UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2015

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission file number: 001-36288

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.)

24 West 40th Street, 8th Floor
New York, NY 10018
(Address of principal executive offices)

(646) 350-0702
Registrant's telephone number, including area code

Securities registered pursuant to Section 12(b) of the Exchange Act:

Title of each class	**Name of each exchange on which registered**
American Depositary Shares, each representing one hundred (100) Ordinary Shares, par value £0.01	The NASDAQ Stock Market LLC

Securities registered pursuant to Section 12(g) of the Exchange Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

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 ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of the registrant's voting and non-voting Ordinary Shares held by non-affiliates of the registrant on June 30, 2015, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $31,193,000 based upon the closing price reported for such date on the NASDAQ Capital Market.

As of March 23, 2016, the registrant had 1,177,693,383 Ordinary Shares outstanding. 11,719,720 shares held as American Depositary Shares (ADSs), each representing one hundred (100) Ordinary Shares, were outstanding as of March 23, 2016.

DOCUMENTS INCORPORATED BY REFERENCE

Certain information required to be disclosed in Part III of this annual report is incorporated by reference from the registrant's definitive proxy statement to be filed not later than 120 days after the end of the fiscal year covered by this annual report.

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Forward-Looking Statements

This Annual Report on Form 10-K contains forward-looking statements. All statements other than statements of historical facts contained in this Annual Report on Form 10-K, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans, objectives of management and expected market growth are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

Words such as "may," "anticipate," "estimate," "expects," "projects," "intends," "plans," "believes" and words and terms of similar substance used in connection with any discussion of future operating or financial performance, identify forward-looking statements. Forward-looking statements represent management's present judgment regarding future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. These risks include, but are not limited to, risks and uncertainties regarding our pre-clinical studies, our ability to conduct clinical trials of our product candidates and the results of such trials, as well as risks and uncertainties relating to litigation, government regulation and third-party reimbursement, economic conditions, markets, products, competition, intellectual property, services and prices, key employees, future capital needs, dependence on third parties and other factors. Please also see the discussion of risks and uncertainties under "Risk Factors" contained in this Annual Report on Form 10-K.

In light of these assumptions, risks and uncertainties, the results and events discussed in the forward-looking statements contained in this Annual Report on Form 10-K might not occur. We are not under any obligation, and we expressly disclaim any obligation, to update or alter any forward-looking statements, whether as a result of new information, future events or otherwise. All subsequent forward-looking statements attributable to us or to any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section.

We have obtained the statistical data, market data and other industry data and forecasts used throughout this Annual Report on Form 10-K from publicly available information. We have not sought the consent of the sources to refer to the publicly available reports in this Annual Report on Form 10-K.

You should read this Annual Report on Form 10-K and the documents that we have filed as exhibits to the Annual Report on Form 10-K with the understanding that our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward-looking statements whether as a result of new information, future events or otherwise, except as required by applicable law.

PART I

All trademarks, trade names or service marks that are used in this Annual Report on Form 10-K are the property of their respective owners. Unless the context requires otherwise, references in this Annual Report on Form 10-K to "Akari," the "Company," "we," "us," and "our" refer to Akari Therapeutics, Plc (formerly Celsus Therapeutics, Plc) and its subsidiaries.

Item 1. BUSINESS

Overview

Akari Therapeutics, Plc ("Akari" or the "Company"), formerly Celsus Therapeutics, Plc ("Celsus"), 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 September 18, 2015, Celsus completed its acquisition of all of the capital stock of Volution Immuno Pharmaceuticals SA ("Volution"), from ` Pharma Limited ("RPC"), Volution's sole shareholder, in exchange for ordinary shares, par value £0.01, ("Ordinary Shares"), of Celsus (the "Acquisition"), in accordance with the terms of the Share Exchange Agreement, dated as of July 10, 2015 (the "Agreement"), by and among Celsus and RPC. In connection with the Acquisition, the name of the combined company was changed to Akari Therapeutics, Plc. The Company's American Depositary Shares ("ADSs"), each representing 100 Ordinary Shares, began trading on The NASDAQ Capital Market under the symbol "AKTX" on September 21, 2015.

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 $2.6 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 (iii) that Coversin can achieve full complement inhibition in the blood of eculizumab-resistant patients tested to date and (iv) that complement inhibition is complete whether measured by Elisa CH50 U Eq/ml assay or sheep red blood cell lytic CH50 assay, as demonstrated in our 28-day safety study in non-human primates (NHP) where Coversin was dosed once a day for 28 days. 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 PNH, aHUS, myasthenia gravis (MG), 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 signaling 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, other respiratory inflammatory diseases, and other disorders where neutrophil or eosinophil infiltration play and important role.

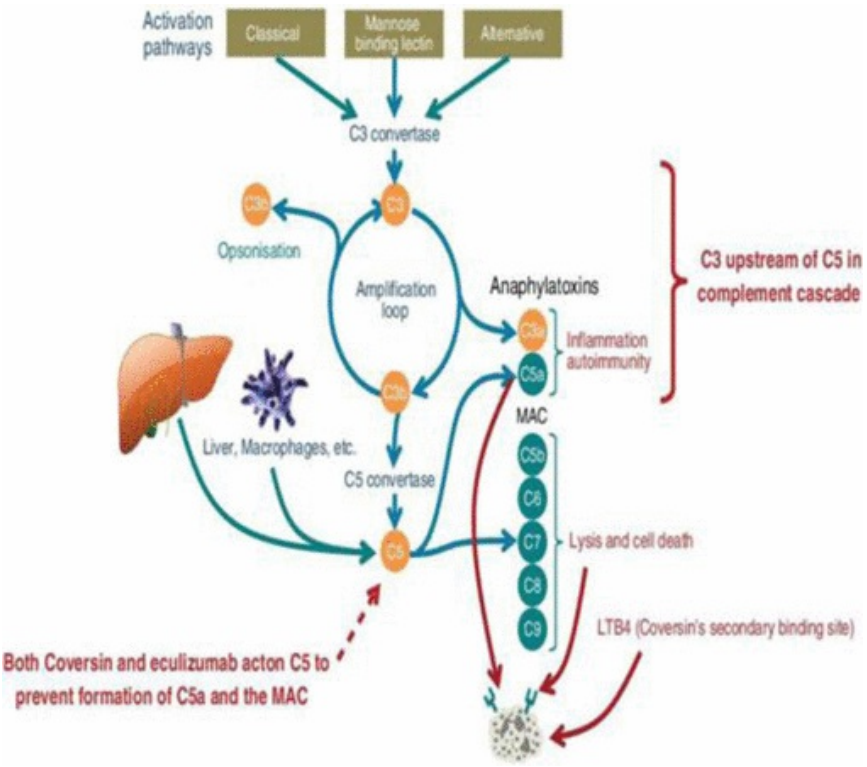


Figure 1

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 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.

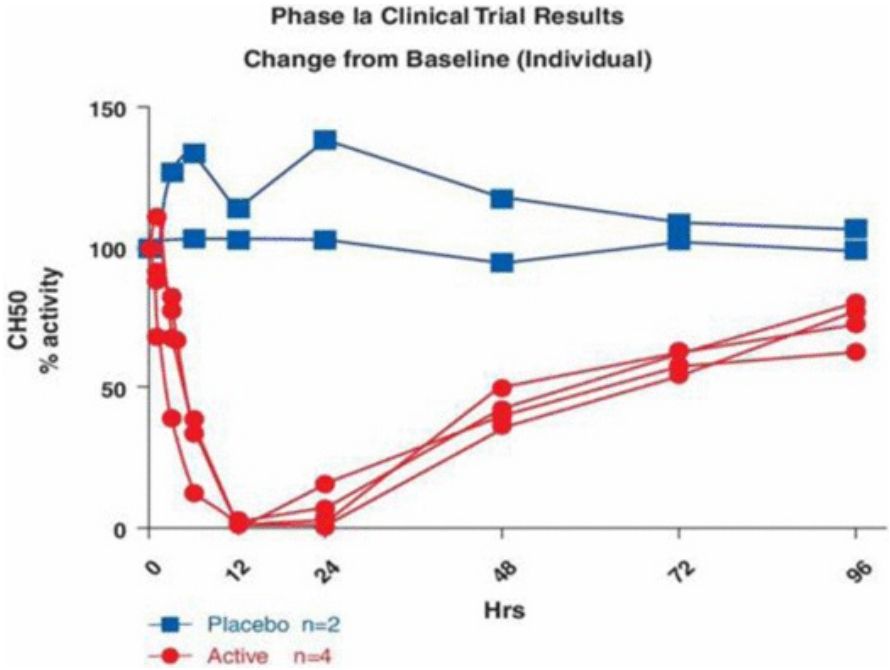
To date, we have demonstrated: (i) 100% inhibition of complement C5 activity by Coversin within 12 hours in a Phase Ia clinical trial in healthy volunteers; (ii) that Coversin inhibits PNH red blood cell lysis in vitro (iii) that Coversin can achieve full complement inhibition in the blood of eculizumab-resistant patients tested to date and (iv) that complement inhibition is complete whether measured by Elisa CH50 U Eq/ml assay or sheep red blood cell lytic CH50 assay, as demonstrated in our 28-day safety study in NHP where Coversin was dosed once a day for 28 days. 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 which was initiated in the first quarter of 2016.



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.

We have initiated treatment in a European patient with PNH and resistant to eculizumab due to a polymorphism on February 8, 2016. The patient is being treated with Coversin under a clinical trial protocol approved by an EU national regulatory authority for treating patients with eculizumab resistance. The primary objective of the eculizumab-resistance program is to provide patients who have clinically demonstrated resistance to eculizumab early access to Coversin as a potentially lifesaving alternative. These patients are entered into an open label protocol where safety and efficacy are measured on an ongoing basis. We expect to present topline results from these patients as they become available. A Phase Ib clinical trial in healthy volunteers was initiated in January 2016, and we expect to initiate a Phase II trial in PNH patients in the second quarter of 2016. We expect to start a Phase II trial in GBS in the middle of 2016 and in aHUS in late 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.

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, a 28-day NHP study, and a one month and three month rodent study. 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 also supported the five day repeat-dose Phase Ib trial initiate on January 29, 2016, and will support the Phase II clinical trial which we expect to initiate in the second quarter of 2016.

With our toxicology studies showing no signs of harmful reactions or laboratory findings outside the generally-accepted normal range, 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 these data support 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 and Ib trials and have 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 have demonstrated that Coversin fully inhibits complement activity in the blood of these patients by blocking C5. As noted above, we have also initiated treatment of a patient with PNH and eculizumab resistance due to a C5 polymorphism.

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%, respectively. At one year, full recovery of motor strength occurs in about 60% of patients, while severe motor problems persist in about 14%. Approximately 5 to 10% 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% of patients with GBS die despite intensive care. Of patients who become ventilator dependent, about 20% 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 5% 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 2.5 million 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 $2.6 billion in sales in 2015, 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 $2.6 billion in 2015. 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, we currently have 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 expect 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 December 31, 2015, we had five full-time employees and two full-time equivalent consultants.

Properties

We do not currently own any property. 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 1,260 square feet of office space in London, England, for approximately $12,000 per month. The lease for this property expires in March 2019.

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 its 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 our 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

The 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 the 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. The FDA must determine if the drug candidate qualifies for fast track designation within 60 days of receipt of the sponsor's request.

Under the fast track program, the 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 the 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 the FDA.

In addition to other benefits such as the ability to use surrogate endpoints and engage in more frequent interactions with the FDA, the 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 the FDA approves, a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, the 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 the FDA if the 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. The 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. The 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 eight years of data exclusivity and an additional two 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 eight years. After eight 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 two years later (or a total of 10 years after the first marketing authorization in the EU of the innovator product), or three 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 eight 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 be significantly lower.

Item 1A. RISK FACTORS

Except for the historical information contained herein or incorporated by reference, this Annual Report on Form 10-K and the information incorporated by reference contains forward-looking statements that involve risks and uncertainties. These statements include projections about our accounting and finances, plans and objectives for the future, future operating and economic performance and other statements regarding future performance. These statements are not guarantees of future performance or events. Our actual results could differ materially from those discussed in this Annual Report on Form 10-K. Factors that could cause or contribute to these differences include, but are not limited to, those discussed in the following section, as well as those discussed in Part II, Item 7 entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere throughout this Annual Report on Form 10-K and in any documents incorporated in this Annual Report on Form 10-K by reference.

