

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

FORM 20-F

(Mark One)

REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934

OR

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2016

OR

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

OR

SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Date of event requiring this shell company report _____

For the transition period from _____ to _____

Commission file number 001-36288

Akari Therapeutics, PLC

(Exact name of Registrant as specified in its charter)

The Laws of England and Wales

(Jurisdiction of incorporation or organization)

75/76 Wimpole Street

London W1G 9RT

United Kingdom

(Address of principal executive offices)

Gur Roshwalb

Chief Executive Officer

75/76 Wimpole Street

London W1G 9RT

United Kingdom

Telephone +44 20 8004 0270

(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

Securities registered or to be registered pursuant to Section 12(b) of the Act.

<u>Title of each class</u>	<u>Name of each exchange on which registered</u>
American Depositary Shares, each representing 100 Ordinary Shares, par value £0.01 per share	The Nasdaq Capital Market
Ordinary Shares, £0.01 par value per share*	

Securities registered or to be registered pursuant to Section 12(g) of the Act. **None**

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act. **None**

The number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report: 1,177,693,383 Ordinary Shares, £0.01 par value per share

* Not for trading, but only in connection with the registration of American Depositary Shares representing such Ordinary Shares pursuant to the requirements of the Securities and Exchange Commission.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes No

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.

Yes No

Note – Checking the box above will not relieve any registrant required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 from their obligations under those Sections.

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 (§232.405 of this chapter) 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 whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of “accelerated filer and large accelerated filer” in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP

International Financial Reporting Standards as issued by the International Accounting Standards Board

Other

If “Other” has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow.

Item 17 Item 18

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes No

TABLE OF CONTENTS

	<u>Page</u>
<u>FORWARD-LOOKING STATEMENTS</u>	1
<u>PART I</u>	
<u>ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS</u>	2
<u>ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE</u>	2
<u>ITEM 3. KEY INFORMATION</u>	2
<u>ITEM 4. INFORMATION OF THE COMPANY</u>	20
<u>ITEM 4A. UNRESOLVED STAFF COMMENTS</u>	37
<u>ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS</u>	38
<u>ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES</u>	43
<u>ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS</u>	54
<u>ITEM 8. FINANCIAL INFORMATION</u>	57
<u>ITEM 9. THE OFFER AND LISTING</u>	57
<u>ITEM 10. ADDITIONAL INFORMATION</u>	58
<u>ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT RISK</u>	64
<u>ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES</u>	64
<u>PART II</u>	
<u>ITEM 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES</u>	66
<u>ITEM 14. MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS</u>	66
<u>ITEM 15. CONTROLS AND PROCEDURES</u>	66
<u>ITEM 16. [RESERVED]</u>	67
<u>ITEM 16A. AUDIT COMMITTEE FINANCIAL EXPERT</u>	67
<u>ITEM 16B. CODE OF ETHICS</u>	67
<u>ITEM 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES</u>	67
<u>ITEM 16D. EXEMPTIONS FROM THE LISTING STANDARDS FOR AUDIT COMMITTEES</u>	68
<u>ITEM 16E. PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS</u>	68
<u>ITEM 16F. CHANGE IN REGISTRANT'S CERTIFYING ACCOUNTANT</u>	68
<u>ITEM 16G. CORPORATE GOVERNANCE</u>	68
<u>ITEM 16H. MINE SAFETY DISCLOSURES</u>	68
<u>PART III</u>	
<u>ITEM 17. FINANCIAL STATEMENTS</u>	68
<u>ITEM 18. FINANCIAL STATEMENTS</u>	68
<u>ITEM 19. EXHIBITS</u>	69
<u>SIGNATURES</u>	70

INTRODUCTION

Unless the context otherwise requires, all references to “Akari,” “we,” “us,” “our,” the “Company” and similar designations refer to Akari Therapeutics PLC and its subsidiaries.

Market data and certain industry data and forecasts used throughout this Annual Report on Form 20-F were obtained from sources we believe to be reliable, including market research databases, publicly available information, reports of governmental agencies, and industry publications and surveys. We have relied on certain data from third-party sources, including internal surveys, industry forecasts, and market research, which we believe to be reliable based on our management's knowledge of the industry. While we are not aware of any misstatements regarding the industry data presented in this Annual Report, our estimates involve risks and uncertainties and are subject to change based on various factors, including those discussed under the heading "Risk Factors" and elsewhere in this prospectus.

All trademarks, service marks, trade names and registered marks used in this report are trademarks, trade names or registered marks of their respective owners.

Statements made in this Annual Report on Form 20-F concerning the contents of any agreement, contract or other document are summaries of such agreements, contracts or documents and are not complete description of all of their terms. If we filed any of these agreements, contracts or documents as exhibits to this Report or to any previous filing with the Securities and Exchange Commission, or SEC, you may read the document itself for a complete understanding of its terms.

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 20-F contains forward-looking statements. All statements other than statements of historical facts contained in this Annual Report on Form 20-F, 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 and clinical studies, 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 20-F.

