.P. (17) | 46,379,800 | 46,379,800 | 463,798 | 0 | 0% |
| Vivo Capital Surplus Fund VIII, L.P. (17) | 6,404,400 | 6,404,400 | 64,044 | 0 | 0% |

(1) The shares directly held by Deerfield Private Design Fund III, L.P. are indirectly beneficially owned by Deerfield Mgmt III, L.P., its general partner, Deerfield Management Company, L.P., its investment advisor, and James E. Flynn. As the sole member of the respective general partners of Deerfield Mgmt III, L.P. and Deerfield Management Company, L.P., Mr. Flynn is the sole natural person possessing beneficial ownership over such shares. The business address for Deerfield Private Design Fund III, L.P. is 780 Third Avenue, 37th floor, New York, NY 10017.

(2) The shares directly held by Deerfield Special Situations Fund, L.P. are indirectly beneficially owned by Deerfield Mgmt, L.P., its general partner, Deerfield Management Company, L.P., its investment advisor, and James E. Flynn. As the sole member of the respective general partners of Deerfield Mgmt, L.P. and Deerfield Management Company, L.P., Mr. Flynn is the sole natural person possessing beneficial ownership over such shares. The address for Deerfield Special Situations Fund, L.P is 780 Third Avenue, 37th Floor, New York, New York 10017.

(3) Baker Bros. Advisors LP is the investment adviser to 667, L.P. ("667") and Baker Brothers Life Sciences, L.P. ("BBLS") and has voting and investment power over the shares directly held by 667 and BBLS. Julian C. Baker and Felix J. Baker are the managing partners of Baker Bros. Advisors LP and may be deemed to be beneficial owners of securities of the Issuer directly held by 667 and BBLS and may be deemed to have the power to vote or direct the vote of and the power to dispose or direct the disposition of such securities. Baker Bros. Advisors LP, Julian C. Baker and Felix J. Baker disclaim beneficial ownership of the securities held directly by 667 and BBLS, except to the extent of their pecuniary interest. The address for Baker Bros. Advisors, LP is 667 Madison Ave., 21$^{st}$ Floor, New York, NY 10065.

(4) Heights Capital Management, Inc., the authorized agent of CVI Investments, Inc. ("CVI"), has discretionary authority to vote and dispose of the shares held by CVI and may be deemed to be the beneficial owner of these shares. Martin Kobinger, in his capacity as Investment Manager of Heights Capital Management, Inc., may also be deemed have investment discretion and voting power over the shares held by CVI. The address for CVI; c/o Heights Capital Management, Inc., its authorized agent is 101 California Street, Suite 3250, San Francisco, CA 94111.

(5) Mark Cohen is the Vice Chairman of our board of directors and was previously our Chairman prior to the consummation of the Acquisition. His business address is Pearl Cohen Zedek Latzer Baratz, LLP, 1500 Broadway, 12th Floor, New York, NY 10036, United States of America. Mark Cohen is a senior partner in PCZL.

(6) Includes 136,500 Ordinary Shares underlying options at an exercise price of £0.80 per share (or $1.21) which expire on August 28, 2017, 75,000 Ordinary Shares underlying options at an exercise price of $1.56 per share, which expire on March 19, 2022, 60,000 Ordinary Shares at an exercise price of $1.56 per share, which expire on June 20, 2022, , 66,666 Ordinary Shares at an exercise price of $2.00 per share, which expire on April 29, 2023, 65,000 Ordinary Shares at an exercise price of $0.75 per share, which expire on February 5, 2024, 65,000 Ordinary Shares at an exercise price of $0.60 per share, which expire on July 22, 2024 and warrants to purchase 182,450 Ordinary Shares at an exercise price of $2.00 per share. Does not include an aggregate of 271,278 Ordinary Shares underlying options at an exercise price of $0.3221 which vest on September 21, 2016. In addition, does not include a warrant issued to Pearl Cohen Zedek Latzer Baratz Law Office, or PCZL, on February 12, 2012, to purchase 309,492 Ordinary Shares at an exercise price of $2.00 per share.

(7) DAFNA Capital Management, LLC is the investment advisor of DAFNA Life Science LP, DAFNA Life Science Market Neutral LP and DAFNA Life Science Select LP (the "DAFNA Funds"). Nathan Fischel is the Chief Executive Officer and Fariba Ghodsian is the Chief Investment Officer of DAFNA Capital Management, LLC and they may be deemed to have shared voting and investment power with respect to the securities held by the DAFNA Funds. The address for DAFNA Lifescience LP, DAFNA Lifescience Market Neutral LP and DAFNA Lifescience Select LP is 10990 Wilshire Boulevard, Suite 1400, Los Angeles, CA 90024.

(8) Oleg Nodelman, with an address of 409 Illinois Street, San Francisco, California, 94158, owns and controls EcoR1 Capital LLC, the general partner of EcoR1 Capital Fund Qualified, L.P., and EcoR1 Capital Fund, L.P., and has voting and disposition power over these securities.

(9) The address for Foresite Capital Fund III, L.P. is 101 California Street, Suite 4100, San Francisco, CA 94111. Foresite Capital Management III, LLC is the general partner of Foresite Capital Fund III, LP. James B. Tananbaum is the managing member of Foresite Capital Management III, LLC. James B. Tananbaum disclaims beneficial ownership of all shares beneficially owned by Foresite Capital Management III, LLC, except to the extent of his indirect pecuniary interest therein.

(10) Portaledge, LLC is the general partner of Ghost Tree Master Fund, LP and has voting and investment power over the shares held by Ghost Tree Master Fund, LP. David Y. Kim is the Managing Member to Portaledge, LLC. The business address of Ghost Tree Master Fund, LP is 150 East 52$^{nd}$ Street, New York, NY 10022.

(11) The shares are directly held by Growth Equity Opportunities Fund IV, LLC ("GEO IV") and indirectly held by New Enterprise Associates 15, L.P. ("NEA 15"), the sole member of GEO IV, NEA Partners 15, L.P. ("NEA Partners 15"), the sole general partner of NEA 15, NEA 15 GP, LLC ("NEA 15 GP"), the sole general partner of NEA Partners 15, and the individual managers of NEA 15 GP. The individual managers of NEA 15 GP are Peter J. Barris, Forest Baskett, Anthony A. Florence, Jr., Krishna "Kittu" Kolluri, Josh Makower, David M. Mott, Jon Sakoda, Scott D. Sandell, Peter W. Sonsini, Ravi Viswanathan and Harry R. Weller. The address for GEO IV is 1954 Greenspring Drive, Suite 600, Timonium, MD 21093.

(12) JFL Capital Management LP is the investment manager of JFL Partners Fund LP. Joseph Lawler, as managing member of JFL Capital Management LP has voting and investment power over the shares held by JFL Partners Fund LP. The business address for JFL Capital Management LP and JFL Partners Fund LP is 10300 Indigo Broom Loop, Austin, TX 78733.