You should consider carefully the following risk factors, together with all of the other information included or incorporated in this Annual Report on Form 10-K. If any of the following risks, either alone or taken together, or other risks not presently known to us or that we currently believe to not be significant, develop into actual events, then our business, financial condition, results of operations or prospects could be materially adversely affected. If that happens, the market price of our Ordinary Shares could decline, and shareholders may lose all or part of their investment.

Risks Relating to Our Financial Position and Our Business

We have a history of operating losses and cannot give assurance of future revenues or operating profits; investors may lose their entire investment.

We do not expect to generate revenue or profitability that is necessary to finance our operations in the short term. We incurred net losses of $45,317,532 and $1,947,553 for the years ended December 31, 2015 and 2014, respectively. In addition, our accumulated deficit as of December 31, 2015 and 2014 was $56,796,613 and $11,479,081, respectively. To date, we have not commercialized any products or generated any revenues from the sale of products, and absent the realization of sufficient revenues from product sales, we may never attain profitability in the future. Our losses have resulted principally from costs incurred in our discovery and development activities.

Our failure to become and remain profitable would depress the market price of our ordinary shares and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations. If we continue to suffer losses as we have in the past, investors may not receive any return on their investment and may lose their entire investment.

We will require additional capital to fund our operations, and if we are unable to obtain such capital, we will be unable to successfully develop and commercialize any product candidates.

As of December 31, 2015, we had existing cash and cash equivalents of $68,919,995. We will require additional capital in order to develop and commercialize our current product candidates or any product candidates that we acquire, if any. There can be no assurance that additional funds will be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available on a timely basis, we may be required to terminate or delay development for one or more of our product candidates.

We may seek to raise any necessary funds through public or private equity offerings, or strategic alliances and licensing arrangements. We may not be able to obtain additional financing on terms favorable to us, if at all. General market conditions may make it very difficult for us to seek financing from the capital markets. We may be required to relinquish rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us, in order to raise additional funds through alliance, joint venture or licensing arrangements.

Future sales and issuances of our ordinary shares or rights to purchase ordinary shares and any equity financing that we pursue, could result in significant dilution of the percentage ownership of our shareholders and could cause our ADS price to fall.

To the extent we raise additional capital by issuing equity securities, our shareholders may experience substantial dilution. In any financing transaction, we may sell ordinary shares (or ADSs), convertible securities or other equity securities. If we sell ordinary shares (or ADSs), convertible securities or other equity securities, our shareholders investment in our ordinary shares (or ADSs) will be diluted. These sales may also result in material dilution to our existing shareholders, and new investors could gain rights superior to our existing shareholders.

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 December 31, 2015, we had an accumulated deficit of $56,796,613. 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 December 31, 2015, we had cash and cash equivalents of $68,919,995. 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, 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 four and eight 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 or other indications 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 December 31, 2015, we had five full-time employees and a further two full-time equivalent consultants. Our focus on the development of Coversin requires us to optimize cash utilization and to manage and operate our business in a highly efficient manner. We cannot assure you that we will be able to hire and/or retain adequate staffing levels to develop Coversin or 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 hire, 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 United States. 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, lyophilization, release testing 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 Ordinary Shares and ADSs

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 2016 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 2015 but may be treated as a PFIC for 2016 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 December 31, 2015, our directors and executive officers, together with their affiliates and related persons, beneficially own, in the aggregate, approximately 61.6% 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.

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. The report from our management on our internal control over financial reporting found that our internal control over financial reporting was effective. 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."

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 after the first sale of our common equity securities pursuant to an effective registration statement under the Securities Act, 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.

Item 1B. UNRESOLVED STAFF COMMENTS

None.

Item 2. PROPERTIES

We do not currently own any property. 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 1,260 square feet of office space in London, England, for approximately $12,000 per month. The lease for this property expires in March 2019.

Item 3. LEGAL PROCEEDINGS

We are not involved in any material legal proceedings.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

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 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 one 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, 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	$ 24.00	$ 13.50

Shareholders

As of March 23, 2016, there were 323 holders of record of our Ordinary Shares. Because many Ordinary Shares are held by broker nominees, we are unable to estimate the total number of shareholders represented by these record holders. Our depositary, Deutsche Bank Trust Company Americas, constitutes a single record holder of our Ordinary Shares.

Dividends

Since our inception, we have not declared or paid any dividends on our Ordinary Shares. We intend to retain any earnings for use in our business and do not currently intend to pay dividends on our Ordinary Shares. The declaration and payment of any future dividends will be at the discretion of our board of directors and will depend upon our results of operations, cash requirements, financial condition, contractual restrictions, restrictions imposed by our indebtedness, any future debt agreements or applicable laws and other factors that our board of directors may deem relevant.

Equity Compensation Plan Information

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	61,362,198	$ 0.34	79,780,222
Equity compensation plans not approved by security holders	—	—	—
Total	61,362,198	$ 0.34	79,780,222

2014 Plan

In order to retain qualified individuals, the Board previously established the 2007 Stock Option Plan. The Company currently has issued Options representing 1,541,500 Ordinary Shares under the 2007 Stock Option Plan.

In acknowledgement of the Company's status as a NASDAQ Capital Market listed company, and in order to comply with new laws put in place since 2007, on June 19, 2014, the Board of Directors approved the 2014 Equity Incentive Plan (the "2014 Plan"). The shareholders approved the 2014 Plan on June 19, 2014. The purpose of the 2014 Plan is to enable the Company to continue to attract and retain professional personnel for the purposes of executing its clinical development plan. The material terms of the 2014 are set forth below.

The option plan is administered by the Company's board of directors and grants are made pursuant thereto by the Compensation Committee. The aggregate number of Ordinary Shares that may be issued upon exercise of options under the 2014 Plan shall be the sum of: (i) 141,142,420 Ordinary Shares and (ii) any Ordinary Shares that are represented by awards granted under the Company's 2007 Stock Option Plan that are forfeited, expire or are cancelled without delivery of Ordinary Shares or which result in the forfeiture of Ordinary Shares back to the Company on or after June 19, 2014, or the equivalent of such number of Ordinary Shares after the administrator, in its sole discretion, has interpreted the effect of any stock split, stock dividend, combination, recapitalization or similar transaction in accordance with the 2014 Plan; provided, however, that no more than 1,541,500 Ordinary Shares shall be added to the 2014 Plan pursuant to subsection (ii). Options may be granted at any time. As of March 23, 2016, options to purchase 61,362,198 of our Ordinary Shares were outstanding under the 2014 Plan. Unless sooner terminated, the Plan shall expire on April 30, 2024.

The per share exercise price for the shares to be issued pursuant to the exercise of an option shall be such price as determined by the board of directors and set forth in the individual option agreement, subject to any guidelines as may be determined by the board of directors from time to time, provided, however, that the exercise price shall be not less than the par value of the shares underlying the option, and subject to other conditions set forth in the 2014 Plan.

Options are exercisable pursuant to the terms under which they were awarded and subject to the terms and conditions of the 2014 Plan. In general, an option, or any part thereof, may not be exercised unless the optionee is then a service provider of our company or any parent or subsidiary thereof (as each such term is defined in the 2014 Plan). Any tax consequences arising from the grant or exercise of any option from the payment for shares covered thereby, the sale or disposition of such shares and any other expenses are the responsibility of the optionee unless otherwise required by applicable law.

2007 Stock Option Plan

On August 28, 2007, the Board of Directors approved the 2007 Stock Option Plan, or the 2007 Stock Option Plan, amended on April 26, 2012, June 20, 2012 and April 29, 2013. The shareholders approved the 2007 Stock Option Plan on June 20, 2013. The purpose of the 2007 Stock Option Plan is to provide an additional incentive to employees, officers, directors, consultants and other service providers of the Company and any parent or subsidiary of the Company (each as defined in the 2007 Stock Option Plan) to further the growth, development and financial success of the company by providing them with opportunities to purchase shares pursuant to the 2007 Stock Option Plan and to promote the success of the business. The material terms of the 2007 Stock Option Plan are set forth below.

The option plan is administered by the board of directors and grants are made pursuant thereto by the Compensation Committee. The aggregate number of Ordinary Shares that may be issued upon exercise of options under the 2007 Stock Option Plan shall not exceed 3,865,000 Ordinary Shares. The board of directors may, at any time during the term of the 2007 Stock Option Plan, increase the number of shares available for grant under the 2007 Stock Option Plan. Options may be granted at any time. As of March 23, 2016, options to purchase 1,541,500 of our Ordinary Shares were outstanding under the 2007 Stock Option Plan. Unless sooner terminated, the Plan shall expire on the tenth anniversary of its effective date, or August 28, 2017.

The per share exercise price for the shares to be issued pursuant to the exercise of an option shall be such price as determined by the board of directors and set forth in the individual option agreement, subject to any guidelines as may be determined by the board of directors from time to time, provided, however, that the exercise price shall be not less than the par value of the shares underlying the option, and subject to other conditions set forth in the 2007 Stock Option Plan.

Options are exercisable pursuant to the terms under which they were awarded and subject to the terms and conditions of the 2007 Stock Option Plan. In general, an option, or any part thereof, may not be exercised unless the optionee is then a service provider of our company or any parent or subsidiary thereof (as each such term is defined in the 2007 Stock Option Plan). Any tax consequences arising from the grant or exercise of any option from the payment for shares covered thereby, the sale or disposition of such shares and any other expenses are the responsibility of the optionee unless otherwise required by applicable law.

Unregistered Sales of Securities

None.

Issuer Purchases of Equity Securities

We did not purchase any of our registered equity securities during the period covered by this Annual Report on Form 10-K.

Item 6. SELECTED FINANCIAL DATA

Not required as we are a smaller reporting company.

Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in the forward-looking statements as a result of certain factors. We discuss factors that we believe could cause or contribute to these differences below and elsewhere in this report including those set forth under Item 1A."Risk Factors" in this Annual Report on Form 10-K.

Overview

We are 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 PNH, GBS and aHUS.

On September 18, 2015, Celsus completed its acquisition of all of the capital stock of Volution, from RPC, Volution's sole shareholder, in exchange for Ordinary Shares, of Celsus (the "Acquisition"), in accordance with the terms of the Share Exchange Agreement, dated as of July 10, 2015, by and among Celsus and RPC. In connection with the Acquisition, the name of the combined company was changed to Akari Therapeutics, Plc. Our ADSs, each representing 100 Ordinary Shares, began trading on The NASDAQ Capital Market under the symbol "AKTX" on September 21, 2015.

For accounting purposes, the Acquisition was treated as a "reverse acquisition" and Volution was considered the accounting acquirer. Accordingly, our combined and consolidated financial statements reflect the historical financial statements of Volution as our historical financial statements, except for the legal capital which reflects our legal capital (Ordinary Shares).

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 product, 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 $2.6 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; (iii) that Coversin can achieve full complement inhibition in the blood of eculizumab-resistant patients tested to date and (iv) that complement inhibition is complete whether measured by Elisa CH50 U Eq/ml assay or sheep red blood cell lytic CH50 assay, as demonstrated in our 28-day safety study in NHP where Coversin was dosed once a day for 28 days. 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 PNH, aHUS, MG, GBS, and Sjögren's syndrome.

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 the Phase Ib repeat dose study initiated in the first quarter of 2016. 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.

We have initiated treatment in a European patient with paroxysmal nocturnal hemoglobinuria (PNH) and resistant to eculizumab due to a polymorphism on February X, 2016. The patient is being treated with Coversin under a clinical trial protocol approved by a EU national regulatory authority for treating patients with eculizumab resistance. The primary objective of the eculizumab-resistance program is to provide patients who have clinically demonstrated resistance to eculizumab early access to Coversin as a potentially lifesaving alternative. These patients are entered into an open label protocol where safety and efficacy are measured on an ongoing basis. We expect to present topline results from these patients as they become available. A Phase Ib clinical trial in healthy volunteers was initiated in January 2016, and we expect to initiate a Phase II trial in PNH patients in the second quarter of 2016. We expect to start a Phase II trial in GBS in the middle of 2016 and in aHUS in late 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 proceed into Phase III pivotal studies in both Europe and the United States. We have decided to discontinue development of Celsus's prior technology. Our reported Results of Operations for the years ended December 31, 2015 and December 31, 2014 and the other financial information presented below, are combined from those of both us and our preceding entity, Varleigh Immuno Pharmaceuticals. Volution was formed in October 2013, and operationally overlapped with Varleigh through July 2014, when Varleigh effectively ceased operations before formal dissolution in September 2014.