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 20-F 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 20-F 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 20-F.

You should read this Annual Report on Form 20-F and the documents that we have filed as exhibits to the Annual Report on Form 20-F 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

ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS

Not applicable.

ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE

Not applicable.

ITEM 3. KEY INFORMATION

A. Selected Financial Data

The following selected financial data should be read in conjunction with “Item 5 Operating and Financial Review and Prospects” and the Financial Statements and Notes thereto included elsewhere in this Annual Report.

We have derived the balance sheet data as of December 31, 2016 and 2015 and the combined and consolidated statement of operations data for the years ended December 31, 2016, 2015 and 2014 from our audited financial statements included elsewhere in this Annual Report. We have derived the balance sheet data as of December 31, 2014 from our audited financial statements not included in this Annual Report. Selected financial data as of, and for the years ended, December 31, 2013 and 2012 have been omitted from this Annual Report because it cannot be made available without unreasonable effort and expense. Our financial statements have been prepared in accordance with US GAAP.

Certain factors that affect the comparability of the information set forth in the following table are described in Item 5 “Operating and Financial Review and Prospects” and the Combined and Consolidated Financial Statements and related notes thereto included elsewhere in this Annual Report.

BALANCE SHEET DATA (In United States Dollars)	As of December 31,		
	2016	2015	2014
Total current assets	\$ 45,633,781	\$ 69,658,487	\$ 3,335,249
Total assets	45,873,678	69,893,562	3,394,666
Total current liabilities	11,714,768	21,124,968	1,171,368
Total liabilities	11,771,128	21,174,037	1,171,368
Capital stock	18,340,894	18,340,894	11,210,804
Shareholders' equity	34,102,550	48,719,525	2,223,298

STATEMENT OF OPERATIONS DATA

(In United States Dollars,
except for per share data)

	As of December 31,		
	2016	2015	2014
Research and development	\$ 17,306,001	\$ 5,799,076	\$ 1,616,204
General and administrative	9,940,557	5,502,214	303,095
Excess Consideration	-	19,293,280	-
Total operating expenses	27,246,558	30,584,570	1,919,299
Other expense (income)	(9,105,561)	14,732,962	28,254
Net loss	(18,140,997)	(45,317,532)	(1,947,553)
Net basic and diluted loss per share	\$ (0.02)	\$ (0.05)	\$ (0.02)
Weighted average number of Ordinary Shares	1,177,693,383	852,088,530	85,515,588

OTHER FINANCIAL DATA (In United States Dollars)

	As of December 31,		
	2016	2015	2014
Net cash used in operating activities	\$ (24,624,535)	\$ (4,965,583)	\$ (1,476,824)
Net cash provided (used) by financial activities	(10,066,632)	1,391,798	-
Net cash provided by financial activities	-	69,044,419	4,235,376

B. Capitalization and Indebtedness

Not applicable.

C. Reasons for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

Except for the historical information contained herein or incorporated by reference, this Annual Report on Form 20-F 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 20-F. 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 Item 5 entitled "Operating and Financial Review and Prospects" and elsewhere throughout this Annual Report on Form 20-F and in any documents incorporated in this Annual Report on Form 20-F 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 20-F. 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 American Depositary Shares, or ADSs, 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 \$18,140,997 and \$45,317,532 for the years ended December 31, 2016 and 2015, respectively. In addition, our accumulated deficit as of December 31, 2016 and 2015 was \$74,937,610 and \$56,796,613, respectively. Losses have principally resulted from costs incurred for manufacturing, 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. As of December 31, 2016, we had cash, cash equivalents and short-term investments of \$44,120,775.

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. 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.

Our failure to become and remain profitable would depress the market price of the ADSs 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, 2016, we had existing cash, cash equivalents and short-term investments of \$44,120,775. 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.

The amount and timing of any expenditure needed will depend on numerous factors, some of which are outside our control, 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 paroxysmal nocturnal hemoglobinuria, or PNH or any 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 or any 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.

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. 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. In addition, the terms of any financing may adversely affect the holdings or the rights of our shareholders and 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.

Future sales and issuances of the ADSs or rights to purchase ADSs 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 the Clinical Development and Regulatory Approval of Our Product Candidates

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 at least one autoimmune disease including PNH, atypical hemolytic-uremic syndrome, or aHUS, Guillain-Barre syndrome, or 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 and for our planned clinical development program for Coversin in aHUS and other indications. 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;
- 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 difficulty in enrollment, variability in patients, adjustments to clinical trial procedures and the need for additional clinical trial sites, which could delay our clinical trial progress;
- our reliance on a sole manufacturer to supply the drug product formulation of Coversin that is being used in our clinical trials;
- 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 II 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, or GBS, and other indications, 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, or a marketing authorisation application, or MAA, to the EMA 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, and other rare and orphan autoimmune and inflammatory diseases 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. 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 I 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.