(13) QVT Financial LP is the investment manager of each Quintessence Fund L.P., QVT Fund IV LP and QVT Fund V LP and shares with QVT Associates GP LLC, their general partner, voting and investment control over the securities held by Quintessence Fund L.P., QVT Fund IV LP and QVT Fund V LP. QVT Financial GP LLC is the general partner of QVT Financial LP and as such has complete discretion in the management and control of the business affairs of QVT Financial LP. We have been advised by the shareholder that the managing members of QVT Financial GP LLC are Daniel Gold, Nicholas Brumm, Arthur Chu and Tracy Fu and that each of Daniel Gold, Nicholas Brumm, Arthur Chu and Tracy Fu disclaims beneficial ownership of the securities held by Quintessence Fund L.P., QVT Fund IV LP and QVT Fund V LP. The address for QVT Financial LP is 1177 Avenue of the Americas, 9th Floor, New York, New York 10036.

(14) Peter Kolchinsky, as Manager of RA Capital Management, LLC, which is the general partner of RA Capital Healthcare Fund, L.P. and the investment advisor of Blackwell Partners, LLC – Series A, has voting and investment power over the shares held by Blackwell Partners, LLC – Series A and RA Capital Healthcare Fund, L.P. The notice address for Blackwell Partners, LLC – Series A and RA Capital Healthcare Fund, L.P. is 20 Park Plaza, Suite 1200, Boston, MA 02116.

(15) Boxer Asset Management ("Boxer Management") is the managing member and majority owner of Boxer Capital. Joseph Lewis is the sole indirect owner and controls Boxer Management. MVA Investors, LLC ("MVA") is the independent, personal investment vehicle of certain employees of Boxer Capital and Tavistock Life Sciences Company, which is a Delaware corporation and an affiliate of Boxer Capital and is controlled by employees of Tavistock Life Sciences Company that are members of MVA. As such, MVA is not controlled by Boxer Capital, Boxer Management or Joseph Lewis. MVA is primarily engaged in the business of investing in securities. The principal business address of Boxer Capital, and MVA is: 440 Stevens Avenue, Suite 100, Solana Beach, CA 92075. The principal business address of both Boxer Asset Management and Joseph Lewis is: c/o Cay House P.O. Box N-7776 E.P. Taylor Drive Lyford Cay, New Providence, Bahamas.

(16) VHCP Management, LLC ("VHCP Management") is the general partner of Venrock Healthcare Capital Partners, L.P. ("VHCP") and the manager of VHCP Co-Investment Holdings, LLC ("Co-Invest") and may be deemed to beneficially own the shares held by either VHCP or Co-Invest. VHCP Management II, LLC ("VHCP Management II") is the general partner of Venrock Healthcare Capital Partners II, L.P. ("VHCP II") and the manager of VHCP Co-Investment Holdings II, LLC ("Co-Invest II") and may be deemed to beneficially own the shares held by either VHCP II or Co-Invest II. Drs. Anders D. Hove and Bong Y. Koh are the managing members of VHCP Management and VHCP Management II and may be deemed to beneficially own the shares beneficially owned by either VHCP Management or VHCP Management II. VHCP Management and VHCP Management II disclaim beneficial ownership over all shares held by VHCP and Co-Invest and VHCP II and Co-Invest II, respectively, except to the extent of their respective pecuniary interests therein. The address for VHCP, VHCP II, Co-Invest and Co-Invest II is 3340 Hillview Avenue, Palo Alto, CA 94304.

(17) Vivo Capital VIII, LLC is the general partner of both Vivo Capital Fund VIII, L.P. and Vivo Capital Surplus Fund VIII, L.P. The voting members of Vivo Capital VIII, LLC are Frank Kung, Albert Cha, Edgar Engleman, Chen Yu and Shan Fu, none of whom has individual voting or investment power with respect to these shares and each of whom disclaims beneficial ownership of such shares. The address for Vivo Capital VIII, LLC is 575 High Street, Suite 201, Palo Alto, CA 94301, United States.

## PRICE RANGE OF OUR ADSs

Our ADSs have been listed on the NASDAQ Capital Market under the symbol "AKTX" since September 21, 2015 and under the symbol "CLTX" from January 31, 2014 until September 18, 2015. Prior to that, our ADSs were quoted on the OTCQB under the symbol "CLSXD" from January 3, 2014 to January 30, 2014 and were quoted on the OTCQB under the symbol "CLSXY" from September 16, 2013 until January 2, 2014 and under the symbol "MRRBY" from February 19, 2013 to September 15, 2013. Effective January 3, 2014, our ratio of ADSs is to Ordinary Shares changed from one ADS per each two Ordinary Shares to one ADS per each ten Ordinary Shares and, effective as of September 17, 2015, our ratio of ADSs is to Ordinary Shares changed from one ADS per each ten Ordinary Shares to one ADS per each on hundred Ordinary Shares. Currently, each ADS represents by one hundred Ordinary Shares.

The following table sets forth the range of high and low sale prices for our ADSs for the periods indicated, as reported by the NASDAQ Capital Market or the OTCQB, as applicable. These prices do not include retail mark-ups, markdowns, or commissions but give effect to the change in the number of Ordinary Shares represented by each ADS to one hundred Ordinary Shares per each ADS, implemented on September 17, 2015. Historical data in the table has been restated to take into account this change.

| | USD High | USD Low |
|---|---|---|
| **Fiscal Year Ended December 31, 2013** | | |
| First Quarter | $ 250.00 | $ 250.00 |
| Second Quarter | $ 250.00 | $ 200.00 |
| Third Quarter | $ 200.00 | $ 200.00 |
| Fourth Quarter | $ 200.00 | $ 71.00 |
| **Fiscal Year Ended December 31, 2014** | | |
| First Quarter | $ 110.00 | $ 61.50 |
| Second Quarter | $ 69.60 | $ 50.00 |
| Third Quarter | $ 62.70 | $ 54.00 |
| Fourth Quarter | $ 60.50 | $ 47.00 |
| **Fiscal Year Ended December 31, 2015** | | |
| First Quarter | $ 61.70 | $ 7.60 |
| Second Quarter | $ 7.90 | $ 4.10 |
| Third Quarter | $ 39.55 | $ 4.90 |
| Fourth Quarter (through October 14, 2015) | $ 24.00 | $ 18.18 |

On October 14, 2015, the last reported sales price of our ADSs on the Nasdaq Capital Market was $18.99 per ADS. As of October 2, 2015 there were 100 shareholders of record of our ADSs. The number of record holders is not representative of the number of beneficial holders of our ADSs.

## TAXATION

The information presented under the caption "Certain material United States federal income taxation considerations" below is a discussion of certain material U.S. federal income tax consequences to U.S. holders (as defined below) of investing in our ADSs. The information presented under the caption "United Kingdom tax considerations" is a discussion of the certain United Kingdom tax consequences of investing in our ADSs.

You should consult your tax adviser regarding the applicable tax consequences to you of investing in our Ordinary Shares under the laws of the United States (federal, state and local), the United Kingdom and any other applicable foreign jurisdiction.

**United Kingdom tax considerations**

*Taxation of dividends*

Under current U.K. tax law, no tax is required to be withheld in the United Kingdom at source from cash dividends paid to U.S. resident shareholders.