Our research and development expenses consist primarily of personnel expenses, fees paid to external service providers for formulation and synthesis activities, manufacturing and costs of pre-clinical studies and clinical trials. We primarily use external service providers to manufacture our product candidates for clinical trials and for all of our pre-clinical and clinical development work. We charge all research and development expenses to operations as they are incurred. We expect our research and development expenses to remain our primary expense in the near future as we continue to develop our product candidates. We currently perform our research and development activity mainly through outsourcing to subcontractors. Since inception we have generated significant losses in connection with our research and development, including the pre-clinical and clinical development of our product candidates. At December 31, 2015, we had an accumulated deficit of $56,796,613. Since inception, we have funded our operations primarily through the sale of equity securities and debt financing. We have not yet generated any revenues and we expect to continue to incur net losses and negative cash flows for the foreseeable future. These net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. At December 31, 2015 we had $68,919,995 of cash and cash equivalents available to fund future operations through 2017.

In connection with the consummation of the Acquisition, Celsus issued an aggregate of 722,345,600 Ordinary Shares to RPC, which represented, prior to giving effect to the Financing (defined below), 92.85% of Celsus's outstanding Ordinary Shares following the closing of the Acquisition (or 91.68% of Celsus Ordinary Shares on a fully diluted basis). This yielded a share exchange ratio of approximately 721:1 of Akari Ordinary Shares to RPC shares. Our earnings per share have been retrospectively adjusted in the statement of comprehensive loss to reflect this recapitalization.

In addition, on September 18, 2015, we completed a private placement of an aggregate of 3,958,811 restricted ADSs representing 395,881,100 Ordinary Shares for gross proceeds of $75 million (the "Financing") at a price of $18.945 per restricted ADS, which represented approximately 33.3% of the outstanding Ordinary Shares of the Company after giving effect to the Acquisition and the Financing.

Critical Accounting Policies and Use of Estimates

The preparation of the consolidated financial statements in conformity with United States Generally Accepted Accounting Principles requires management to make estimates, judgments and assumptions. Our management believes that the estimates, judgments and assumptions used are reasonable based upon information available at the time they are made. These estimates, judgments and assumptions can affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the dates of the financial statements, and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

JOBS Act

On April 5, 2012, the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, was enacted. Section 107 of the JOBS Act 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 chose 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. Additionally, we are continuing to evaluate the benefits of relying on other exemptions and reduced reporting requirements provided by the JOBS Act.

Subject to certain conditions set forth in the JOBS Act, as an "emerging growth company," we intend to rely on certain of these exemptions, including without limitation, (i) providing an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404 and (ii) complying with any requirement that may be adopted by the PCAOB regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (auditor discussion and analysis). These exemptions will apply for a period of five years following the first sale of our common equity securities pursuant to an effective registration statement under the Securities Act or until we are no longer an "emerging growth company," whichever is earlier.

Stock-Based Compensation and Fair Value of Ordinary Shares

We account for awards of equity instruments issued to employees and directors under the fair value method of accounting and recognize such amounts in our Consolidated Statements of Comprehensive Loss. We measure compensation cost for all stock-based awards at fair value on the date of grant and recognize compensation expense in our Consolidated Statements of Comprehensive Loss using the straight-line method over the service period over which we expect the awards to vest.

We estimate the fair value of all time-vested options as of the date of grant using the Black-Scholes option valuation model, which was developed for use in estimating the fair value of traded options that have no vesting restrictions and are fully transferable. Option valuation models require the input of highly subjective assumptions, including the expected stock price volatility, which we calculate based on the historical volatility of our common stock. We use a risk-free interest rate, based on U.S. Treasury instruments in effect at the time of the grant, for the period comparable to the expected term of the option. Given our limited history with stock option grants and exercises, we use the "simplified" method in estimating the expected term, the period of time that options granted are expected to be outstanding, for our grants.

We classify our share-based payments as either liability-classified awards or as equity-classified awards. We remeasure liability-classified awards to fair value at each balance sheet date until the award is settled. We measure equity-classified awards at their grant date fair value and do not subsequently remeasure them. We have classified our share-based payments which are settled in our common stock as equity-classified awards and our share-based payments that are settled in cash as liability-classified awards. Compensation costs related to equity-classified awards generally are equal to the grant-date fair value of the award amortized over the vesting period of the award. The liability for liability-classified awards generally is equal to the fair value of the award as of the balance sheet date multiplied by the percentage vested at the time. We charge (or credit) the change in the liability amount from one balance sheet date to another to compensation expense.

Warrants

In connection with the issuance of certain warrants, we applied ASC 470-20, "Debt with Conversion and Other Options" ("ASC 470-20 "). In accordance with ASC 470-20, we first allocated the proceeds received to the warrant, freestanding liability instrument that is measured at fair value at each reporting date, with changes in the fair values being recognized in our statement of comprehensive loss as changes in fair value of warrant liabilities. The fair value of the warrants granted was valued by using the Binomial method of valuation. The anti-dilution rights of the warrants were calculated by using the Binomial method of valuation put option using the same parameters as the warrants call option. The computation of expected volatility is based on realized historical stock price volatility of peer companies. The expected term is based on the contractual term. The risk free interest rate assumption is the implied yield currently available on U.S. Treasury yield zero-coupon issues with a remaining term equal to the expected life of the options. The dividend yield assumption is based on our historical experience and expectation of no future dividend payouts and may be subject to substantial change in the future. We have historically not paid cash dividends and have no foreseeable plans to pay cash dividends in the future. The fair value of the warrants on September 18, 2015 (Acquisition date) was $1,800,154. On December 31, 2015, the fair value of the warrants was $685,141. The change in fair value of the warrants in the year ended December 31, 2015 was a decrease of $1,115,013 and was recognized as a change in fair value of warrant liabilities in the statement of comprehensive loss.

RPC options

In connection with a short-term working capital loan of approximately $3 million that included options in RPC, equivalent to 15% of the current outstanding equity issued by RPC. The initial fair value of the RPC options were estimated using the fair value of Akari shares times RPC's ownership in Akari shares times 15% and was approximately $26 million. The exact terms of these options have not been finalized. We recorded a non-cash liability to options for $26 million, allocated $3 million as a loan discount, $23 million as a non-cash financing expense and recorded interest expense in the amount of $3 million in statement of comprehensive loss as a credit to the loan discount. On December 31, 2015, the fair value of the options was $15,711,017. The change in fair value of the options in the year ended December 31, 2015 was a decrease of $10,293,218 and was recognized as a change in fair value of option liabilities in the statement of comprehensive loss.

On December 31, 2015, the fair value of the options and warrants was $16,396,158.

Functional Currency

The functional currency of Akari is U.S. dollars as that is the primary economic environment in which the Company operates as well as the currency in which it has been financed. The functional currency of Volution is Swiss Francs, as that was the primary economic environment in which the Company operated. The functional currency of Varleigh was the British Pound.

The reporting currency of the Company is U.S. Dollars. The Company translated its non-U.S. operations' assets and liabilities denominated in foreign currencies into U.S. dollars at current rates of exchange as of the balance sheet date and income and expense items at the average exchange rate for the reporting period. Translation adjustments resulting from exchange rate fluctuations are recorded as foreign currency translation adjustments, a component of accumulated other comprehensive income. Gains or losses from foreign currency transactions are included in exchange losses.

Results of Operations

For the years ended December 31, 2015 and December 31, 2014

Research and development expenses

Research and development expenses for the year ended December 31, 2015 were approximately $5,799,000 compared to $1,616,000 for the year ended December 31, 2014. This 258% or $4,183,000 increase was due to higher expenses of approximately $3,511,000 for manufacturing and clinical trial related activities, $346,000 of salary expenses, $189,000 of patent expenses and $137,000 of other expenses.

We expect our research and development expenses to increase in the future as we conduct additional clinical trials to support the clinical development of Coversin, and advance other product candidates into pre-clinical and clinical development.

General and administrative expenses

General and administrative expenses for the year ended December 31, 2015 were approximately $5,502,000 compared to $303,000 for the year ended December 31, 2014. This 1,716% or $5,199,000 increase was primarily due to higher expenses of legal, consulting, professional and accounting expenses of approximately $1,774,000, $1,044,000 of stock-based compensation expense, $809,000 of salary expenses, $750,000 of compensation expenses for advisory services related to the Acquisition, $229,000 of insurance expenses, $132,000 of board expenses, $118,000 of rent expenses, $112,000 of travel related expenses primarily related to the Acquisition and the Financing and $216,000 of other expenses.

We expect our general and administrative expenses to increase due to increased legal, accounting and professional fees associated with being a publicly reporting company in the United States and rental expense associated with offices in the United States and London to support the Company's operations and anticipated growth.

Excess Consideration

Excess consideration of $19,283,280 was calculated as the difference between the fair value of the consideration expected to be realized from the Acquisition and the values assigned to the identifiable tangible and intangible assets acquired and liabilities assumed of Celsus. We have recorded this non-cash charge in the statements of comprehensive loss.

Other income/expenses

Other expense for the year ended December 31, 2015 was approximately $14,733,000 compared to approximately $28,000 for the year ended December 31, 2014. This change was primarily attributed to non-cash financing expense of approximately $23,000,000 and $3,000,000 of non-cash interest expense related to options of RPC granted in connection with a working capital loan to Volution, higher foreign exchange losses of approximately $91,000 and $44,000 of other expenses, offset by the revaluation of stock option and warrant liabilities of approximately $11,408,000.

Liquidity and Capital Resources

Net cash used in operating activities was approximately $4,966,000 during the year ended December 31, 2015 compared to $1,477,000 used by operating activities during the year ended December 31, 2014. The 236% increase in cash flow used in operating activities of approximately $3,489,000 can be primarily attributed to the ongoing research activities to support Coversin, including manufacturing and clinical trial activities

Net cash provided by investing activities was approximately $1,392,000 in the year ending December 31, 2015. This is due to approximately $1,411,000 cash received from the reverse acquisition offset by approximately $19,000 from the purchase of property and equipment and a receivable from related party. In the year ending December 31, 2014 we had no investment activity. We anticipate that our investment activities will include income generated from our investment in interest bearing securities in the future.

Net cash provided by financing activities was approximately $69,044,000 during the year ended December 31, 2015 compared to approximately $4,235,000 during the year ended December 31, 2014. This increase is primarily attributed to the net proceeds of approximately $69,574,000 from the Financing completed after the Acquisition and approximately $3,000,000 net proceeds from stockholder loans offset by approximately $3,561,000 of repayments of stockholder loans and $3,690,000 of proceeds from issuance of shares in 2014.

As of December 31, 2015, we had approximately $68,920,000 in cash and cash equivalents, an increase of approximately $65,593,000 from December 31, 2014. In addition, as of December 31, 2015, we had accumulated losses in the total amount of approximately $56,797,000. Since inception, we have funded our operations primarily through the sale of equity securities and debt financing. We have not yet generated any revenues and we expect to continue to incur net losses and negative cash flows for the foreseeable future. These net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. We believe our current cash and cash equivalents are sufficient to fund future operations through 2017. This forecast of cash resources is forward-looking information that involves risks and uncertainties, and the actual amount of our expenses over the next twelve months could vary materially and adversely as a result of a number of factors, including the risks and uncertainties set forth in Item 1A under the heading "Risk Factors" of this Annual Report on Form 10-K.

Since inception, we have funded our operations primarily through the sale of equity securities and debt financings. In October 2013, we issued 100,000 shares in exchange for a note receivable of $112,300. The note was paid in full in 2014. In March 2014, we issued 1,750 shares in exchange for $237,090. In November 2014, we effectuated a 10 for 1 stock split. In December 2014, we issued 900,000 shares in exchange for $3,453,633. In September 2013, Varleigh, the predecessor to Volution issued 2,635,659 Ordinary Shares in exchange for $1,339,940. In September 2015, we completed a private placement of an aggregate of 3,958,811 restricted ADSs representing 395,881,100 Ordinary Shares for gross proceeds of $75 million at a price of $18.945 per restricted ADS.