While we have conducted toxicity studies in certain animals without any evidence of toxicity, 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, or LTB₄. LTB₄ synthesis from eicosanoid fatty acids can be induced by a variety of triggers including complement. LTB₄ is a pro-inflammatory mediator which attracts and activates white blood cells at the area of inflammation. 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. Although Coversin has in a single clinical patient to date in our Phase II eculizumab resistance trial shown beneficial effects, a larger scale Phase II trial is ongoing in PNH and the efficacy or non-efficacy of Coversin will ultimately be determined by the applicable regulatory agencies. The long-term safety consequences of inhibition of C5 with Coversin is not known. Regulatory approval of 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 have obtained orphan drug status for Coversin in PNH and GBS, both in the United States and the EU, but we may be unable to maintain the benefits associated with orphan drug status, including market exclusivity.

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. Although we have received orphan drug designation for Coversin in PNH and GBS and intend to seek orphan product designation for Coversin in further indications, we may never receive such additional designations.

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 for a particular indication, 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.

In the EU, where a marketing authorization in respect of an orphan medicinal product is granted, the Agency and the Member States shall not, for a period of 10 years, accept another application for a marketing authorization, or grant a marketing authorization or accept an application to extend an existing marketing authorization, for the same therapeutic indication, in respect of a similar medicinal product. A marketing authorization may be granted, for the same therapeutic indication, to a similar medicinal product if: (i) the holder of the marketing authorization for the original orphan medicinal product has given his consent to the second applicant, or; (ii) the holder of the marketing authorization for the original orphan medicinal product is unable to supply sufficient quantities of the medicinal product, or; (iii) the second applicant can establish in the application that the second medicinal product, although, similar to the orphan medicinal product already authorized, is safer, more effective or otherwise clinically superior.

The receipt of orphan drug designation status does not change the regulatory requirements or process for obtaining marketing approval and designation does not mean that marketing approval will be received.

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 meets 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 and, conversely, even if we obtain regulatory approval of Coversin in the EU, we or our partners may never obtain approval or commercialize our products outside the EU.

In order to market any products in a country, 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 regulatory approvals in other countries 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 rely on contract research organizations for 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.

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 employees, principal investigators, consultants, commercial partners or vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards.

We are also exposed to the risk of employees, independent contractors, principal investigators, consultants, commercial partners or vendors engaging in fraud or other misconduct. Misconduct by employees, independent contractors, principal investigators, consultants, commercial partners and vendors could include intentional failures to comply with EU regulations, to provide accurate information to the EMA or EU Member States authorities or to comply with manufacturing or quality standards we have or will have established. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices such as promotion of products by medical practitioners. Of general application are the European Anti-Fraud Office Regulation 883/2013, and the UK Bribery Act 2010. Under the latter, a commercial organisation can be guilty of the offence if the bribery is carried out by an employee, agent, subsidiary, or another third-party, and the location of the third-party is irrelevant to the prosecution. The advertising of medicinal products in the EU is regulated by Title VIII of European Directive 2001/83/EC. The corresponding UK implementing legislation is Part 14 of the Human Medicines Regulations 2012 (S.I. 2012/1916 as amended). Such laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programmes and other business arrangements. Misconduct could also involve the improper use of information obtained in the course of clinical studies, which could result in regulatory sanctions and serious and irreparable harm to our reputation. This could also apply with respect to data privacy. In the EU, the collection and use of Personal Data is governed by EU Directive 95/46/EEC. In the UK this was implemented by the Data Protection Act 1998. However, the current legislation is in the process of being replaced by the General Data Protection Regulation (EU) 2016/679, or GDPR, on the protection of natural persons with regard to the processing of personal data and on the free movement of such data. The GDPR entered into force on May 24, 2016 and repealed Directive 95/46/EC. The GDPR will apply directly in all member states (including the UK) from May 25, 2018. It is not always possible to identify and deter misconduct by employees or other parties. The precautions we take to detect and prevent this activity may not protect us from legal or regulatory action resulting from a failure to comply with applicable laws or regulations. Misconduct by our employees, principal investigators, consultants, commercial partners or vendors could result in significant financial penalties, criminal sanctions and thus have a material adverse effect on our business, including through the imposition of significant fines or other sanctions, and our reputation.

Risks Related to our Intellectual Property

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 patents for Coversin and its uses are expected to expire between 2024 and 2031 (excluding any patent term adjustment or potential patent term extension). Our pending patent applications cover formulations, combination products and use of Coversin to treat various indications and, if issued, are expected to expire at various times that range from 2024 to 2037 (excluding any potential patent term adjustment or extension).

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.

Risks Related to our Business Operations

We currently have no marketing, sales or distribution infrastructure with respect to Coversin. 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, 2016, we had fifteen 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 could have a material adverse effect on our business.

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' Soliris® (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. More recently, President Trump and other U.S. lawmakers have made statements about potentially repealing and/or replacing the ACA, although specific legislation for such a repeal or replacement is still in its early stages. While we are unable to predict what changes may ultimately be enacted, to the extent that future changes affect how our products are paid for and reimbursed by government and private payers our business could be adversely impacted.