*Taxation of capital gains*

Subject to the comments in the following paragraph, a holder of Celsus Ordinary Shares or ADSs who, for U.K. tax purposes, is not resident in the U.K will not be liable for U.K. taxation on capital gains realized on the disposal of Celsus Ordinary Shares or ADSs unless at the time of the disposal:

- the holder carries on a trade, or in the case of an individual, a profession or vocation through, in the case of an individual, a branch or agency in the United Kingdom, or, in the case of a company, a permanent establishment in the United Kingdom, and
- the Celsus Ordinary Shares or ADSs are or have been used, held, or acquired for the purpose of such trade, profession, vocation, branch, agency or permanent establishment.

A holder of Celsus Ordinary Shares or ADSs who (1) is an individual who has ceased to be resident for U.K. tax purposes in the United Kingdom, (2) was resident for U.K. tax purposes in the United Kingdom for at least four out of the seven U.K. tax years immediately preceding the year in which he or she ceased to be resident in the United Kingdom, (3) only remains non-resident for U.K. tax purposes in the United Kingdom for a period of less than five tax years, and (4) disposes of his or her Celsus Ordinary Shares or ADSs during that period may also be liable, upon returning to the United Kingdom, for U.K. tax on capital gains, subject to any available exemptions or reliefs, even though he or she was not resident in the United Kingdom at the time of the disposal.

*Inheritance Tax*

Celsus Ordinary Shares and ADSs are assets situated in the United Kingdom for the purposes of U.K. inheritance tax (the U.K. equivalent of U.S. estate and gift tax). Subject to the discussion of the U.K.-U.S. estate and gift tax treaty in the next paragraph, U.K. inheritance tax may apply (subject to any available exemptions or reliefs) if an individual who holds Celsus Ordinary Shares or ADSs gifts them or dies even if he or she is neither domiciled in the United Kingdom nor deemed to be domiciled there under U.K. law. For U.K. inheritance tax purposes, a transfer of Celsus Ordinary Shares or ADSs at less than full market value may be treated as a gift for these purposes. Special inheritance tax rules apply (1) to gifts if the donor retains some benefit, (2) to close companies and (3) to trustees of settlements.

However, as a result of the U.K.-U.S. estate tax treaty, Celsus Ordinary Shares or ADSs held by an individual who is domiciled in the United States for the purposes of the U.K.-U.S. estate and gift tax treaty, and who is not a U.K. national, will not be subject to U.K. inheritance tax on that individual's death or on a gift of the Celsus Ordinary Shares or ADSs unless the Ordinary Shares or ADSs:

- are part of the business property of a permanent establishment in the United Kingdom, or
- pertain to a fixed base in the United Kingdom used for the performance of independent personal services.

The U.K.-U.S. estate and gift tax treaty provides a credit mechanism if the Celsus Ordinary Shares or ADSs are subject to both U.K. inheritance tax and to U.S. estate and gift tax.

*U.K. Stamp Duty and Stamp Duty Reserve Tax (SDRT)*

In general no stamp duty should be payable on any transfer of ADSs provided that the ADSs and any separate instrument of transfer are executed and retained at all times outside the United Kingdom. A transfer of shares (including our Ordinary Shares) in registered form would attract ad valorem stamp duty generally at the rate of 0.5% of the purchase price of the shares. There is no charge to ad valorem stamp duty on gifts of shares.

An agreement to transfer ADSs should not give rise to SDRT. SDRT would generally be payable on an unconditional agreement to transfer shares in registered form at 0.5% of the amount or value of the consideration for the transfer. However, the SDRT is repayable if, within six years of the date of the agreement, an instrument transferring the shares is executed and is duly stamped. Equally, if the SDRT on the transfer of the shares has not, at the point in time at which the instrument is executed, already been paid (again, within six years of the date of the agreement), the liability to pay the charge to SDRT (but not necessarily interest and penalties) is cancelled by the execution, and due stamping, of the instrument of transfer.

Following a recent U.K. court case, the U.K. tax authority (HMRC) now accepts that neither stamp duty nor SDRT is payable on issues of shares and securities in U.K. companies to depositary receipt issuers and clearance services anywhere in the world, provided that the issue to the depository receipt issuer or clearance service is an integral part of an issue of share capital. HMRC still contends, however, that stamp duty and/or SDRT is payable at a rate of 1.5% on transfers (by sale or otherwise) of shares and securities in U.K. companies to depository receipt systems or clearance services if the transfers are not an integral part of an issue of share capital.

**Certain Material United States Federal Income Taxation Considerations**

The following summary contains a description of certain material United States federal income tax considerations of the acquisition, ownership and disposition of our ADSs to a U.S. Holder (as defined below). The summary is based the U.S. Internal Revenue Code of 1986, as amended (the "Code"), existing, proposed and temporary U.S. Treasury Regulations promulgated thereunder and administrative and judicial interpretations thereof, in each case as in effect and available on the date hereof. All of the foregoing is subject to change, which change could apply retroactively, and to differing interpretations, all of which could affect the tax considerations below.

For purposes of this description, a "U.S. Holder" includes any beneficial owner of ADSs that is (or is treated as), for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the United States;
- a corporation (or other entity treated as a corporation for U.S. federal income tax purposes) created or organized in or under the laws of the United States or organized under the laws of any state thereof, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust if (1) a court within the United States is able to exercise primary supervision over its administration and one or more United States persons have the authority to control all of the substantial decisions of such trust; or (2) such trust has a valid election in effect to be treated as a United States person for U.S. federal income tax purposes.

This section does not purport to be a comprehensive description of all of the tax considerations that may be relevant to any particular investor. This discussion assumes that you are familiar with the tax rules applicable to investments in securities generally, and with any special rules to which you may be subject. In particular, the discussion deals only with investors that will hold ADSs as capital assets, and does not address all of the tax consequences that may be relevant in light of a U.S. Holder's particular circumstances including alternative minimum, gift and estate tax consequences, and does not address the tax treatment of investors that are subject to special rules, such as banks, financial institutions, insurance companies, dealers or traders in securities or currencies, persons that elect mark-to-market treatment, tax-exempt entities or organizations (including 401 pensions plans), real estate investment trusts, regulated investment companies, grantor trusts, individual retirement and other tax-deferred accounts, persons that received our ADSs as compensation for the performance of services, persons who own, directly, indirectly through non-U.S. entities or by attribution by application of the constructive ownership rules of section 958(b) of the Code, 10% or more of our voting shares, persons that are residents of the U.K. for U.K. tax purposes or that conduct a business or have a permanent establishment in the U.K., persons that hold our ADSs as a position in a straddle, hedging, conversion, integration, constructive sale or other risk reduction transaction, certain former citizens or long-term residents of the U.S., partnerships and their partners, persons whose functional currency is not the U.S. dollar and a U.S. Holder who holds ADSs through a financial account at a foreign financial institution that does not meet the requirements for avoiding future withholding with respect to certain payments under Sections 1471 through 1474 of the Code.

If an entity that is classified as a partnership for U.S. federal income tax purposes holds ADSs, the U.S. federal income tax treatment of a partner will generally depend on the status of the partner and the activities of the partnership. Partnerships holding ADSs and partners in such partnerships should consult their tax advisers as to the particular U.S. federal income tax consequences of owning and disposing of ADSs.