We are constantly addressing our liquidity and will seek additional fund raisings when necessary to implement our operating plan. Failure to do so may delay research and development activities. We cannot be certain that such funding will be available on acceptable terms or available at all. To the extent that we raise additional funds by issuing equity securities, our shareholders may experience significant dilution. There can be no assurance that we will be successful in obtaining an adequate level of financing needed for our long-term research and development activities. If we are unable to raise sufficient capital resources, we will not be able to continue the development of all of our products or may be required to delay part of our development programs and significantly reduce our activities in order to maintain our operations. We believe that our cash and cash equivalents as of December 31, 2015 will be sufficient to fund operations through 2017. We will require additional capital in order to complete the clinical development of and to commercialize our product candidates and our pre-clinical product candidates.

Research and Development, Patents and Licenses

Our research and development expenditures were approximately $5,799,000 and $1,616,000 in the years ended December 31, 2015 and 2014, respectively. Most of such research and development expenditures were in the form of payments to third parties third parties to carry out our manufacturing, pre-clinical and clinical research activities.

We incurred the following research and development expenses in the years ended 2015 and 2014 (in $000's):

	Years ended December 31,	
	2015	**2014**
Direct Expenses:		
Coversin	$ 2,437	$ 547
Other	1,087	329
Clinical trials	41	11
Total direct expenses	$ 3,565	$ 887
Indirect Expenses:		
Staffing	621	232
Other indirect	1,613	497
Total indirect expenses	$ 2,234	$ 729
Total Research and Development	$ 5,799	$ 1,616

Off-balance Sheet Arrangements

We currently do not have any off-balance sheet arrangements.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not required as we are a smaller reporting company.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements required to be filed pursuant to this Item 8 are appended to this report. An index of those financial statements is found in Item 15.

Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable.

Item 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our principal executive officer and principal financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this Annual Report on Form 10-K, have concluded that, based on such evaluation, our disclosure controls and procedures were effective at a reasonable assurance level. In designing and evaluating our disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2015, based on the framework in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). Based on this evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2015.

Changes in Internal Control over Financial Reporting

As required by Rule 15d-15(d) under the Securities and Exchange Act of 1934, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, an evaluation of our internal control over financial reporting was conducted to determine whether any changes occurred during the quarter ended December 31, 2015, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. As reported in our Form 10-Q for the quarterly period ended September 30, 2015 (the "Form 10-Q"), our management identified a material weakness in our internal control over financial reporting prior to the Acquisition that related to the lack of internal expertise and resources to analyze and timely record under US GAAP certain non-routine complex transactions that were directly related to and arose as a result of the Acquisition. Prior to the completion of the Acquisition on September 18, 2015, Volution, as a private company, lacked sufficient resources to properly analyze and record complex non-routine transactions. Therefore, management concluded that our disclosure controls and procedures were not effective as of September 30, 2015. During the quarter ended December 31, 2015, our management began to implement the following remediation measures to address these issues:

- Our Chief Financial Officer performs a rigorous and timely review of non-routine complex agreements prior to their execution;
- The hiring of additional accounting personnel, that is intended to reasonably assure management that its disclosure controls and procedures are effective; and
- In the event we enter into non-routine complex transactions, we intend to retain an accounting consultant or other expert advice to assist in the review of the accounting treatment: detailing the facts, circumstances, research and conclusions concerning the accounting treatment of such transaction and communicate its findings to senior management for resolution as needed.

Management believes that the actions described above remediated the material weakness described in the Form 10-Q.

Other than the steps taken to address the material weakness described above, there were no changes in our internal control over financial reporting, identified in connection with the evaluation of such internal control, that occurred during the last fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. OTHER INFORMATION

None.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The response to this item is incorporated by reference from the discussion responsive thereto under the captions "Management and Corporate Governance Matters," "Section 16(a) Beneficial Ownership Reporting Compliance," and "Code of Conduct and Ethics" in the Company's Proxy Statement for the 2016 Annual Meeting of Shareholders.

Item 11. EXECUTIVE COMPENSATION

The response to this item is incorporated by reference from the discussion responsive thereto under the caption "Executive Officer and Director Compensation" in the Company's Proxy Statement for the 2016 Annual Meeting of Shareholders.

Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The response to this item is incorporated by reference from the discussion responsive thereto under the captions "Security Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information" in the Company's Proxy Statement for the 2016 Annual Meeting of Shareholders.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The response to this item is incorporated by reference from the discussion responsive thereto under the captions "Certain Relationships and Related Transactions" and "Management and Corporate Governance Matters" in the Company's Proxy Statement for the 2016 Annual Meeting of Shareholders.

Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The response to this item is incorporated by reference from the discussion responsive thereto under the caption "Independent Public Accountants" in the Company's Proxy Statement for the 2016 Annual Meeting of Stockholders.

PART IV

Item 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

Financial Statements and Schedules

(a) The following documents are filed as part of this report:

(1) Financial Statements:

See "Index to Consolidated Financial Statements" on page F-1 of this Annual Report on Form 10-K.

AKARI THERAPEUTICS, PLC

COMBINED AND CONSOLIDATED FINANCIAL STATEMENTS

AS OF DECEMBER 31, 2015

U.S. DOLLARS IN THOUSANDS

INDEX

(2) Financial Statement Schedules:

All financial statement schedules have been omitted because they are not applicable, not required or the information required is shown in the financial statements or the notes thereto.

(3) Exhibits. The exhibits filed as part of this Annual Report on Form 10-K are set forth on the Exhibit List immediately following our consolidated ıcial statements. The Exhibit List is incorporated herein by reference.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Akari Therapeutics, Plc

Date: March 23, 2016 By: /s/ Gur Roshwalb

Gur Roshwalb
Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities indicated below and on the dates indicated.

Signature	Title	Date
/s/ Gur Roshwalb Gur Roshwalb	Chief Executive Officer and Director (Principal Executive Officer)	March 23, 2016
/s/ Dov Elefant Dov Elefant	Chief Financial Officer (Principal Financial and Accounting Officer)	March 23, 2016
/s/ Ray Prudo Ray Prudo	Executive Chairman of the Board of Directors	March 23, 2016
/s/ Mark S. Cohen Mark S. Cohen	Vice Chairman of the Board of Directors	March 23, 2016
/s/ James Hill James Hill	Director	March 23, 2016
/s/ Stuart Ungar Stuart Ungar	Director	March 23, 2016
/s/ Allan Shaw Allan Shaw	Director	March 23, 2016
/s/ Clive Richardson Clive Richardson	Director	March 23, 2016

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BDO AG
Fabrikstrasse 50
8031 Zürich
Switzerland

Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders
Akari Therapeutics, Plc

We have audited the accompanying combined and consolidated balance sheets of Akari Therapeutics, Plc as of December 31, 2015 and 2014 and the related combined and consolidated statements of comprehensive loss, changes in stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2015. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the combined and consolidated financial statements referred to above present fairly, in all material respects, the financial position of Akari Therapeutics, Plc at December 31, 2015 and 2014, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2015**,** in conformity with accounting principles generally accepted in the United States of America.

Zurich, March 23, 2016

BDO AG

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

AKARI THERAPEUTICS, Plc

COMBINED AND CONSOLIDATED BALANCE SHEETS
As of December 31, 2015 and December 31, 2014
(in U.S. Dollars, except share data)

	December 31, 2015	December 31, 2014
Assets		
Current Assets:		
Cash and cash equivalents	$ 68,919,995	$ 3,327,468
Prepaid expenses and other current assets	728,126	7,781
Receivable from related party	10,366	-
Total Current Assets	69,658,487	3,335,249
Restricted cash	142,079	-
Property and equipment, net	40,513	-
Patent acquisition costs, net	52,483	59,417
Total Assets	$ 69,893,562	$ 3,394,666
Liabilities and Shareholders' Equity		
Current Liabilities:		
Accounts payable	4,320,588	555,528
Accounts payable - related party	-	39,236
Accrued expenses	408,222	42,999
Loans payable - shareholders	-	533,605
Liability related to options and warrants	16,396,158	-
Total Current Liabilities	21,124,968	1,171,368
Other long-term liability	49,069	-
Total liabilities	21,174,037	1,171,368
Commitments and Contingencies		
Shareholders' Equity:		
Share capital of GBP .01 par value Authorized: 5,000,000,000 shares; issued and outstanding: 1,177,693,383 and 722,345,600 at December 31, 2015 and 2014, respectively	18,340,894	11,210,804
Additional paid-in capital	87,018,764	2,445,494
Accumulated other comprehensive income	156,480	46,081
Accumulated deficit	(56,796,613)	(11,479,081)
Total Shareholders' Equity	48,719,525	2,223,298
Total Liabilities and Shareholders' Equity	$ 69,893,562	$ 3,394,666

See notes to combined and consolidated financial statements.

AKARI THERAPEUTICS, Plc

COMBINED AND CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
For the Years Ended December 31, 2015 and 2014
(in U.S. Dollars)

	Years Ended December 31, 2015	December 31, 2014
Operating Expenses:		
Research and development costs	$ 5,799,076	$ 1,616,204
General and administrative expenses	5,502,214	303,095
Excess consideration	19,283,280	-
Total Operating Expenses	30,584,570	1,919,299
Loss from Operations	(30,584,570)	(1,919,299)
Other Income (Expense):		
Interest income	20,705	91
Changes in fair value of option and warrant liabilities - gains	11,408,231	-
Financing expense	(22,973,138)	-
Exchange loss	(90,588)	(22,909)
Interest expense	(3,053,948)	(5,436)
Other expenses	(44,224)	-
Total Other Income (Expense)	(14,732,962)	(28,254)
Loss before Income Taxes	(45,317,532)	(1,947,553)
Income Taxes	-	-
Net Loss	(45,317,532)	(1,947,553)
Other Comprehensive Income:		
Foreign Currency Translation Adjustment	110,399	79,438
Comprehensive Loss	$ (45,207,133)	$ (1,868,115)
Loss per common share (basic and diluted)	$ (0.05)	$ (0.02)
Weighted average common shares (basic and diluted)	852,088,530	85,515,588

See notes to combined and consolidated financial statements.

AKARI THERAPEUTICS, Plc

COMBINED AND CONSOLIDATED STATEMENT OF CHANGES IN SHAREHOLDERS' EQUITY
As of and for the Year Ended December 31, 2015 and 2014
(in U.S. Dollars)

	Varleigh Immuno Pharmaceuticals Ltd Share Capital		*Akari Therapeutics, Plc* Share Capital		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	
	Shares	Amount	Shares	Amount	Capital	Income	Deficit	Total
Shareholders' Equity, January 1, 2014	11,727,149	$ 1,888,435	72,108,370	$ 1,119,122	$ 6,958,018	$ (33,357)	$ (9,531,528)	$ 400,690
Issuance of share capital (related to the recapitalization of Volution)	-	-	650,237,230	10,091,682	(6,400,959)	-	-	3,690,723
Payment of share subscription receivable	-	-	-	-	-	-	-	-
Dissolution of Varleigh	(11,727,149)	(1,888,435)	-	-	1,888,435	-	-	-
Comprehensive Loss	-	-	-	-	-	79,438	(1,947,553)	(1,868,115)
Shareholders' Equity, December 31, 2014	-	-	722,345,600	11,210,804	2,445,494	46,081	(11,479,081)	2,223,298
Issuance of share capital related to acquisition (Celsus shares outstanding at date of acquisition)	-	-	55,636,283	926,567	19,412,573	-	-	20,339,140
Issuance of share capital related to financing, net of issuance costs	-	-	395,881,100	6,144,075	63,430,279	-	-	69,574,354
Issuance of share capital for advisory fees	-	-	3,830,400	59,448	690,552	-	-	750,000
Stock-based compensation	-	-	-	-	1,039,866	-	-	1,039,866
Comprehensive Loss	-	-	-	-		110,399	(45,317,532)	(45,207,133)
Shareholders' Equity, December 31, 2015	-	-	1,177,693,383	$ 18,340,894	$ 87,018,764	$ 156,480	$ (56,796,613)	$ 48,719,525

See notes to combined and consolidated financial statements.