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.

Although we currently carry clinical trial insurance, the amount of such insurance coverage may not be adequate. In addition, we will need to obtain more comprehensive 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, EMA 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 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 our 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, EMA 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 involve 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 2017 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 believe we are not a PFIC for 2016 but may be deemed a PFIC for 2017 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. An active trading market for our shares has not developed and, even if it does, it may not be sustained. In addition, we cannot assure you that we will be successful in meeting the continuing listing standards of the NASDAQ Capital Market and cannot assure you that our ADSs will be listed on a national securities exchange. If an active market for our common stock does not develop or is not sustained, it may be difficult for investors to sell their shares without depressing the market price for the shares or at all. Further, an inactive market may also impair our ability to raise capital and may impair our ability to enter into strategic partnerships or acquire companies or products by using our ADSs or Ordinary Shares as consideration.

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 or EMA 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;
- 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 or EMA approval or non-approval of our product candidates or delays in or adverse events during the FDA or EMA 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;
- unanticipated problems in the supply of the raw materials used to produce our product candidates;
- the commercial success of any product approved by the FDA, EMA or any other foreign counterpart;
- 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 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 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, 2016, our directors and executive officers, together with their affiliates and related persons, beneficially own, in the aggregate, approximately 62.1% of our outstanding Ordinary Shares. RPC, which is controlled by our chairman Dr. Ray Prudo, beneficially owns approximately 61.3% of our outstanding Ordinary Shares. Accordingly, these shareholders, if acting together, or Dr. 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 ADSs or rights to purchase Ordinary Shares or ADSs 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 ADSs by our existing shareholders in the public market could cause our stock price to fall.

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

The vote by the United Kingdom to leave the European Union could adversely affect our business, financial condition, results of operations and prospects.

On March 29, 2017, the Prime Minister of the United Kingdom submitted formal notice to the European Union in order to trigger Article 50 of the Treaty on European Union. This is the formal mechanism which begins the two-year process of negotiating the UK's exit from the EU, and to determine the future terms of the UK's relationship with the EU, including the terms of trade between the UK and the EU, and potentially other countries. The effects of the UK exiting the EU (commonly referred to as Brexit) will depend on any agreements the UK makes to retain access to EU markets. In addition, Brexit could lead to legal uncertainty and potentially divergent national laws and regulations as the UK determines which EU laws to replace or replicate. Brexit could adversely affect economic or market conditions in the UK, Europe or globally and could contribute to instability in global financial markets, in particular until there is more certainty as to the outcome of the aforementioned decisions and negotiations. Exports from the United Kingdom may incur increased duties and tariffs following Brexit, or Brexit could result in the regulatory compliance and patent costs associated with our business compliance costs increasing significantly so as to adversely affect our financial condition, results of operations and prospects. Our regulatory compliance costs may increase as a result of Brexit. Following an exit by the UK from the EU, we may be required to register any current EU-wide patents separately with the UK Intellectual Property Office, which could require significant additional expense. Further, our regulatory compliance costs may increase as a result of Brexit, as on an exit from the EU, the UK may cease compliance with the EU and the EMA's legislative regime for medicines, their research, development and commercialisation. Any changes to such regulatory regimes could require us to comply with separate regimes in the UK and the EU, or to develop new policies and procedures to reorganise our operations, any of which could increase our compliance costs. Brexit has also led to a decrease in the value of pounds sterling against the U.S. dollar, as well as general volatility in currency exchange markets. The challenges faced by the UK following Brexit could result in an overall decline in trade and economic growth and/or an increase in economic volatility and therefore may affect the attractiveness of the UK as a leading centre for business and commerce. Any of the aforementioned possible effects of Brexit, and others that we cannot anticipate, may materially adversely affect our business, financial condition, results of operations and prospects.

Provisions in our articles of association 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 association may delay or prevent an acquisition or a change in management. These provisions include a staggered board and prohibition on actions by written consent of 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 are required to furnish an annual report by our management on our internal control over financial reporting. 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 are an “emerging growth company” and a “foreign private issuer” and as a result of this and other reduced disclosure requirements applicable to emerging growth companies and foreign private issuers, 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 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. We cannot predict if investors will find our Ordinary Shares or ADSs less attractive because of our reduced disclosure requirements. If some investors find our Ordinary Shares or ADSs 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 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, on July 1, 2016 we became a foreign private issuer having previously lost this status at the end of 2014. As a foreign private issuer, we are not subject to the same requirements that are imposed upon U.S. domestic issuers by the SEC. Under the Securities Exchange Act of 1934, or the Exchange Act, we are subject to reporting obligations that, in certain respects, are less detailed and less frequent than those of U.S. domestic reporting companies. For example, we will not be required to issue proxy statements that comply with the requirements applicable to U.S. domestic reporting companies. We will also have four months after the end of each fiscal year to file our annual reports with the SEC and will not be required to file current reports as frequently or promptly as U.S. domestic reporting companies. Furthermore, our officers, directors, and principal shareholders will be exempt from the requirements to report transactions in our equity securities and from the short-swing profit liability provisions contained in Section 16 of the Exchange Act. These exemptions and leniencies, along with other corporate governance exemptions resulting from our ability to rely on home country rules, will reduce the frequency and scope of information and protections to which you may otherwise have been eligible in relation to a U.S. domestic reporting companies. If we were to lose our foreign private issuer status, the regulatory and compliance costs to us under U.S. securities laws as a U.S. domestic issuer will be significantly more than costs we incur as a foreign private issuer.