**You are urged to consult with your own advisers regarding the tax consequences of the acquisition, ownership, and disposition of our ADSs in the light of your particular circumstances, including the effect of any state, local, or other national laws.**

*U.S. Taxation of Distributions*

The gross amount of any distributions made by us to a U.S. Holder will generally be subject to U.S. federal income tax as dividend income to the extent paid or deemed paid out of our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Such dividends will not be eligible for the dividends received deduction generally allowed to U.S. corporations with respect to dividends received from other U.S. corporations. To the extent that an amount received by a U.S. Holder exceeds its allocable share of our current and accumulated earnings and profits, such excess would, subject to the discussion below, be treated first as a tax-free return of capital which will reduce such U.S. Holder's tax basis in his ADSs and then, to the extent such distribution exceeds such U.S. Holder's tax basis, it will be treated as capital gain.

Subject to applicable holding period and other limitations, the U.S. Dollar amount of dividends received on the our ADSs by certain non-corporate U.S. Holders are currently subject to taxation at a maximum rate of 20% if we are a "qualified foreign corporation" and certain other requirements are met. A non-United States corporation (other than a corporation that is classified as a PFIC for the taxable year in which the dividend is paid or the preceding taxable year) generally will be considered to be a qualified foreign corporation if it is eligible for the benefits of a comprehensive tax treaty with the United States which the Secretary of Treasury of the United States determines is satisfactory for purposes of this provision and which includes an exchange of information provision, or with respect to any dividend it pays on shares of stock which are readily tradable on an established securities market in the United States. Our ADSs are listed on the NASDAQ Capital Market, which is an established securities market in the United States, and we expect the ADSs to be readily tradable on the NASDAQ Capital Market. However, there can be no assurance that our ADSs will be considered readily tradable on an established securities market in the United States in later years. The Company, which is incorporated under the laws of the United Kingdom, believes that it qualifies as a resident of the United Kingdom for the purposes of, and is eligible for the benefits of, the Convention between the Government of the United States of America and the Government of the United Kingdom of Great Britain and Northern Ireland for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with Respect to Taxes on Income and Capital Gains, signed on July 24, 2001, or the U.S.-U.K. Tax Treaty, although there can be no assurance in this regard. Further, the IRS has determined that the U.S.-U.K. Tax Treaty is satisfactory for purposes of the qualified dividend rules and that it includes an exchange-of-information program. Therefore, subject to the discussion under "Passive foreign investment company rules," below, such dividends will generally be "qualified dividend income" in the hands of individual U.S. holders, provided that a holding period requirement (more than 60 days of ownership, without protection from the risk of loss, during the 121-day period beginning 60 days before the ex-dividend date) and certain other requirements are met.

We have not maintained and do not plan to maintain calculations of earnings and profits under U.S. federal income tax principles. Accordingly, it is unlikely that U.S. Holders will be able to establish whether a distribution by us is in excess of our and accumulated earnings and profits (as computed under U.S. federal income tax principles). If U.S. Holders are unable to establish that distributions are in excess of our accumulated earnings and profits as determined under U.S. federal income tax principles, any distribution by us may be treated as taxable in its entirety as a dividend to U.S. Holders for U.S. federal income tax purposes.

For foreign tax credit computation purposes, dividends will generally constitute foreign source income, and with certain exceptions, will constitute "passive category income."

*U.S. Taxation of a Sale, Exchange or Other Taxable Disposition of the ADSs*

Gain or loss realized by a U.S. Holder on the sale, exchange or other taxable disposition of ADSs will be subject to U.S. federal income taxation as capital gain or loss in an amount equal to the difference between the U.S. Holder's adjusted tax basis in the ADSs and the amount realized on the disposition. Such gain or loss generally will be treated as long-term capital gain or loss if the ADSs have been held for more than one year. Any such gain or loss realized will generally be treated as U.S. source gain or loss. In the case of a U.S. Holder who is an individual, capital gains are currently subject to federal income tax at preferential rates if specified minimum holding requirements are met. The deductibility of capital losses is subject to significant limitations.

For a cash basis taxpayer, units of foreign currency paid or received are translated into U.S. dollars at the spot rate on the settlement date of the purchase or sale. In that case, no foreign currency exchange gain or loss will result from currency fluctuations between the trade date and the settlement date of such a purchase or sale. An accrual basis taxpayer, however, may elect the same treatment required of cash basis taxpayers with respect to purchases and sales of the ADSs that are traded on an established securities market, provided the election is applied consistently from year to year. Such election may not be changed without the consent of the IRS. For an accrual basis taxpayer who does not make such election, units of foreign currency paid or received are translated into U.S. dollars at the spot rate on the trade date of the purchase or sale. Such an accrual basis taxpayer may recognize exchange gain or loss based on currency fluctuations between the trade date and settlement date. Any foreign currency gain or loss a U.S. holder realizes will be U.S. source ordinary income or loss.

*Medicare Tax*

Certain U.S. Holders that are individuals, estates and trusts are subject to a 3.8% tax ("Medicare tax") on all or a portion of their "net investment income," including in particular dividends, interest, and capital gain from the sale of ADSs. The Medicare tax will apply to the lesser of such net investment income or the excess of the taxpayer's adjusted gross income (with certain modifications) over a specified amount. The specified amount is $250,000 for married individuals filing jointly, $125,000 for married individuals filing separately, and $200,000 for single individuals.

*Passive foreign investment company rules*

We were not treated as a PFIC for 2014 but we may be treated as a passive foreign investment company, or PFIC, for U.S. federal income tax purposes for the current taxable year and in future taxable years.

We would be a PFIC for U.S. federal income tax purposes in any taxable year if 75% or more of our gross income would be passive income, or on average at least 50% of the gross value of our assets is held for the production of, or produces, passive income. In making the above determination, we are treated as earning our proportionate share of any income and owning our proportionate share of any asset of any company in which we are considered to own, directly or indirectly, 25% or more of the shares by value. Passive income for this purpose generally includes dividends, interest, royalties, rents, gains from commodities and securities transactions, the excess of gains over losses from the disposition of assets which produce passive income, and includes amounts derived by reason of the temporary investment of funds raised in offerings of the ADSs. If we were considered a PFIC at any time when a U.S. Holder held ADSs, we generally should continue to be treated as a PFIC with respect to that U.S. Holder in all succeeding years during which the U.S. Holder owns the ADSs, regardless of whether we continue to meet the tests described above.