AKARI THERAPEUTICS, Plc

COMBINED AND CONSOLIDATED STATEMENTS OF CASH FLOWS
As of and for the Years Ended December 31, 2015 and 2014
(in U.S. Dollars)

	Year Ended December 31, 2015	December 31, 2014
Cash Flows from Operating Activities:		
Net loss	$ (45,317,532)	(1,947,553)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	10,162	4,942
Stock-based compensation	1,039,866	-
Compensation expense	750,000	-
Amortization of debt discount	3,031,304	-
Excess consideration	19,283,280	-
Financing expense	22,973,138	
Changes in fair value of the liability for options and warrants	(11,408,231)	-
Changes in operating assets and liabilities:		
Decrease (increase) in assets:		
Prepaid expenses and other assets	913,788	(8,422)
Increase (decrease) in liabilities:		
Accounts payable and accrued expenses	3,755,173	474,209
Other liabilities	3,469	-
Total adjustments	40,351,949	470,729
Net Cash Used in Operating Activities	(4,965,583)	(1,476,824)
Cash Flows from Investing Activities:		
Cash received from reverse acquisition	1,410,577	-
Receivable from related party	(8,219)	-
Purchase of property and equipment	(10,560)	-
Net Cash Provided by Investing Activities	1,391,798	-
Cash Flows from Financing Activities:		
Proceeds from shareholder loans	3,031,304	432,353
Payments of shareholder loans	(3,561,239)	-
Proceeds from issuance of shares	75,000,000	3,690,723
Issuance costs	(5,425,646)	-
Proceeds from stock subscription	-	112,300
Net Cash Provided by Financing Activities	69,044,419	4,235,376
Effect of Exchange Rates on Cash and Cash Equivalents	121,893	15,262
Net Increase in Cash and Cash Equivalents	65,592,527	2,773,814
Cash and Cash Equivalents, beginning	3,327,468	553,654
Cash and Cash Equivalents, end	$ 68,919,995	$ 3,327,468
Supplemental Disclosures of Cash Flow Information:		
Cash paid during the year for:		
Interest	$ 22,945	$ 5,400

See notes to combined and consolidated financial statements.

NOTE 1 - Nature of Business

Akari Pharmaceuticals, Plc, (the "Company" or "Akari"), formerly Celsus Therapeutics Plc ("Celsus"), is incorporated in the United Kingdom. The Company is a clinical stage biotechnology company, and is 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.

On September 18, 2015, Celsus Therapeutics Plc completed its acquisition of all of the capital stock of Volution Immuno Pharmaceuticals SA ("Volution"), from RPC Pharma Limited ("RPC"), Volution's sole shareholder, in exchange for ordinary shares, par value £0.01, ("Ordinary Shares"), of Celsus (the "Acquisition"), in accordance with the terms of the Share Exchange Agreement, dated as of July 10, 2015 (the "Agreement"), by and among Celsus and RPC. In connection with the Acquisition, the name of the combined company was changed to Akari Therapeutics, Plc. The Company's American Depositary Shares ("ADSs"), each representing 100 Ordinary Shares, began trading on The NASDAQ Capital Market under the symbol "AKTX" on September 21, 2015.

In connection with the consummation of the Acquisition, Celsus issued an aggregate of 722,345,600 Ordinary Shares to RPC, which represented, prior to giving effect to the Financing (defined below), 92.85% of Celsus's outstanding Ordinary Shares following the closing of the Acquisition (or 91.68% of Celsus Ordinary Shares on a fully diluted basis). This yielded a share exchange ratio of approximately 721:1 of Akari ordinary shares to RPC shares. The Company's earnings per share have been retrospectively adjusted in the statement of comprehensive loss to reflect this recapitalization. Since the Volution securityholders owned a majority of the 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 has been accounted for as a reverse acquisition under the acquisition method of accounting for business combinations in accordance with U.S. GAAP. Accordingly, the assets and liabilities of Celsus have been recorded as of the acquisition closing date at fair value and the combined and consolidated financial statements reflect the historical financial statements of Volution as our historical financial statements.

The Company, as used in the accompanying notes to the combined and consolidated financial statements, refers to Volution prior to the Acquisition and Akari subsequent to the completion of the Acquisition.

In addition, on September 18, 2015, the Company completed a private placement of an aggregate of 3,958,811 restricted ADSs representing 395,881,100 Ordinary Shares for gross proceeds of $75 million (the "Financing") at a price of $18.945 per restricted ADS, which represented approximately 33.3% of the outstanding Ordinary Shares of the Company after giving effect to the Acquisition and the Financing.

Volution was originally incorporated in Switzerland as a private limited company and commenced business on October 9, 2013. On October 23, 2013, Varleigh Immuno Pharmaceuticals Ltd ("Varleigh"), a UK limited company, transferred certain patent rights to Volution in exchange for a payment of approximately $107,000, (GBP 65,000), which was the carrying value of the patents in accordance with local accounting standards. Effective September 12, 2014 Varleigh ceased its operations and was dissolved. The transaction resulted in the transfer of the business of Varleigh to Volution. On the date of transfer, the controlling/majority shareholders of Volution were also the controlling/majority shareholders of Varleigh. Upon dissolution, there were no reported assets, liabilities, or accumulated comprehensive income remaining in Varleigh, as such no gain or loss on dissolution was recognized.

NOTE 1 - Nature of Business (cont.)

On July 3, 2015, the shareholders of Volution exchanged their shares for RPC shares with no changes in individual share ownerships. This qualified as a reorganization.

The Company is subject to a number of risks similar to those of clinical stage companies, including dependence on key individuals, uncertainty of product development and generation of revenues, dependence on outside sources of capital, risks associated with clinical trials of products, dependence on third-party collaborators for research operations, need for regulatory approval of products, risks associated with protection of intellectual property, and competition with larger, better-capitalized companies. Successful completion of the Company's development program and, ultimately, the attainment of profitable operations is dependent upon future events, including obtaining adequate financing to fulfill its development activities and achieving a level of revenues adequate to support the Company's cost structure. There are no assurances that the Company will be able to obtain additional financing on favorable terms, or at all or successfully market its products.

NOTE 2 - Summary of Significant Accounting Policies

Principles of Combination and Consolidation - The combined and consolidated financial statements include the accounts of the Company, Volution and Volution Immuno Ltd (a UK Ltd Company), its wholly-owned subsidiary, which was incorporated in London on August 22, 2014.

The financial statements of Varleigh, which was the predecessor business to the Company, have been combined through the date of its dissolution on September 12, 2014.

All intercompany transactions have been eliminated.

Foreign Currency - The functional currency of Akari is U.S. dollars as that is the primary economic environment in which the Company operates as well as the currency in which it has been financed. The functional currency of Volution is Swiss Francs, as that was the primary economic environment in which the Company operated. The functional currency of Varleigh was the British Pound.

The reporting currency of the Company is U.S. Dollars. The Company translated its non-U.S. operations' assets and liabilities denominated in foreign currencies into U.S. dollars at current rates of exchange as of the balance sheet date and income and expense items at the average exchange rate for the reporting period. Translation adjustments resulting from exchange rate fluctuations are recorded as foreign currency translation adjustments, a component of accumulated other comprehensive income. Gains or losses from foreign currency transactions are included in exchange losses.

Use of Estimates - The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and judgments that may affect the reported amounts of assets, liabilities, equity, revenue, expenses and related disclosure of contingent assets and liabilities. Management's estimates and judgments include assumptions used for accrued liabilities, deferred income taxes, liabilities related to options and warrants, stock-based compensation and various other assumptions that are believed to be reasonable under the circumstances. Actual results may differ from those estimates under different assumptions or conditions.

Fair Value Measurements - The carrying amounts of financial instruments, including cash and cash equivalents, restricted cash, receivable from related party, accounts payable, and loans payable shareholders approximate fair value due to their short-term maturities.

The Company's liability related to options and warrants are warrants related to equity and debt financing rounds and options related to RPC and are recognized on the balance sheet at their fair value, with changes in the fair value accounted for in the statement of comprehensive loss and included in financing income or expenses.

(in U.S. Dollars)

NOTE 2 - Summary of Significant Accounting Policies (cont.)

Cash and Cash Equivalents - The Company considers all highly-liquid investments with original maturities of 90 days or less at the time of acquisition to be cash equivalents. The Company had no cash equivalents at December 31, 2015 and December 31, 2014.

Restricted cash - Restricted cash are investments held as collateral for a letter of credit related to the Company's office lease.

Prepaid Expenses and Other Current Assets - Prepaid expenses and other assets consist principally of VAT receivables and prepaid expenses.

Property and equipment, net - Property and equipment are stated at cost, net of accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets at the following annual rates:

	%
Computers, peripheral, and scientific equipment	33
Office furniture and equipment	25

Long-Lived Assets - The Company reviews all long-lived assets for impairment whenever events or circumstances indicate the carrying amount of such assets may not be recoverable. Recoverability of assets to be held or used is measured by comparison of the carrying value of the asset to the future undiscounted net cash flows expected to be generated by the asset. If such asset is considered to be impaired, the impairment recognized is measured by the amount by which the carrying value of the asset exceeds the discounted future cash flows expected to be generated by the asset.

Patent Acquisition Costs – Patent acquisition costs and related capitalized legal fees are amortized on a straight-line basis over the shorter of the legal or economic life. The estimated useful life is twenty two years.

The Company expenses costs associated with maintaining and defending patents subsequent to their issuance in the period incurred.

Accrued Expenses - As part of the process of preparing the combined and consolidated financial statements, it requires the estimate of accrued expenses. This process involves identifying services that third parties have performed on the Company's behalf and estimating the level of service performed and the associated cost incurred on these services as of each balance sheet date in our combined and consolidated financial statements. Examples of estimated accrued expenses include contract service fees in conjunction with pre-clinical and clinical trials and professional service fees. In connection with these service fees, our estimates are most affected by our understanding of the status and timing of services provided relative to the actual services incurred by the service providers. In the event that we do not identify certain costs that have been incurred or we under or over-estimate the level of services or costs of such services, our reported expenses for a reporting period could be understated or overstated. The date on which certain services commence, the level of services performed on or before a given date, and the cost of services are often subject to our judgment. We make these judgments based upon the facts and circumstances known to us in accordance with U.S. GAAP.

Research and Development Expenses - Costs associated with research and development are expensed as incurred. Research and development expenses include, among other costs, costs incurred by outside laboratories and other accredited facilities in connection with clinical trials and preclinical studies. Research and development expense for the years ended December 31, 2015 and December 31, 2014 amounted to $5,799,076 and $1,616,204, respectively.

(in U.S. Dollars)

NOTE 2 - Summary of Significant Accounting Policies (cont.)

Stock-Based Compensation Expense -

Stock-based compensation costs are recognized in earnings using the fair-value based method for all awards granted. Compensation costs for unvested options and awards are recognized in earnings over the requisite service period based on the fair value of those options and awards. For employees, fair value is estimated at the grant date and for non-employees fair value is re-measured at each reporting date as required by ASC 718, "Compensation-Stock Compensation", and ASC 505-50, "Equity-Based Payments to Non-Employees." Fair values of awards granted under the share option plans are estimated using a Black-Scholes option pricing model. The determination of fair value for stock-based awards on the date of grant using an option pricing model requires management to make certain assumptions regarding a number of complex and subjective variables.

Concentration of Credit Risk - Financial instruments that subject the Company to credit risk consist of cash and cash equivalents. The Company maintains cash and cash equivalents with well-capitalized financial institutions. At times, those amounts may exceed insured limits. The Company has no significant concentrations of credit risk.

Income Taxes - The Company accounts for income taxes in accordance with the accounting rules that require an asset and liability approach to accounting for income taxes based upon the future expected values of the related assets and liabilities. Deferred income tax assets and liabilities are determined based on the differences between the financial reporting and tax bases of assets and liabilities and for tax loss and credit carry forwards, and are measured using the expected tax rates estimated to be in effect when such basis differences reverse. Valuation allowances are established, if necessary, to reduce the deferred tax asset to the amount that will, more likely than not, be realized. The Company accounts for R&D tax credits at the time its realization becomes probable.