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. A majority 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.

The rights of our shareholders may differ from the rights typically offered to shareholders of a U.S. corporation.

We are incorporated under English law. The rights of holders of Ordinary Shares and, therefore, certain of the rights of holders of ADSs, are governed by English law, including the provisions of the Companies Act 2006, and by our Articles of Association. These rights differ in certain respects from the rights of shareholders in typical U.S. corporations.

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 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 depository 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 depository 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 depository may, at its discretion, decide that it is inequitable or impractical to make a distribution available to any holders of ADSs. For example, the depository 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 depository may decide not to distribute such property and holders of our ADSs will not receive any such distribution.

ITEM 4. INFORMATION ON THE COMPANY

A. History and Development of the Company

Our Corporate History

Our legal and commercial name is Akari Therapeutics, PLC. We were originally established as a private limited company under the laws of England and Wales on October 7, 2004 under the name Freshname No. 333 Limited. On January 19, 2005, we changed our name to Morria Biopharmaceuticals Limited and on February 3, 2005, we completed a reverse merger with Morria Biopharmaceuticals Inc., or Morria, a Delaware corporation, in which Morria became our wholly-owned subsidiary and we re-registered as a non-traded public limited company under the laws of England and Wales. Morria was dedicated to the discovery and development of novel, first-in-class, non-steroidal, synthetic anti-inflammatory drugs. On March 22, 2011, we incorporated an Israeli subsidiary, Morria Biopharma Ltd. On June 25, 2013, we changed our name to Celsus Therapeutics PLC and on October 13, 2013 Morria was renamed Celsus Therapeutics Inc. As of the date of this report, Celsus Therapeutics Inc. and Morria Biopharma Ltd. do not conduct any operations.

On September 18, 2015, we completed an acquisition of all of the capital stock of Volution Immuno Pharmaceuticals SA, or Volution, a private Swiss company, from Pharma Limited, or RPC, Volution's sole shareholder, in exchange for our Ordinary Shares, in accordance with the terms of a Share Exchange Agreement, dated as of July 10, 2015. In connection with the acquisition, our name was changed to Akari Therapeutics, PLC and the combined 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, aHUS and GBS.

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 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.

Our principal office is located at 75/76 Wimpole Street, London W1G 9RT, United Kingdom, and our telephone number is 44 20 8004 0270.

Our website address is www.akarix.com. The information contained on, or that can be accessed from, our website does not form part of this Annual Report.

Capital Expenditures

Our capital expenditures for the years ended December 31, 2016 and 2015 were \$54,750 and \$10,560, respectively. Our current capital expenditures primarily consist of computer equipment.

B. Business Overview

We are a clinical-stage biopharmaceutical company focused on developing inhibitors of acute and chronic inflammation, specifically the complement system, the eicosanoid system and the bioamine system for the treatment of rare and orphan diseases. Each of these systems has scientifically well-supported causative roles in the diseases being targeted by Akari. Akari believes that blocking early mediators of inflammation will prevent initiation and continual amplification of the processes that cause certain diseases.

All Akari molecules are derived from ticks which have undergone 300 million years of natural selection to produce inhibitors that bind tightly to key highly-conserved inflammatory mediators, are generally well tolerated in humans, and remain fully functional when a host is repeatedly exposed to the molecule.

Our lead product candidate, Coversin™, which is a second-generation 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), and independently also inhibits LTB4 activity, both elements that are co-located as part of the immune/inflammatory response. Coversin is a recombinant small protein (16,740 Da) derived from a protein originally 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.

Our initial clinical targets for Coversin are paroxysmal nocturnal haemoglobinuria, or PNH, atypical Hemolytic Uremic Syndrome, or aHUS, and Guillain Barré syndrome, or GBS. Akari is also targeting patients with polymorphisms of the C5 molecule which interfere with correct binding of Soliris® (eculizumab), a first-generation C5 inhibitor currently approved for PNH and aHUS treatment, making these patients resistant to treatment with that drug. In addition to disease targets where complement dysregulation is the key driver, Akari is also targeting a range of inflammatory diseases where the inhibition of both C5 and LTB4 are implicated.