If we are a PFIC, and you are a U.S. Holder, then unless you make one of the elections described below, you generally will be subject to special rules with respect to (a) any gain realized on the sale or other disposition of the ADSs and (b) any "excess distribution" by us to the U.S. Holder in respect of the ADSs (generally, your ratable portion of distributions in any year which are greater than 125% of the average annual distribution received by you in the shorter of the three preceding years or your holding period for the ADSs). Under the PFIC rules: (i) the gain or excess distribution would be allocated ratably over the U.S. Holder's holding period for the ADSs, (ii) the amount allocated to the taxable year in which the gain or excess distribution was realized or to any year before we became a PFIC would be taxable as ordinary income and (iii) the amount allocated to each other taxable year would be subject to tax at the highest tax rate in effect in that year and an interest charge generally applicable to underpayments of tax would be imposed in respect of the tax attributable to each such year. In addition, dividend distributions made to you will not qualify for the lower rates of taxation applicable to long-term capital gains discussed above under "U.S. Taxation of Distributions." Because a U.S. Holder that is a direct (and in certain cases indirect) shareholder of a PFIC is deemed to own its proportionate share of interests in any lower-tier PFICs, U.S. Holders should be subject to the foregoing rules with respect to any of our subsidiaries characterized as PFICs, if we are deemed a PFIC. A U.S. shareholder can make a "qualified electing fund" or QEF election to avoid the "excess distributions" or gains rules, by completing the relevant portions of and filing IRS Form 8621 in accordance with the instructions thereto. A QEF election generally may not be revoked without the consent of the IRS. Upon request of any shareholder or pursuant to an agreement with any shareholder, we will annually furnish U.S. shareholders with information needed in order to complete IRS Form 8621 (which form would be required to be filed with the IRS on an annual basis by the U.S. shareholder) and to make and maintain a valid QEF election for any year in which we or any of our subsidiaries are a PFIC.

A U.S. Holder may be able to avoid many of these adverse tax consequences if it elects to mark the ADSs to market on an annual basis. However, any such mark-to-market election would not be available for a lower-tier PFIC. If a U.S. Holder makes the mark-to-market election, the U.S. Holder generally will recognize as ordinary income any excess of the fair market value of the ADSs at the end of each taxable year over their adjusted tax basis, and will recognize an ordinary loss in respect of any excess of the adjusted tax basis of the ADSs over their fair market value at the end of the taxable year (but only to the extent of the net amount of income previously included as a result of the mark-to-market election). If a U.S. Holder makes the election, the U.S. Holder's tax basis in the ADSs will be adjusted to reflect these income or loss amounts. Any gain recognized on the sale or other disposition of ADSs in a year when we are a PFIC will be treated as ordinary income and any loss will be treated as an ordinary loss (but only to the extent of the net amount of income previously included as a result of the mark-to-market election). The mark-to-market election is available only if we are a PFIC and the ADSs are "regularly traded" on a "qualified exchange." The ADSs will be treated as "regularly traded" in any calendar year in which more than a de minimis quantity of the ADSs are traded on a qualified exchange on at least 15 days during each calendar quarter (subject to the rule that trades that have as one of their principal purposes the meeting of the trading requirement as disregarded). The NASDAQ Capital Market is a qualified exchange for this purpose and, consequently, if the ADSs are regularly traded, the mark-to-market election will be available to a U.S. holder. U.S. Holders are urged to consult their tax advisors with respect to the availability and tax consequences of a mark-to-market election with respect to our ADSs.

A U.S. Holder will be required to file Internal Revenue Service Form 8621 if such U.S. Holder owns ADSs in any year in which we are classified as a PFIC.

**The U.S. federal income tax rules relating to PFICs are complex. Prospective U.S. investors are urged to consult their own tax advisers with respect to the acquisition, ownership and disposition of the ADSs, the consequences to them of an investment in a PFIC, any elections available with respect to the ADSs and the IRS information reporting obligations with respect to the acquisition, ownership and disposition of the ADSs.**

*Information reporting and backup withholding*

A U.S. Holder may be subject to information reporting to the IRS and possible backup withholding with respect to dividends paid on, or proceeds of the sale or other disposition of the ADSs unless such U.S. Holder is a corporation or qualifies within certain other categories of exempt recipients or provides a taxpayer identification number and certifies as to no loss of exemption from backup withholding and otherwise complies with applicable requirements of the backup withholding rules. Amounts withheld under these rules may be credited against the U.S. Holder's U.S. federal income tax liability and a U.S. Holder may obtain a refund of any excess amounts withheld under the backup withholding rules by timely filing the appropriate IRS forms and furnishing any required information. A U.S. Holder who does not provide a correct taxpayer identification number may be subject to penalties imposed by the IRS.

*Certain Reporting Requirements With Respect to Payments of Offer Price*

U.S. Holders paying more than U.S. $100,000 for the ADSs generally may be required to file IRS Form 926 reporting the payment of the offer price for the ADSs to us. Substantial penalties may be imposed upon a U.S. Holder that fails to comply. Each U.S. holder should consult its own tax advisor as to the possible obligation to file IRS Form 926.

*Foreign Asset Reporting*

Certain U.S. Holders who are individuals are required to report information relating to an interest in the ADSs, subject to certain exceptions (including an exception for shares held in accounts maintained by U.S. financial institutions) by filing IRS Form 8938 (Statement of Specified Foreign Financial Assets) with their U.S. federal income tax return. U.S. Holders are urged to consult their tax advisors regarding their information reporting obligations, if any, with respect to their ownership and disposition of the ADSs.

## PLAN OF DISTRIBUTION

The Selling Shareholders, which as used herein includes donees, pledgees, transferees or other successors-in-interest selling securities or interests in securities received after the date of this prospectus from a Selling Shareholder as a gift, pledge, partnership distribution or other transfer, may, from time to time, sell, transfer or otherwise dispose of any or all of their securities or interests in securities on any stock exchange, market or trading facility on which the securities are traded or in private transactions. These dispositions may be at fixed prices, at prevailing market prices at the time of sale, at prices related to the prevailing market price, at varying prices determined at the time of sale, or at negotiated prices.

The Selling Shareholders may use any one or more of the following methods when disposing of securities or interests therein:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the securities as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- short sales effected after the date the registration statement of which this Prospectus is a part is declared effective by the SEC;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- through broker-dealers that agree with the selling shareholders to sell a specified number of such securities at a stipulated price per share;
- a combination of any such methods of sale; or
- any other method permitted pursuant to applicable law.

The Selling Shareholders may, from time to time, pledge or grant a security interest in some or all of the securities owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the securities, from time to time, under this prospectus, or under an amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act amending the list of Selling Shareholders to include the pledgee, transferee or other successors in interest as Selling Shareholders under this prospectus. The Selling Shareholders also may transfer the securities in other circumstances, in which case the transferees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

In connection with the sale of securities or interests therein, the Selling Shareholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the securities in the course of hedging the positions they assume. The Selling Shareholders may also sell securities short and deliver these securities to close out their short positions, or loan or pledge the securities to broker-dealers that in turn may sell these securities. The Selling Shareholders may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution of securities offered by this prospectus, which securities such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The aggregate proceeds to the Selling Shareholders from the sale of the securities offered by them will be the purchase price of the securities less discounts or commissions, if any. Each of the Selling Shareholders reserves the right to accept and, together with their agents from time to time, to reject, in whole or in part, any proposed purchase of securities to be made directly or through agents. We will not receive any of the proceeds from this offering.

The Selling Shareholders also may resell all or a portion of the securities in open market transactions in reliance upon Rule 144 under the Securities Act of 1933, provided that they meet the criteria and conform to the requirements of that rule.