Uncertain Tax Positions - The Company follows the provisions of "Accounting for Uncertainty in Income Taxes", which prescribes recognition thresholds that must be met before a tax position is recognized in the financial statements and provides guidance on de-recognition, classification, interest and penalties, disclosure, and transition. Under "Accounting for Uncertainty in Income Taxes", an entity may only recognize or continue to recognize tax positions that meet a "more-likely-than-not" threshold. Interest and penalties related to uncertain tax positions are recognized as income tax expense.

Earnings Per Share - Basic earnings (loss) per common share is computed by dividing net income (loss) available to common shareholders by the weighted-average number of shares of common stock outstanding during the period. Diluted earnings (loss) per common share is computed by dividing net income (loss) available to common shareholders by the sum of (1) the weighted-average number of shares of common stock outstanding during the period, (2) the dilutive effect of the assumed exercise of options and warrants using the treasury stock method, and (3) the dilutive effect of other potentially dilutive securities.

Comprehensive Income (Loss) - Comprehensive income (loss) is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. The Company's other comprehensive income (loss) is comprised of foreign currency translation adjustments.

The following table provides details with respect to changes in accumulated other comprehensive income (AOCI), which is comprised of foreign currency translation adjustments, as presented in the combined balance sheets for the years ended December 31, 2015 and 2014:

Balance January 1, 2014	$	(33,357)
Net current period other comprehensive income		79,438
Balance December 31, 2014		46,081
Net current period other comprehensive income		110,399
Balance December 31, 2015	$	156,480

(in U.S. Dollars)

NOTE 2 - Summary of Significant Accounting Policies (cont.)

New Accounting Pronouncements –

Not Adopted - In August 2014, the FASB issued Accounting Standard Update 2014-15, Disclosure of Uncertainties About an Entity's Ability to Continue as a Going Concern. The amendments require management to perform interim and annual assessments of an entity's ability to continue as a going concern and provides guidance on determining when and how to disclose going concern uncertainties in the financial statements. The standard applies to all entities and is effective for annual and interim reporting periods ending after December 15, 2016, with early adoption permitted. The Company is currently evaluating the impact on its combined and consolidated financial statements and disclosures.

Not Adopted - In November 2015, the FASB issued ASU (ASU) 2015-17, Balance Sheet Classification of Deferred Taxes, which requires that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. The amendments in this update apply to all entities that present a classified statement of financial position. The current requirement that deferred tax liabilities and assets of a tax-paying component of an entity be offset and presented as a single amount is not affected by the amendments in this update. The amendments in this update are effective for the company's financial statements issued for annual periods beginning after December 15, 2017, and interim periods within annual periods beginning after December 15, 2018. Earlier application is permitted for all entities as of the beginning of an interim or annual reporting period. The amendments in this update may be applied either prospectively to all deferred tax liabilities and assets or retrospectively to all periods presented. If an entity applies the guidance prospectively, the entity should disclose in the first interim and first annual period of change, the nature of and reason for the change in accounting principle and a statement that prior periods were not retrospectively adjusted. If an entity applies the guidance retrospectively, the entity should disclose in the first interim and first annual period of change the nature of and reason for the change in accounting principle and quantitative information about the effects of the accounting change on prior periods. The Company is currently evaluating the impact of this standard on its combined and consolidated financial statements. We do not expect this standard to have a material impact on the Company's reported results of operations or financial position.

NOTE 3 – Reverse Acquisition

We completed our acquisition as discussed in Note 1. Based on the terms of the Acquisition and since 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 has been accounted for as a reverse acquisition under the acquisition method of accounting for business combinations in accordance with U.S. GAAP. Accordingly, the assets and liabilities of Celsus have been recorded as of the acquisition closing date at fair value.

Accordingly, the acquisition consideration for accounting purposes consisted of the Celsus Ordinary Shares and the fair value of vested options and warrants issued by Celsus that were outstanding at the date of the Acquisition immediately prior to closing. Assets and liabilities of Celsus were measured at fair value and added to the assets and liabilities of Volution, and the historical results of operations of Volution were reflected in the results of operations of the Company following the Acquisition.

In connection with the consummation of the Acquisition, the Company issued an aggregate of 722,345,600 Ordinary Shares to RPC, Volution's sole shareholder, in exchange for the outstanding shares of common stock of Volution.

Purchase Consideration

The purchase price for Celsus on September 18, 2015, the closing date of the Acquisition, was as follows:

Fair value of Celsus common stock outstanding	$	20,034,625	(a)
Fair value of Celsus stock options		277,461	(2,516,690 options)
Fair value of Celsus warrants		27,054	(1,782,246 warrants)
Total purchase price	$	20,339,140	

(a) computed by multiplying 55,636,283 ordinary shares of Celsus at acquisition by the closing price on September 18, 2015 of $0.3601.

(in U.S. Dollars)

NOTE 3 – Reverse Acquisition (cont.)

Allocation of Purchase Consideration - preliminary

Under the acquisition method of accounting, the total purchase price was allocated to tangible and identifiable intangible assets acquired and liabilities assumed of Celsus on the basis of their estimated fair values as of the transaction closing date on September 18, 2015. The excess of the total purchase price over the fair value of assets acquired and liabilities assumed was allocated to excess consideration.

The following table summarizes the allocation of the purchase consideration to the assets acquired and liabilities assumed based on their fair values as of September 18, 2015:

Cash and cash equivalents	$ 1,410,577
Restricted cash	142,079
Prepaid expenses and other assets acquired	1,672,028
Excess consideration	19,283,280
Liability related to options and warrants	(1,800,154)
Other assumed liabilities	(368,670)
Total	$ 20,339,140

The Company believes that the historical values of Celsus's current assets and current liabilities approximate fair value based on the short-term nature of such items.

Excess consideration is calculated as the difference between the fair value of the consideration expected to be realized and the values assigned to the identifiable tangible and intangible assets acquired and liabilities assumed. The Company has recorded this non-cash charge in the statements of comprehensive loss due to the fact that Goodwill could not be justified and was considered fully impaired.

NOTE 4 – Patent Acquisition Costs

Patent acquisition costs, net, are the asset costs of purchased patents that and are amortized over the useful life of the patent determined to be 22 years, at December 31, 2015 and December 31, 2014 consisted of the following:

	December 31, 2015	December 31, 2014
Patent acquisition and related costs	$ 95,050	$ 95,192
Less: Accumulated amortization	(42,567)	(35,775)
	$ 52,483	$ 59,417

Amortization of patent acquisition costs for the years ended December 31, 2015 and December 31, 2014 was $3,122 and $1,891, respectively.

Approximate amortization expense of patent acquisition costs for the next five years is as follows:

2016	$ 3,100
2017	3,100
2018	3,100
2019	3,100
2020	3,100
Thereafter	36,983

(in U.S. Dollars)

NOTE 5 – Loans Payable - Shareholders

Loans payable – shareholders at December 31, 2015 and December 31, 2014 consisted of the following:

	December 31, 2015	December 31, 2014
Unsecured demand loan (CHF 100,500) bearing interest at 3.5% per annum	$ -	$ 101,252
Unsecured demand loan (EUR 224,250) bearing interest at 4.5% per annum	-	275,241
Unsecured demand loan (GBP 100,000) bearing interest at 4.5% per annum	-	157,112
Unsecured demand loan (GBP 1,998,000) bearing interest at 3.0% per annum	-	-
	$ -	$ 533,605

At a Volution shareholder meeting held on June 22, 2015, Volution raised short-term working capital in the form of loans from shareholders of approximately $3 million. The loans carry with them, options in RPC, equivalent to 15% of the current outstanding equity issued by RPC which have been accounted for in accordance with ASC 718 since RPC is a private company that is a majority shareholder of the Company. The fair value of the RPC options is estimated using the fair value of Akari shares times RPC's ownership in Akari shares times 15 percent and was approximately $26 million. The exact terms of these options have not been finalized. These options do not relate to the share capital of Akari. The Company recorded a liability to options and warrants for $26 million reflected in current liabilities on the balance sheet, allocated $3 million as a loan discount and recorded interest expense over the estimated term of the loan amounting to $3 million in statement of comprehensive loss as a credit to the loan discount (see note 6). The remaining $23 million was recorded as a non-cash financing expense in the statement of comprehensive loss.

Interest expense included in the statement of comprehensive loss related to these loans for the years ended December 31, 2015 and 2014 amounted to $3,053,948 and $5,436, respectively. The 2014 shareholder loans were repaid in April 2015 and the 2015 loans were repaid in October 2015.

NOTE 6 – Fair Value Measurements

Fair value of financial instruments:

The estimated fair value of financial instruments has been determined by the Company using available market information and valuation methodologies. Considerable judgment is required in estimating fair values. Accordingly, the estimates may not be indicative of the amounts the Company could realize in a current market exchange.

The carrying amounts of cash and cash equivalents, receivable from related party, restricted cash, accounts payable, loans payable and liability related to option and warrants approximate their fair value due to the short-term maturity of such instruments.

Fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or a liability. As a basis for considering such assumptions, ASC 820, "Fair Value Measurements and Disclosures" establishes a three-tier value hierarchy, which prioritizes the inputs used in the valuation methodologies in measuring fair value:

Level 1 - quoted prices in active markets for identical assets or liabilities;

Level 2 - inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices in active markets for similar assets or liabilities, quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities; or

Level 3 - unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The fair value hierarchy also requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value.

(in U.S. Dollars)

NOTE 6 – Fair Value Measurements (cont.)

	Carrying Amount $	December 31, 2015 Fair Value $	December 31, 2014 Carrying Amount $	Fair Value $	Fair Value Levels	Reference
Cash and cash equivalents	68,919,995	68,919,995	3,327,468	3,327,468	1	Note 2
Receivable from related party	10,366	10,366	-	-	3	Note 8
Restricted cash	142,079	142,079	-	-	1	Note 2
Accounts payable	4,320,588	4,320,588	555,528	555,528	1	-
Accounts payable-related party	-	-	39,236	39,236	3	-
Loans payable – shareholders	-	-	533,605	533,605	1	Note 5
Liability related to options and warrants	16,396,158	16,396,158	-	-	3	Note 6

In accordance with ASC 820, the Company measures its liability related to options and warrants on a recurring basis at fair value. The liability related to options and warrants is classified within Level 3 value hierarchy because the liability is based on present value calculations and external valuation models whose inputs include market interest rates, estimated operational capitalization rates, volatilities and illiquidity. Unobservable inputs used in these models are significant.

Upon completion of the Acquisition, the Company assumed certain warrants that were issued in connection with several private placements by Celsus and certain investors where it sold ordinary shares and warrants. Some of the issued warrants contain non-standard anti-dilution.

As of September 18, 2015, the Acquisition date, warrants to purchase 5,617,977 ordinary shares had full ratchet anti-dilution protection (which would be triggered by a share or warrant issuance at less than $0.1958 price share or exercise price per share). The issuance of ordinary shares in connection with the Financing (see Note 1) triggered the full ratchet anti-dilution protection resulting in an additional 188,303 ordinary shares issuable upon exercise of such warrants for a total of 5,806,280 and reducing the exercise price to $0.18945. As of December 31, 2015, the fair value of the warrants was $685,141. The net change in fair value was recognized as change in fair value of option and warrant liabilities in the Company's consolidated statement of comprehensive loss. The warrants expire on April 3, 2017.

(in U.S. Dollars)

NOTE 6 – Fair Value Measurements (cont.)

The Company accounts for the liability warrants issued in accordance with ASC 815, "Derivatives and Hedging" as a freestanding liability instrument that is measured at fair value at each reporting date, based on its fair value, with changes in the fair values being recognized in the Company's consolidated statement of comprehensive loss as financing income or expense.

The fair value of warrants granted was measured using the Binomial method of valuation.

Fair values were estimated using the following assumptions for the options as of December 31, 2015:

Expected dividend yield	0%
Expected volatility	233.0%
Risk-free interest	0.75%
Expected life	1.26 years

The Company raised short-term working capital in the form of loans from shareholders of approximately $3 million with the loans carrying with it, options in RPC, equivalent to 15% of the current outstanding equity issued by RPC. RPC is a private company that is a majority shareholder of the Company. The options were accounted for in accordance with ASC 718. The fair value of the RPC options is estimated using the fair value of Akari shares times RPC's ownership in Akari shares times 15 percent and was approximately $26 million. These options do not relate to the share capital of Akari. The Company recorded a liability to options and warrants for $26 million, allocated $3 million as a loan discount and recorded interest expense over the estimated term of the loan amounting to $3 million recognized in the statement of comprehensive loss as a credit to the loan discount (see note 5). The remaining $23 million was recorded as a non-cash financing expense in the statement of comprehensive loss.