Other compounds in our pipeline include engineered versions of Coversin that potentially decrease the frequency of administration, improve potency, or allow for specific tissue targeting, as well as new proteins targeting LBT4 alone, as well as bioamine inhibitors (for example, anti-histamines). In general, these inhibitors act as ligand binding compounds, which may provide additional benefit versus other modes of inhibition. For example, off target effects are less likely with ligand capture. One example of this benefit is seen with LTB4 inhibition through ligand capture. LTB4 acts to amplify the inflammatory signal by bringing and activating white blood cells to the area of inflammation. Compounds that have targeted the production of leukotrienes will inhibit both the production of pro-inflammatory as well as anti-inflammatory leukotrienes—often diminishing the potential benefit of the drug on the inflammatory system. Coversin has demonstrated that, by capturing LTB4, it is limited to disrupting the white blood cell activation and attraction aspects, without interfering with the anti-inflammatory benefits of other leukotrienes.

To date, we have demonstrated: (i) full complement inhibition and marked lactate dehydrogenase reduction in a PNH patient with eculizumab resistance and who has now been self-administering Coversin daily for over one year pursuant to an approved clinical protocol in the Netherlands; (ii) 100% inhibition of complement C5 activity by Coversin with once daily subcutaneous injections during our Phase Ib clinical trial in healthy volunteers; (iii) that Coversin inhibits PNH red blood cell lysis in vitro; 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 both our Phase Ib healthy volunteer study and our 28-day safety study in non-human primates.

In the fourth quarter of 2016, we commenced enrollment for a 90 day open-label Phase II, single arm trial in patients with PNH in 5 centers in the European Union. To date, five patients have been enrolled. This trial is designed to test the safety and efficacy of Coversin in patients with PNH who have not received any other complement blocking therapies. Patients who complete the trial will have the option to continue self-administration with Coversin in an open-label long term safety study. We expect to provide interim results from the Phase II trial in April, 2017. Assuming results from this trial confirm the safety and efficacy of Coversin in PNH, we expect to begin our Phase III program before the end of 2017.

Coversin has received orphan drug status from the FDA and EMA for PNH and GBS. Orphan drug designation provides the sponsor certain benefits and incentives, including a period of marketing exclusivity if regulatory approval of the drug is ultimately received for the designated indication. The receipt of orphan drug designation status does not change the regulatory requirements or process for obtaining marketing approval and designation does not mean that marketing approval will be received. We intend to apply in the future for further orphan drug designation in indications we deem appropriate.

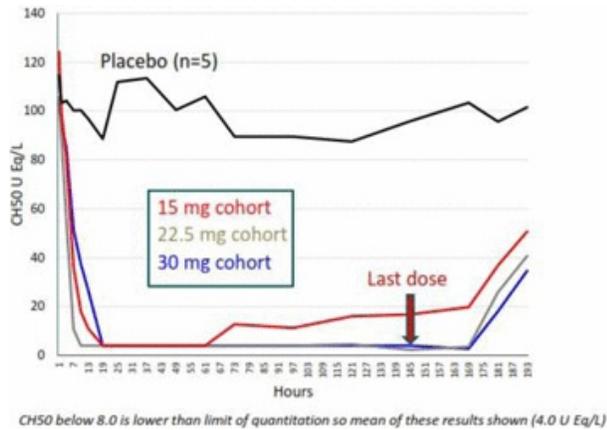
On March 29, 2017, we received notice from the FDA of fast track designation for the investigation of Coversin for treatment of PNH in patients who have polymorphisms conferring eculizumab resistance. The fast track program was created by the FDA to facilitate the development and expedite the review of new drugs which show promise in treating a serious or life-threatening disease and address an unmet medical need. Drugs that receive this designation benefit from more frequent communications and meetings with FDA to review the drug's development plan including the design of the proposed clinical trials, use of biomarkers and the extent of data needed for approval. Drugs with fast track designation may also qualify for priority review to expedite the FDA review process, if relevant criteria are met.

Coversin 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 we believe will provide considerable benefits in terms of patient convenience. We believe that the subcutaneous formulation of Coversin may accelerate recruitment for our clinical trials, and, as an alternative to intravenous infusion, may accelerate patient uptake if Coversin is approved by regulatory authorities for commercial sale. Patient surveys contracted by us suggest that a majority of patients would prefer to self-inject daily than undergo intravenous infusions.

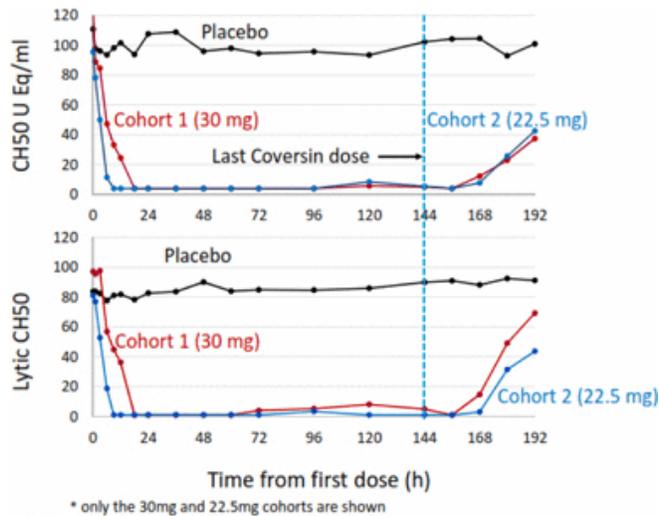
Clinical Development Program — Past and Future

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 in 24 subjects. 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 within 12 hours.