The Selling Shareholders and any underwriters, broker-dealers or agents that participate in the sale of the securities or interests therein may be "underwriters" within the meaning of Section 2(11) of the Securities Act. Any discounts, commissions, concessions or profit they earn on any resale of the securities may be underwriting discounts and commissions under the Securities Act. Selling Shareholders that are "underwriters" within the meaning of Section 2(11) of the Securities Act will be subject to the prospectus delivery requirements of the Securities Act.

To the extent required, the securities to be sold, the names of the Selling Shareholders, the respective purchase prices and public offering prices, the names of any agents, dealer or underwriter, any applicable commissions or discounts with respect to a particular offer will be set forth in an accompanying prospectus supplement or, if appropriate, a post-effective amendment to the registration statement that includes this prospectus.

In order to comply with the securities laws of some states, if applicable, the securities may be sold in these jurisdictions only through registered or licensed brokers or dealers. In addition, in some states the securities may not be sold unless it has been registered or qualified for sale or an exemption from registration or qualification requirements is available and is complied with.

We have advised the Selling Shareholders that the anti-manipulation rules of Regulation M under the Exchange Act may apply to sales of securities in the market and to the activities of the Selling Shareholders and their affiliates. In addition, to the extent applicable we will make copies of this prospectus (as it may be supplemented or amended from time to time) available to the Selling Shareholders for the purpose of satisfying the prospectus delivery requirements of the Securities Act. The Selling Shareholders may indemnify any broker-dealer that participates in transactions involving the sale of the securities against certain liabilities, including liabilities arising under the Securities Act.

We have agreed to indemnify the Selling Shareholders against liabilities, including liabilities under the Securities Act and state securities laws, relating to the registration of the securities offered by this prospectus.

We have agreed with the Selling Shareholders to keep the registration statement of which this prospectus constitutes a part effective until the earlier of (1) such time as all of the securities covered by this prospectus have been disposed of pursuant to and in accordance with the registration statement or Rule 144 under the Securities Act or (2) the date on which all of the securities may be sold without restriction or condition pursuant to Rule 144 under the Securities Act.

## EXPERTS

The consolidated financial statements of Akari Therapeutics Plc and its subsidiaries as of December 31, 2014 and 2013 and for each of the two years in the period ended December 31, 2014 incorporated by reference into this prospectus have been audited by Kost, Forer, Gabbay & Kasierer, a member of Ernst &Young Global, an independent registered public accounting firm, as set forth in their report thereon appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

The combined and consolidated financial statements of Volution Immuno Pharmaceuticals SA and Affiliate as of December 31, 2014 and 2013 and for each of the two years in the period ended December 31, 2014 incorporated by reference in this Prospectus have been so included in reliance on the report of BDO AG, an independent registered public accounting firm (the report on the financial statements contains an explanatory paragraph regarding the Company's ability to continue as a going concern), incorporated herein by reference, given on the authority of said firm as experts in auditing and accounting.

## LEGAL MATTERS

The validity of the Ordinary Shares being offered by this prospectus and other legal matters concerning this offering relating to English law will be passed upon for us by DLA Piper UK LLP.

## ENFORCEABILITY OF CIVIL LIABILITIES

We are incorporated under the laws of England and Wales. Several of our directors and officers reside outside the United States, and a portion of our assets and all or a substantial portion of the assets of such persons are located outside the United States. As a result, it may be difficult for you to serve legal process on us or certain of our directors and executive officers or have any of them appear in a U.S. court.

It may be difficult for U.S. investors to bring and/or effectively enforce suits against our company in England. Although English courts do recognize U.S. judgments unless there is an overriding jurisdictional or public policy reason not to do so, if a judgment is obtained in the U.S. courts based on the civil liability provisions of U.S. federal securities laws against us, difficulties may arise in enforcing the judgment against us in the English courts. The enforceability of any U.S. judgment in the United Kingdom will depend on the particular facts of the case as well as the laws and treaties in effect at the time. The United States and the United Kingdom do not currently have a treaty providing for reciprocal recognition and enforcement of judgments (other than arbitration awards) in civil and commercial matters. It may similarly be difficult for U.S. investors to bring an original action in the English courts to enforce liabilities based on U.S. federal securities laws.

# AKARI THERAPEUTICS PLC

**395,881,100 Ordinary Shares**
**Represented by 3,958,811 American Depositary Shares**

**_____, 2015**

## PART II
## INFORMATION NOT REQUIRED IN PROSPECTUS

**Item 14. Other Expenses of Issuance and Distribution**.

We will pay all expenses in connection with the registration and sale of the Ordinary Shares represented by ADSs by the Selling Shareholders. The estimated expenses of issuance and distribution are set forth below.

| | | |
|---|---|---|
| SEC filing fee | $ | 7,969.06 |
| Legal expenses | $ | 75,000.00 |
| Accounting expenses | $ | 25,000.00 |
| Miscellaneous | $ | 2,030.94 |
| Total | $ | 110,000.00 |

**Item 15. Indemnification of Directors and Officers**

The Registrant's articles of association provide that, subject to the Companies Act 2006, every director or other officer (excluding an auditor) of the Registrant may be indemnified out of the assets of the Registrant against all costs, charges, expenses, losses or liabilities incurred by him in performing his duties or the exercise of his powers or otherwise in relation to or in connection with his duties, powers or office.

The Registrant also maintains directors and officers insurance to insure such persons against certain liabilities.

**Item 16. Exhibits and Financial Statement Schedule**

See Exhibit Index immediately following the signature page.

**Item 17. Undertakings**

The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by section 10(a)(3) of the Securities Act of 1933;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) (§230.424(b) of this chapter) if, in the aggregate, the changes in volume and price represent no more than 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.

The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, as amended each filing of the registrant's annual report pursuant to section 13(a) or section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of New York, New York on this 16th day of October, 2015.

AKARI THERAPEUTICS PLC

By: /s/ Gur Roshwalb
Gur Roshwalb
Chief Executive Officer

**POWER OF ATTORNEY**

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitute and appoint Gur Roshwalb and Dov Elefant, and each one of them, as his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her and in their name, place, and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this registration statement, and to sign any registration statement for the same offering covered by this registration statement that is to be effective upon filing pursuant to Rule 462(b) under the Securities Act of 1933, as amended, and all post-effective amendments thereto, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or any of them, or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed below by the following persons in the capacities and on the dates indicated:

| Name | Title | Date |
|---|---|---|
| /s/ Gur Roshwalb<br>Gur Roshwalb | Chief Executive Officer and Director<br>(principal executive officer) | October 16, 2015 |
| /s/ Dov Elefant<br>Dov Elefant | Chief Financial Officer<br>(principal financial officer and principal accounting officer) | October 16, 2015 |
| /s/ Ray Prudo<br>Ray Prudo | Executive Chairman of the Board | October 16, 2015 |
| /s/ Mark S. Cohen<br>Mark S. Cohen | Vice Chairman of the Board | October 16, 2015 |
| /s/ Stuart Ungar<br>Stuart Ungar | Director | October 16, 2015 |
| /s/ James Hill<br>James Hill | Director | October 16, 2015 |
| /s/ Clive Richardson<br>Clive Richardson | Director | October 16, 2015 |
| /s/ Allan Shaw<br>Allan Shaw | Director | October 16, 2015 |