As of December 31, 2015, the fair value of the RPC options was $15,711,017. The net change in fair value was recognized as change in fair value of option and warrant liabilities in the Company's consolidated statement of comprehensive loss. The Company accounted for the options as a liability in accordance with ASC 815-40-25, "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock" and ASC 815-40-15, "Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock."

The Company's financial assets and liabilities measured at fair value on a recurring basis, consisted of the following types of instruments as of the following dates:

	December 31, 2015	December 31, 2014
	Fair value measurements using input type Level 3	
Warrants	$ 685,141	-
RPC options	$ 15,711,017	-
Liability related to options and warrants	**$ 16,396,158**	**$ -**

(in U.S. Dollars)

NOTE 6 – Fair Value Measurements (cont.)

Fair value measurements using significant unobservable inputs (Level 3):

	Fair value of liability related to stock options and warrants
Balance at December 31, 2014	-
Balance at September 18, 2015 (Acquisition)	1,800,154
Changes in values of liability related to warrants	(11,408,231)
Value of liability related to options - transfer in	26,004,235
Balance at December 31, 2015	$ 16,396,158

NOTE 7 – Shareholders' Equity

Share Capital – The Company has 5,000,000,000 shares of authorized capital and 1,177,693,383 shares outstanding as of December 31, 2015.

On September 18, 2015, in connection with the Acquisition, 55,636,283 shares were issued to Celsus. All periods have been recast to reflect this reverse acquisition.

On September 18, 2015, the Company completed a private placement of 395,881,100 shares for gross proceeds of $75 million at a price of $0.18945 per share.

On September 18, 2015, the Company issued 3,830,400 shares to MTS Health Partners ("MTS"), as partial compensation for financial advisory services to the Company in connection with the Acquisition with a value of $750,000 at a price of $0.1958 per share. The Company also paid MTS $500,000 in cash. These amounts were recorded in general and administrative expenses on the statement of comprehensive loss.

Share option plan –

There were no options granted and outstanding for the year ended December 31, 2014.

Upon completion of the Acquisition, the Company assumed the former Celsus 2014 Equity Incentive Plan (the "Plan"). In accordance with the Plan, the number of shares that may be issued upon exercise of options under the Plan, shall not exceed 141,142,420 shares. As of December 31, 2015, 79,780,222 ordinary shares are available for future issuance under the Plan. The option plan is administered by the Company's board of directors and grants are made pursuant thereto by the compensation committee. The per share exercise price for the shares to be issued pursuant to the exercise of an option shall be such price equal to the fair market value of the Company's ordinary shares on the grant date and set forth in the individual option agreement. Options terminate ten years after the grant date and typically vest over three to four years.

(in U.S. Dollars)

NOTE 7 – Shareholders' Equity (cont.)

The following is a summary of the Company's stock option activity and related information for the year ended December 31, 2015:

	Number of shares	Weighted average exercise price	Weighted average grant date fair value	Weighted average remaining contractual term (in years)	Aggregate intrinsic value
Options outstanding as of January 1, 2015	-	$ -		-	$ -
Changes during the period:					
Assumed in Acquisition	2,516,690	$ 1.47	$ 0.55		
Granted Following the Acquisition	59,710,698	$ 0.31	$ 0.20		
Forfeited	(865,190)	$ 1.22			
Options outstanding as of December 31, 2015	61,362,198	$ 0.34		9.7	$ -
Exercisable options as of December 31, 2015	2,882,017	$ 0.74		8.6	$ -

The following is a summary of the Company's non-vested stock options as of December 31, 2015 and changes during the period:

	Number of shares	Weighted average grant date fair value
Non-vested options as of December 31, 2014	-	$ -
Non-vested options assumed in Acquisition	851,668	$ 0.40
Options granted	59,710,698	$ 0.20
Options vested	(1,858,851)	$ 0.17
Non-vested options forfeited	(223,334)	
Non-vested as of December 31, 2015	58,480,181	$ 0.21

On September 21, 2015, the Company granted 52,883,513 options to its employees at an exercise price of $0.3221 that vest quarterly over 4 years. In addition, the Company granted 945,112 options to its non-employee directors at an exercise price of $0.3221 that vest in 1 year. On November 16, 2015, the Company granted 1,627,185 options to a non-employee at an exercise price of $0.19 that fully vested on December 31, 2015. On November 25, 2015, the Company granted 4,254,888 options to its non-employee directors at an exercise price of $0.19165 that vest annually over 3 years.

The Company accounts for awards of equity instruments issued to employees and directors under the fair value method of accounting and recognize such amounts in its Consolidated Statements of Comprehensive Loss. The Company measures compensation cost for all stock-based awards at fair value on the date of grant and recognize compensation expense in its Consolidated Statements of Comprehensive Loss using the straight-line method over the service period over which it expects the awards to vest.

The Company estimates the fair value of all time-vested options as of the date of grant using the Black-Scholes option valuation model, which was developed for use in estimating the fair value of traded options that have no vesting restrictions and are fully transferable. Option valuation models require the input of highly subjective assumptions, including the expected stock price volatility, which is calculated based on the historical volatility of the Company's common stock. The Company uses a risk-free interest rate, based on the U.S. Treasury instruments in effect at the time of the grant, for the period comparable to the expected term of the option. Given its limited history with stock option grants and exercises, the Company uses the "simplified" method in estimating the expected term, the period of time that options granted are expected to be outstanding, for its grants.

(in U.S. Dollars)

NOTE 7 – Shareholders' Equity (cont.)

The Company classifies its stock-based payments as either liability-classified awards or as equity-classified awards. The Company remeasures liability-classified awards to fair value at each balance sheet date until the award is settled. The Company measures equity-classified awards at their grant date fair value and do not subsequently remeasure them. The Company has classified its stock-based payments which are settled in common stock as equity-classified awards and share-based payments that are settled in cash as liability-classified awards. Compensation costs related to equity-classified awards generally are equal to the grant-date fair value of the award amortized over the vesting period of the award. The liability for liability-classified awards generally is equal to the fair value of the award as of the balance sheet date multiplied by the percentage vested at the time. The Company charges (or credits) the change in the liability amount from one balance sheet date to another to compensation expense. Below are the assumptions used for the options assumed and granted in the year ended December 31, 2015:

	2015
Expected dividend yield	0%
Expected volatility	71.28%-81.79%
Risk-free interest	1.51%-2.27%
Expected life	5.5-10 years

The following is a summary of the Company's stock options granted separated into ranges of exercise price:

Exercise price (range)	Options outstanding as of December 31, 2015	Weighted average remaining contractual life (years)	Weighted average exercise price	Options exercisable as of December 31, 2015	Remaining contractual life (years for exercisable options	Weighted average exercise price
$			$			$
0.19	5,882,073	9.89	0.19	1,627,185	9.89	0.19
0.32	53,828,625	9.72	0.32	-	-	-
0.60-0.75	380,000	8.23	0.71	380,000	8.23	0.71
1.19-1.56	311,500	4.24	1.40	311,500	4.24	1.40
2.00	960,000	7.73	2.00	563,332	7.73	2.00
	61,362,198			2,882,017		

During the year ended December 31, 2015, the Company recorded approximately $854,000 in share based compensation expenses for employees and directors; and recorded approximately $186,000 in share based compensation expenses for non-employees. As of December 31, 2015, there was approximately $11,149,000 unrecognized compensation cost related to unvested share-based compensation arrangements granted under the Company's stock option plans.

Warrants to service providers and investors -

The warrants assumed in the Acquisition and outstanding as of December 31, 2015 are as follows:

Grant date	Number of warrants	Exercise Price	Expiration date
2012 warrants	1,383,086	$ 1.72 - $2.25	January 16, 2017-November 30, 2017
2013 warrants	399,160	$ 2.00	January 16, 2018-September 17, 2018
	1,782,246		

(in U.S. Dollars)

NOTE 8 – Related Party Transactions

Accounting Services - An entity related to a shareholder provided accounting and bookkeeping services of approximately $131,000 and $25,000, respectively, to the Company during the years ended December 31, 2015 and December 31, 2014.

Other – As of December 31, 2015, there is a receivable balance in the amount of $10,366 with RPC, a major shareholder. The Company paid certain registration fees on RPC's behalf and is treating this as short term in nature with no interest. This is recorded under "Receivable from related party" within current assets on the balance sheet.

NOTE 9 - Commitments and Contingencies

Lease commitment – In March 2014, the Company entered into a lease agreement for offices in London. The lease term commenced on December 1, 2014 and expires in March 2019. The lease can be cancelled early by either party upon 3 months' notice.

The Company also has a five year lease for offices in the United States effective July 2014. The lease expires in August 2019.

Future minimum lease payments under the Company's operating leases are as follows as of December 31, 2015:

	London	United States
2016	$ 39,100	$ 297,260
2017	39,100	312,909
2018	39,100	330,291
2019	9,775	225,297
	$ 127,075	$ 1,165,757

For the years ended December 31, 2015 and December 31, 2014, the Company incurred rental expense in the amount of approximately $104,000 and $1,800.

NOTE 10 – Earnings Per Share

Basic earnings (loss) per common share is computed by dividing net income (loss) available to common shareholders by the weighted-average number of shares of common stock outstanding during the period. Diluted earnings (loss) per common share is computed by dividing net income (loss) available to common shareholders by the sum of (1) the weighted-average number of shares of common stock outstanding during the period, (2) the dilutive effect of the assumed exercise of stock options using the treasury stock method, and (3) the dilutive effect of other potentially dilutive securities.

	Years Ended December 31,	
Earnings per share	2015	2014
Company posted	Net loss	Net loss
Basic weighted average shares outstanding	852,088,530	85,515,588
Dilutive effect of common stock equivalents	None	None
Dilutive weighted average shares outstanding	852,088,530	85,515,588

(in U.S. Dollars)

NOTE 10 – Earnings Per Share (cont.)

For purposes of the diluted net loss per share calculation, stock options and warrants are considered to be potentially dilutive securities and are excluded from the calculation of diluted net loss per share because their effect would be anti-dilutive. Therefore, basic and diluted net loss per share was the same for the periods presented due to the Company's net loss position.

The following table shows the number of stock equivalents that were excluded from the computation of diluted earnings per share for the respective period because the effect would have been anti-dilutive:

	Year ended December 31, 2015	Year ended December 31, 2014
Total stock options	61,362,198	-
Total warrants-equity classified	1,782,246	-
Total warrants-liability classified	5,806,280	-
Total stock options and warrants	68,950,724	-

NOTE 11 – Taxes

Tax rates:

The Company is incorporated in Great Britain. The effective corporate tax rate applying to a company that is incorporated in Great Britain on December 31, 2015 is 20.25%, reduced from 21.50% from December 31, 2014. For companies with taxable income of less than £300,000 and having no related companies the corporate tax rate is 20%.

Tax assessment:

The periods open to enquiry by the United Kingdom ("UK") tax authorities are 2014 and 2015. The Company has not been issued final tax assessments since its establishment in Switzerland.

Deferred taxes:

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Management currently believes that since the Company has a history of losses, it is more likely than not that the deferred tax assets relating to the loss carryforwards and other temporary differences will not be realized in the foreseeable future. Therefore, the Company provided a full valuation allowance to reduce the deferred tax assets.

The main reconciling item between the statutory tax rate of the Company and the effective tax rate is the recognition of valuation allowances in respect of deferred taxes relating to accumulated net operating losses carried forward due to the uncertainty of the realization of such deferred taxes.

As of December 31, 2015 and 2014, there were no known uncertain tax positions. We have not identified any tax positions for which it is reasonably possible that a significant change will occur during the next 12 months.

(in U.S. Dollars)

NOTE 11 – Taxes (cont.)