A Phase Ib repeat dose study was initiated in the first quarter of 2016. In this double-blind, randomized Phase Ib trial, each cohort of six normal healthy volunteers was given either a loading dose of subcutaneous placebo twice a day for two days followed by five days of a single daily placebo dose (n=2) or a loading dose of 30 mg of subcutaneous Coversin twice a day for two days followed by five days of a single daily subcutaneous maintenance dose (n=4) of either 15 mg, 22.5 mg or 30 mg.



Data from the 22.5 mg once daily maintenance cohort and 30 mg once daily maintenance cohort demonstrated that subcutaneous Coversin achieved complete complement inhibition (Elisa CH50 < 8 Eq/ml, lower limit of quantification) within the first day, and demonstrated complete complement inhibition at the end of dosing on day seven whether measured using the ELISA or lytic CH50 assays.



The data from the 15 mg once daily maintenance cohort demonstrated that subcutaneous Coversin achieved complete complement inhibition (Elisa CH50 < 8 Eq/ml, lower limit of quantification) within the first day but by day three was unable to maintain complete complement inhibition at the 24-hour trough measurement. A final cohort of 4 healthy volunteers was given 22.5 mg of Coversin as a maintenance dose for 21 days. Complete complement inhibition was demonstrated at the end of the 21 day period of once daily dosing and there were no neutralizing antibodies detected. One volunteer receiving the Coversin in the 30 mg 7 day cohort stopped dosing on day three due to a non-serious adverse event possibly related to antibiotics administered for meningitis prophylaxis. The trial was conducted at Hammersmith Medicines Research Ltd, in London.

In February 2016, we initiated an open-label Phase II single arm trial for PNH patients with eculizumab resistance due to C5 polymorphisms, pursuant to a clinical trial protocol approved by the European Union national regulatory authority. Patients are to be treated with Coversin by daily subcutaneous injection for 6 months in order to determine the safety and efficacy of the drug in these circumstances. If satisfactory control of the PNH is achieved, patients will have the option of remaining on Coversin and being entered into the long term follow-up study. The primary objective of the eculizumab-resistance program is to provide patients who have clinically demonstrated resistance to eculizumab with early access to Coversin as a potentially lifesaving alternative. Patients are entered into an open label protocol where safety and efficacy parameters are evaluated on an ongoing basis including measures of complement activity such as CH50 and biomarkers of hemolysis activity such as LDH. Initial results from a patient with PNH who is resistant to eculizimab due to a C5 polymorphism have demonstrated complete complement inhibition (Elisa CH50 < 8 Eq/ml, lower limit of quantification) and marked LDH reduction to below 1.5 ULN (upper limit of normal), which have continued through more than 12 months of therapy to date. This patient has been self-administering Coversin™. We expect to present topline results from these patients as they become available.

In December, 2016, we announced that the U.S. Food and Drug Administration (FDA) has allowed our Investigational New Drug Application (IND) for the clinical development of Coversin in patients with PNH. The FDA's allowance of the IND permits us to expand its clinical program for the development of Coversin in PNH to the United States. We plan to open the ongoing Phase II trial of Coversin in eculizumab resistant PNH in the United States in the second quarter of 2017.

In the fourth quarter of 2016, we commenced a 90 day open-label Phase II single arm trial in patients with PNH in 5 centers in the European Union. This trial is designed to test the safety and efficacy of Coversin in patients with PNH who have not received any other complement blocking therapies. The primary endpoint is measuring the change of LDH from baseline at 28 days and secondary endpoints include hemoglobin, CH50, quality of life and safety. Five patients have been recruited to the trial and we expect to present interim data in April, 2017. Patients who complete the trial will have the option to continue self-administration with Coversin in an open-label long term safety study. Assuming results from this trial confirm the safety and efficacy of Coversin in PNH, we plan to begin our Phase III program before the end of 2017.

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 we believe will provide considerable benefits in terms of patient convenience. Patient surveys contracted by us suggest that a significant proportion 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.

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 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. No neutralizing antibodies have been detected to date, including in the healthy volunteers in the Phase Ia and Ib trials and the ongoing PNH patient treated for over one year in the eculizumab resistance trial.

PAS-Coversin

Using PASylation®, a proprietary process of XL-protein GmbH, XL-protein has modified Coversin by adding a 600 amino acid proline/alanine/serine (PAS) N-terminal fusion tag to generate PAS-Coversin (68kDa). The unstructured and uncharged PAS polypeptide increases the apparent molecular size to approximately 720kDa, slowing kidney clearance and extending the half-life.