## EXHIBIT INDEX

| Exhibit Number | Exhibit Description |
|---|---|
| 3.1 | Memorandum of Association of Akari Therapeutics, Plc (formerly Celsus Therapeutics Plc) (incorporated by reference to the exhibit previously filed with the Registrant's Registration Statement on Form 20-F (No. 000-54749) filed on June 28, 2012). |
| 3.2 | New Articles of Association of Akari Therapeutics, Plc (formerly Celsus Therapeutics Plc) (incorporated by reference to the exhibit previously filed with the Registrant's Registration Statement on Form 20-F (No. 000-54749) filed on June 28, 2012). |
| 4.1 | Form of Deposit Agreement among the Registrant, Deutsche Bank Trust Company Americas, as Depositary, and all Owners and Holders from time to time of American Depositary Shares issued thereunder (incorporated by reference to the exhibit previously filed with the Registrant's Registration Statement on Form F-6 (No. 333-185197) filed on November 30, 2012). |
| 4.2 | Amendment to Deposit Agreement among the Registrant, Deutsche Bank Trust Company Americas, as Depositary, and all Owners and Holders from time to time of American Depositary Shares issued thereunder (incorporated by reference to the registrant's Post-Effective Amendment No. 1 to Registration Statement on Form F-6 (No. 333-185197) filed on December 24, 2013). |
| 4.3 | Form of Amendment No. 2 to Deposit Agreement (incorporated by reference to the exhibit previously filed with the Registrant's Post-Effective Amendment on Registration Statement Form F-6 (File No. 333-185197) filed on September 9, 2015). |
| 4.4 | Form of American Depositary Receipt; the Form is Exhibit A of the Form of Amendment to the Deposit Agreement (incorporated by reference to the exhibit previously filed with the Registrant's Post-Effective Amendment on Registration Statement Form F-6 (File No. 333-185197) filed on September 9, 2015). |
| 5.1* | Opinion of DLA Piper UK LLP. |
| 10.1 | Form of Securities Purchase Agreement, dated August 17, 2015 by and among Akari Therapeutics, Plc (formerly known as Celsus Therapeutics Plc) and the Buyers (as defined therein) (incorporated by reference to Exhibit 10.1 of the Current Report on Form 8-K filed by the Registrant on August 18, 2015). |
| 10.2 | Form of Registration Rights Agreement, dated August 17, 2015 by and among Akari Therapeutics, Plc (formerly known as Celsus Therapeutics Plc) and the Buyers (as defined therein) (incorporated by reference to Exhibit 10.1 of the Current Report on Form 8-K filed by the Registrant on August 18, 2015). |
| 23.1* | Consent of Kost, Forer, Gabbay & Kasierer, a member of Ernst &Young Global, Independent Registered Public Accounting Firm. |
| 23.2* | Consent of BDO AG, Independent Registered Public Accounting Firm. |
| 23.3* | Consent of DLA Piper UK LLP (included in Exhibit 5.1). |
| 24.1 | Power of Attorney (included on the signature page to this Registration Statement). |

*Filed herewith

**Exhibit 5.1**

Akari Therapeutics plc
C/O Pearl Cohen Zedek Latzer Baratz UK LLP
One Pancras Square
London
N1C 4AG

15 October 2015

Dear Sirs

AKARI THERAPEUTICS PLC (THE "COMPANY")

This opinion ("Opinion") is being delivered to you in connection with the filing by the Company of a registration statement on form S-3 ("Registration Statement") with the Securities and Exchange Commission under the Securities Act of 1933, as amended, relating to the resale of 395,881,100 ordinary shares of £0.01 each in the capital of the Company (the "Resale Ordinary Shares") by certain selling shareholders which were allotted to such shareholders pursuant to a Securities Purchase Agreement dated 17 August 2015 ("Agreement").

For the purposes of this Opinion, we have examined only the following and, without limitation, we have not made any other enquiries of the Company or otherwise:

1.1 an on-line search of Companies House in respect of the Company on the day before the date of this Opinion (**"Companies Registry Search"**) and oral enquiries regarding any entry in respect of the Company on the Central Index of Winding Up Petitions on the day before the date of this Opinion (the **"Central Index Search"**) (together, the **"Searches and Enquiries"**);

1.2 the articles of association and memorandum of association of the Company in the form provided to us by the Company; and

1.3 a copy of the minutes of a meeting of the board of directors of the Company dated 11 August 2015, which approved the allotment of the Resale Ordinary Shares (**"Board Resolutions"**).

**1. Opinions**

Subject to the assumptions, qualifications and limitations stated herein, we are of the opinion that:

1.1 the allotment of the Resale Ordinary Shares has been duly authorized by all necessary corporate or other organizational action and the Resale Ordinary Shares are validly issued and fully paid and nonassessable. For the purposes of this Opinion, we have assumed that the term "non-assessable" in relation to the Resale Ordinary Shares means under English law that holders of such Resale Ordinary Shares, in respect of which all amounts due on such Resale Ordinary Shares as to the nominal amount and any premium thereon have been fully paid, will be under no obligation to contribute to the liabilities of the Company solely in their capacity as holders of such Resale Ordinary Shares; and

1.2 the Searches and Enquiries not revealing any of the same, that on the date of this Opinion no members or creditors' voluntary winding up resolution has been passed and no petition has been presented and no order has been made for the administration, winding up or dissolution of the Company and no receiver, administrative receiver, administrator, liquidator, provisional liquidator, trustee or similar officer has been appointed in relation to the Company or any of its assets.

**2. Assumptions**

For the purposes of this Opinion we have assumed (without making any investigation) that:

2.1 the Company received the issue proceeds of the Resale Ordinary Shares and that the subscribing shareholders were duly entered in the register of members of the Company;

2.2 the Company received in full in cash the subscription price payable for the Resale Ordinary Shares and the Company shall have entered the holder or holders thereof in the register of members of the Company showing that all the Resale Ordinary Shares shall have been fully paid up as to their nominal value and any premium thereon as at the date of their allotment;

2.3 any documents submitted to us as originals are authentic, final and complete, all signatures, stamps and seals on the documents submitted to us are genuine and all documents submitted to us as copies are final and complete and conform to the original documents;

2.4 in respect of all parties to the Agreement other than the Company:

(i) each of the parties to the Agreement (other than the Company) is duly established and validly existing in accordance with the laws of its place of establishment;

(ii) such parties have capacity, power and authority to enter into and perform their obligations under the Agreement;

(iii) the Agreement have been duly executed and delivered by such parties in compliance with all requisite corporate authorisations by each such party; and

(iv) the obligations of all such parties are binding upon such parties under all applicable laws;

2.5 the copies of the Articles of Association and Memorandum of Association provided by the Company to us are complete, accurate and up to date as at the date of this Opinion and, without verifying this, we have assumed that those forms are identical to the copies contained in our Company Search;

2.6 the Agreement has been executed by the person(s) authorised to execute the same by the resolutions of the board of directors of the Company;