The components of loss before income taxes are as follows:

	December 31, 2015	December 31, 2014
Domestic	(39,599,123)	(332,663)
Foreign	(5,718,409)	(1,614,890)
Loss before income tax	(45,317,532)	(1,947,553)

Income taxes relating to the Company's operations are as follows:

	December 31, 2015	December 31, 2014
Current income taxes		
Domestic	-	-
Foreign	-	-
Deferred income taxes	-	-
Domestic	-	-
Foreign	-	-
Income tax expense/recovery		

Income taxes at the UK statutory rate compared to the Company's income tax expenses as reported are as follows:

	December 31, 2015	December 31, 2014
Net loss before income tax	(45,317,532)	(1,947,553)
Statutory rate	20.25%	21.50%
Expected income tax recovery	(9,176,800)	(418,724)
Impact on income tax expense/recovery from		
Change in valuation allowance	1,771,655	572,139
Permanent differences – excess consideration	3,904,864	-
Permanent differences - liability related to options and warrants	2,955,733	-
Change of tax rate from prior year	15,595	-
Tax rate difference in foreign jurisdictions	528,953	(153,415)
Income tax expense	-	-

The Company's deferred tax assets and liabilities consist of the following:

	December 31, 2015	December 31, 2014
Deferred tax assets		
Stock-based compensation	210,573	-
Tax loss carry forward	3,968,414	2,407,332
Valuation allowance	(4,178,987)	(2,407,332)
Deferred tax assets/liabilities	-	-

Pursuant to ASC 740-10-25-3 *Income Taxes*, an income tax provision has not been made for UK or additional foreign taxes since the Company is not generating income nor are expected to in the foreseeable future. The Company expects that future earnings will be reinvested, but could become subject to additional tax if they were remitted as dividends or were loaned to the Company, or if the Company should sell or dispose of its stock in the foreign subsidiaries. It is not practical to determine the deferred tax liability, if any, that might be payable on foreign earnings because if the Company were to repatriate these earnings, the Company believes there would be various methods available to it, each with different UK tax consequences.

(in U.S. Dollars)

NOTE 11 – Taxes (cont.)

The Company's operating loss carry forward of all jurisdictions expire according to the following schedule:

	Domestic	Foreign
2016	-	-
2017	-	-
2018	-	-
2019	-	-
2020	-	-
Beyond 2020	15,643,618	7,278,009
Total operating loss carry forwards	15,643,618	7,278,009

As of December 31, 2015 the Company had approximately $21.3 million of UK operating loss carryforwards to reduce future UK taxable income. These carryforwards to do not expire. As of December 31, 2015 the Company had approximately $16.9 million of foreign operating loss carryforwards in Switzerland ($2.8 million). The carryforwards in Switzerland expire in seven years.

Research and development credits:

The Company carries out extensive research and development activities, and may benefit from the UK research and development tax relief regime, whereby the Company can receive an enhanced UK tax deduction on its research and development activities. Where the Company is loss making for the period it can elect to surrender taxable losses for a refundable tax credit. The losses available to surrender are equal to the lower of the sum of the research and development qualifying expenditure and enhanced tax deduction and the Company's taxable losses for the period with the tax credit for December 31, 2015 available at a rate of 14.5%. The credit therefore gives a cash flow advantage to Company's at a lower rate than would be available if the enhanced losses were carried forward and relieved against future taxable profits.

Qualifying expenditures comprise of chemistry and manufacturing consumables, employment costs for research staff, clinical trials management and other subcontracted research expenditures.

In August 2015, the Company filed a credit claim for 2014 tax year. The credit claim was in the amount of £1,033,484 for the year ended 31 December 2014 and was received in September 2015.

For the year ended December 31, 2015 the Company ceased one research and development activity in the first quarter of 2015 and commenced another in the third quarter of 2015. The first quarter's research and development activity was based on the Company's trade prior to the Group restructure and a claim may be possible on the basis the Company was a going concern during this period.

As the third quarter's research and development expenditure involved the commencement of a new research and development activity a new research and development report will be required and assessed the UK tax authorities. Due to the uncertainty of the approval of these tax credit claims and the potential that an election for a tax credit in the form of cash is not made, the Company did not a record a related receivable as of December 31, 2015.

(in U.S. Dollars)

NOTE 12 – Segment Information

The chief operating decision maker ("CODM") is the Company's CEO. Neither the CODM nor the Company's directors receive disaggregated financial information about the locations in which research and development is occurring. Therefore, the Company considers that it has only one reporting segment.

The following table presents the Company's tangible fixed assets by geographic region:

	December 31, 2015	December 31, 2014
United States	$ 32,373	$ -
United Kingdom	8,140	-
Switzerland	-	-
Total	$ 40,513	$ -

NOTE 13 – Subsequent Events

In January 2016, we entered into a new lease for our offices in London through March 13, 2019 for approximately 1,260 square feet, effective January 1, 2016.

Exhibit No.	Exhibit Description
2.1	Share Exchange Agreement, dated as of July 10, 2015, by and between Celsus Therapeutics Plc and RPC Pharma Limited (incorporated by reference to the exhibit previously filed on the Registrant's Current Report on Form 8-K filed on July 13, 2015.)
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 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 Registration Statement on Form F-6 (No. 333-185197) filed on November 30, 2012.)
4.4	Form of April 2012 Warrant (incorporated by reference to the exhibit previously filed with the Registrant's Registration Statement on Form 20-F/A (No. 000-54749) filed on August 8, 2012.)
4.5	Form of Warrant dated November 30, 2012 (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.)
4.6	Form of Series A Warrant dated January 17, January 31 and February 28, 2013 (incorporated by reference to the exhibit previously filed with the Registrant's Post-Effective Amendment on Registration Statement on Form F-1 (No. 333-185247) filed on March 22, 2013.)
4.7	Form of Series B Warrant dated January 17, 2013 (incorporated by reference to the exhibit previously filed with the Registrant's Post-Effective Amendment on Registration Statement on Form F-1 (No. 333-185247) filed on March 22, 2013.)
4.8	Form of Series C Warrant dated January 17, 2013 (incorporated by reference to the exhibit previously filed with the Registrant's Post-Effective Amendment on Registration Statement on Form F-1 (No. 333-185247) filed on March 22, 2013.)
4.9	Form of Series GSS Warrant dated January 17, January 31 and February 28, 2013 (incorporated by reference to the exhibit previously filed with the Registrant's Post-Effective Amendment on Registration Statement on Form F-1 (No. 333-185247) filed on March 22, 2013.)
4.10	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).
4.11	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).
10.1+	Amended and Restated 2007 Stock Option Plan, dated April 26, 2012 (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.)
10.2 +	Second Amendment to Amended and Restated 2007 Stock Option Plan, dated June 20, 2012 (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.)
10.3 +	2014 Equity Incentive Plan (incorporated by reference to the exhibit previously filed with the Registrant's Report of Foreign Private Issuer on Form 6-K (No. 001-36288) filed on June 24, 2014.)
10.4+	Separation Agreement, dated April 30, 2015, by and between Celsus Therapeutics Plc and Pablo Jimenez (incorporated by reference to the exhibit previously filed with the Registrant's Current Report on Form 8-K filed on May 1, 2015.)

10.5	Relationship Agreement, dated as of July 10, 2015, by and between Celsus Therapeutics Plc and RPC Pharma Limited. (incorporated by reference to the exhibit previously filed with the Registrant's Current Report on Form 8-K filed on July 13, 2015.)
10.6	Form of Working Capital Agreement, by and between Celsus Therapeutics Plc and RPC Pharma Limited. (incorporated by reference to the exhibit previously filed with the Registrant's Current Report on Form 8-K filed on July 13, 2015.)
10.7	Form of Lock-Up Agreement, by and among Celsus Therapeutics Plc and RPC Pharma Limited. (incorporated by reference to the exhibit previously filed with the Registrant's Current Report on Form 8-K filed on July 13, 2015.)
10.8+	Amended and Restated 2014 Equity Incentive Plan (incorporated by reference to the exhibit previously filed with the Registrants Definitive Proxy Statement on Schedule 14A filed on August 3, 2015.)
10.9	Form of Securities Purchase Agreement, dated August 17, 2015 by and among Celsus Therapeutics Plc and the Buyers (as defined therein) (incorporated by reference to the exhibit previously filed with the Registrant's Current Report on Form 8-K filed on August 18, 2015.)
10.10	Form of Registration Rights Agreement, dated August 17, 2015 by and among Celsus Therapeutics Plc and the Buyers (as defined therein) (incorporated by reference to the exhibit previously filed with the Registrant's Current Report on Form 8-K filed on August 18, 2015.)
10.11+	Executive Employment Agreement, dated as of September 21, 2015, by and between the Company and Gur Roshwalb, M.D. (incorporated by reference to the exhibit previously filed with the Registrant's Current Report on Form 8-K filed on September 22, 2015.)
10.12+	Executive Employment Agreement, dated as of September 21, 2015, by and between the Company and Dov Elefant (incorporated by reference to the exhibit previously filed with the Registrant's Current Report on Form 8-K filed on September 22, 2015.)
10.13+	Employment Contract, dated as of September 21, 2015, by and between the Company and Clive Richardson (incorporated by reference to the exhibit previously filed with the Registrant's Current Report on Form 8-K filed on September 22, 2015.)
10.14+	Amended and Restated Non-Employee Director Compensation Policy (incorporated by reference to the exhibit previously filed with the Registrant's Current Report on Form 8-K filed on November 25, 2015.)
16.1	Letter from Kost, Forer, Gabbay & Kasierer, a member of Ernst & Young Global, to the Securities and Exchange Commission, dated December 24, 2015 (incorporated by reference to the exhibit previously filed with the Registrant's Current Report on Form 8-K filed on December 24, 2015.)
21.1	List of subsidiaries
23.1	Consent of registered public accounting firm
31.1	Certification of Chief Executive Officer
31.2	Certification of the Chief Financial Officer
32	Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Schema Linkbase Document
101.CAL	XBRL Taxonomy Calculation Linkbase Document
101.DEF	XBRL Taxonomy Definition Linkbase Document
101.LAB	XBRL Taxonomy Labels Linkbase Document
101.PRE	XBRL Taxonomy Presentation Linkbase Document

+ Indicates management contract or compensatory plan.

Exhibit 21.1

Company Subsidiaries

1. Celsus Therapeutics Inc. (Incorporation date: 2 December 2002; Jurisdiction: Delaware)
2. Morria Biopharma Ltd. (Incorporation date: 22 March 2011; Jurisdiction: Israel)
3. Volution Immuno Pharmaceuticals SA (Incorporation date: 9 October 2013; Jurisdiction: Switzerland)
4. Volution Immuno Pharmaceutical (UK) Limited (Incorporation date: 22 August 2014; Jurisdiction: London)

Exhibit 23.1

Akari Therapeutics, Plc
London, UK

We hereby consent to the incorporation by reference in the Registration Statements on Form F3 (No. 333-198107), Form S-3 (No. 333-207443), Form S-8 (Nos. 333-198109 and 333-207444) and the Registration Statements on Post-Effective Amendments to Form F-1 on Form F-3 (Nos. 333-185247, 333-187826 and 333-191880) of Akari Therapeutics, Plc. of our report dated March 23, 2016, relating to the combined and consolidated financial statements, which appears in this Form 10-K.

Zurich, March 23, 2016

BDO AG

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

Exhibit 31.1

CERTIFICATIONS UNDER SECTION 302

I, Gur Roshwalb, certify that:

1. I have reviewed this annual report on Form 10-K of Akari Therapeutics, Plc;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 23, 2016

/s/ Gur Roshwalb_____
Gur Roshwalb
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS UNDER SECTION 302

I, Dov Elefant, certify that:

1. I have reviewed this annual report on Form 10-K of Akari Therapeutics, Plc;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 23, 2016

/s/ Dov Elefant_____
Dov Elefant
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32

CERTIFICATIONS UNDER SECTION 906

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), each of the undersigned officers of Akari Therapeutics, Plc, a corporation organized under the laws of England and Wales (the "Company"), does hereby certify, to such officer's knowledge, that:

The Annual Report for the year ended December 31, 2015 (the "Form 10-K") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 23, 2016

/s/ Gur Roshwalb
Chief Executive Officer
Principal Executive Officer

Dated: March 23, 2016

/s/ Dov Elefant
Chief Financial Officer
Principal Financial Officer