2.7 the Board Resolutions:

(i) were duly passed at a properly convened meeting of the board of duly appointed directors of the Company at which a quorum was present at all times and those directors attending acted in good faith throughout; and

(ii) have not been amended or rescinded and are in full force and effect,

and due disclosure has been made by each director of any interest they have in the transactions to which the Agreement relates in accordance with the provisions of sections 177 and 182 of the Companies Act 2006 (**"2006 Act"**) and the Articles of Association of the Company and that no director has any such interest except to the extent permitted by the Articles of Association of the Company;

2.8 there are no agreements, letters or other arrangements having contractual effect which modify the terms of, or affect, the Agreement or which render a party to the same incapable of or prohibit it from performing its obligations under the Agreement and no provision of the Agreement has been waived;

2.9 in relation to the Company Search and the Winding-up Search:

2.9.1 all documents, forms and notices which should have been delivered to the Registrar of Companies by or on behalf of the Company have been delivered;

2.9.2 the results of the Company Search and the Winding-up Search were complete, accurate and up to date at the time that they were obtained;

2.9.3 no additional matters would have been disclosed by any search undertaken at Companies House or enquiry made of the Central Registry of Winding-up Petitions in relation to the Company after the Company Search was obtained or, as the case may be, the Winding-up Search was carried out or by a search of any District Registry of the High Court in relation to the Company at any time;

2.10 in relation to the Company and its members:

(i) the execution of the Agreement by the Company was a proper use of the powers of its directors acting in accordance with their duties and in good faith; and

(ii) in entering into the Agreement, the Company acted in good faith;

2.11 immediately after the execution of the Agreement each of the parties to them was solvent and:

(i) no steps have been taken by any person with a view to achieving the dissolution of the Company and the Company has not passed a resolution for voluntary winding up;

(ii) no petition has been presented, or order made, for the winding up of the Company;

(iii) no application has been made to court for an administration order or notice of an intention to appoint an administrator filed or given in relation to the Company;

(iv) no liquidator, receiver, receiver and manager, administrative receiver, administrator or similar officer has been appointed in relation to the whole Company or any part of its assets, rights or revenues;

(v) the Company is not unable or capable of being deemed unable to pay its debts within the meaning of section 123 of the Insolvency Act 1986 (for which purpose account is to be taken of its contingent and prospective liabilities);

(vi) no steps have been taken by any person to obtain a moratorium in relation to the Company;

(vii) there is no composition or arrangement with the Company's creditors in place, including (without prejudice to the generality of the foregoing) a voluntary arrangement under the Insolvency Act 1986 or a scheme of arrangement under the 2006 Act and there are no proposals for any such composition or arrangement to be entered into; and

(viii) no proceedings have been commenced under any law, regulation or procedure relating to the reconstruction or adjustment of the Company's debts.

2.12 none of the parties is or will be seeking to achieve any purpose not apparent from the Agreement which might render them illegal or void;

2.13 as at each date of allotment and issue of the Resale Ordinary Shares and grant of rights to subscribe for Resale Ordinary Shares, the directors of the Company had sufficient authority and powers conferred on them to allot and issue such Resale Ordinary Shares and grant such rights (as applicable) under section 551 of the 2006 Act and under section 570 of the 2006 Act as if section 561 of the 2006 Act did not apply to such allotment and issue or grant, and the directors of the Company shall not allot or issue (or purport to allot or issue) Resale Ordinary Shares and shall not grant rights (or purport to grant rights) to acquire Resale Ordinary Shares in excess of such powers or in breach of any other limitation on their powers to allot and issue Resale Ordinary Shares or grant rights to acquire Resale Ordinary Shares;

2.14 there are no provisions of the laws of any jurisdiction outside England which:

(i) would be contravened by the execution or performance of the Agreement; or

(ii) would otherwise have any implication for the opinions which we express; and

2.15 insofar as any obligation under the Agreement falls to be performed in any jurisdiction outside England, its performance:

(i) will not be illegal or adversely affected by virtue of the laws or regulations of, or applicable in, that jurisdiction; or

(ii) would not otherwise have any implication for the opinions which we express.

Qualifications

3. The opinions which are expressed in this letter are subject to the following qualifications:

3.1 notice of a winding-up order or resolution, notice of an administration order and notice of the appointment of a receiver or administrative receiver or administrator may not be filed with or scanned by the Registrar of Companies immediately and there may be a delay in the relevant notice appearing on the public file of the company concerned;

3.2 a company search is not capable of revealing whether or not a winding-up petition or a petition for the making of an administration order has been presented or an administration application has been made or notice of intention to appoint an administrator has been given;

4. For the purposes of this Opinion we have not investigated and make no comments with regard to any warranties, facts, opinions or representations in the Agreement or on their accuracy or adequacy.

5. The opinions expressed in this letter are strictly limited to the matters stated herein and do not apply by implication to other matters.

This Opinion speaks only as at the date hereof. Notwithstanding any reference herein to future matters or circumstances, we have no obligation to advise the addressees (or any third party) of any changes in the law or facts that may occur after the date of this Opinion.

This Opinion is given on condition that it is governed by and shall be construed in accordance with English law in force and as interpreted at the date of this Opinion and that any action arising out of this Opinion is subject to the exclusive jurisdiction of the English courts.

This Opinion is given solely in connection with the filing of the Registration Statement by or on behalf of the Company. We hereby consent to the filing of this Opinion in its full form as an exhibit to the Registration Statement.

Yours faithfully

/s/ DLA Piper UK LLP
DLA Piper UK LLP

**Exhibit 23.1**

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We consent to the reference to our firm under the caption "Experts" in the Registration Statement (Form S-3 No. 333-198107) and related Prospectus of Akari Therapeutics Plc. (formerly Celsus Therapeutics Plc.), for the registration of 395,881,100 shares of its ordinary shares, par value £0.01 and to the incorporation by reference therein of our report dated February 11, 2015, with respect to the consolidated financial statements and schedules of Akari Therapeutics Plc. (formerly Celsus Therapeutics Plc.) included in its Annual Report (Form 10-K) for the year ended December 31, 2014, filed with the Securities and Exchange Commission.

Tel-Aviv, Israel
October 15, 2015

/s/ KOST FORER GABBAY & KASIERER
A Member of Ernst & Young Global

**Exhibit 23.2**

Akari Therapeutics Plc (formerly Celsus Therapeutics Plc)

London, United Kingdom

We hereby consent to the incorporation by reference in the Prospectus constituting a part of this Registration Statement of our report dated June 17, 2015 except for Notes 10, 11, and 13 as to which the date is October 15, 2015, relating to the combined and consolidated financial statements of Volution Immuno Pharmaceuticals SA and Affiliate appearing in the Form 8-K/A of Akari Therapeutics Plc filed on October 16, 2015. Our report contains an explanatory paragraph regarding the Company's ability to continue as a going concern.

We also consent to the reference to us under the caption "Experts" in the Prospectus.

BDO AG

/s/ Christoph Tschumi /s/ ppa. Julian Snow

Zurich, Switzerland
October 15, 2015