Data from mouse and rat studies of PAS-Coversin demonstrated that the expected terminal half-life in humans should be approximately 4 days. Based on these data, Pk modeling supports that a once weekly dosing regimen is feasible. We are currently moving to GMP manufacturing and maximizing yield. We expect first in man trials to begin in the first half of 2018.

Target Indications

Paroxysmal nocturnal haemoglobinuria (PNH)

PNH is an ultra-rare, life-threatening and debilitating disease of the blood with an estimated 8,000 – 10,000 patients globally. 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.

Soliris®, (eculizumab) is the only FDA approved drug for the treatment of PNH. 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 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 been treating a patient with PNH and eculizumab resistance due to a C5 polymorphism for over 12 months.

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 approximately 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 mechanism of action, it is anticipated that Coversin will be effective in treating aHUS patients.

We plan to commence a single arm open-label Phase II trial in the second half of 2017.

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.

We believe 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 pursuing pre-clinical studies to support potential clinical development.

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, GBS, Myasthenia Gravis, 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 \$2.8 billion in sales in 2016.

Competition in Complement Mediated Diseases

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 our ability to leverage our collective experience in drug discovery, development and commercialization to:

- discover and develop drugs that are differentiated from other products in the market, including eculizumab;
- obtain patent and/or proprietary protection for our product candidates and technologies;
- obtain required regulatory approvals;
- obtain a commercial partner;
- commercialize our product candidates, 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 Soliris®, (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 \$2.8 billion in 2016. Clinicians, nurses and patient groups contacted by us 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 product candidates. If our lead 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. We will adopt a similar strategy for the other compounds in our pipeline.

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 have successfully completed a commercial scale process batch in 2016. We are manufacturing multiple lots of Coversin in 2017.

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 product candidates that we may develop for larger scale preclinical and clinical testing, as well as for commercial quantities of any product 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, including auto-injecting pens.

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

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 five United States patents, 74 national patents in Europe derived from five patents granted by the European Patent Office and 18 foreign issued patents in other jurisdictions, and six United States and 22 foreign or international 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 has granted patents in the jurisdictions of United States, Canada, major European countries, Japan, China, Australia and New Zealand and pending applications in the jurisdictions of United States, Canada, Europe, Japan, China, Brazil, Israel, India, Republic of Korea, Mexico, Russia, Australia and New Zealand.

Issued United States patents which cover our product candidate Coversin and its uses will expire between 2024 and 2031, 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 also 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 2037, 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 including complement inhibitor molecule; methods for treating myasthenia gravis; methods for treating peripheral nerve disorders; methods for treating respiratory disorders; methods for treating viral infections of the respiratory tract; and methods of treating complement-mediated diseases in patients with C5 polymorphisms.

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 we are developing. A new drug must be approved by the FDA, generally 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 applicable 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 trials, 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, responsible for the research conducted 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 may be 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 initially 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 are 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 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. 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.

NDAs or BLAs may receive either standard or priority review. Under current FDA review goals, standard review of an NDA for a new molecular entity (NME) or original BLA will be 10 months from the date that the NDA or BLA is filed. A drug representing a significant improvement in treatment, prevention or diagnosis of disease may receive a priority review of six months. 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 additional studies after approval, potentially including additional adequate and well-controlled 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 with 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 pediatric studies can begin. After April 2013, the FDA must send a non-compliance letter to any sponsor that fails to submit a required pediatric assessment within specified deadlines or fails to submit a timely request for approval of a pediatric formulation, if required.

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 partial compensation for effective patent term lost due to time spent 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 may be extended, 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, under certain circumstances, 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.

From time to time, FDA has issued a number of final and draft guidances in order to implement various aspects of the law, including the testing, review and approval requirements for new drugs and biological products. These guidance documents provide FDA's current thinking and recommendations on approaches to the development, testing, review and approval of proposed new drugs and biological products, including demonstrating that a proposed biological product is biosimilar to a reference product. The FDA is expected to continue issuing guidance documents in the future. Nevertheless, the absence of final guidance documents does not prevent a sponsor for seeking approval of new drug products, including licensure of biosimilar biological products under the BPCIA.

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 itself 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, for the same designated orphan indication 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.

Most of Coversin's target disease indications are rare diseases, and therefore we plan to pursue orphan drug designation where possible. Eculizumab has been granted orphan status for some of the same disease indications that we propose to treat with Coversin and in 2016 Coversin was granted orphan drug designation for PNH and GBS by the FDA and EMA. However, Coversin is not considered structurally similar to eculizumab, and so we believe these preceding orphan designations should not pose a barrier to approval or market entry for Coversin. There is also a possibility for us to obtain additional orphan designation(s) for Coversin for indications beyond those already covered by designations granted to eculizumab, based on the substantial medical benefits that Coversin may offer in terms of its efficacy in certain clinical populations and dosage forms.

Fast Track Designation and Accelerated Approval

The FDA is required to facilitate the development, and expedite the review, of drugs that it finds 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. On March 29, 2017, we received notice from the FDA of fast track designation for the investigation of Coversin for treatment of PNH in patients who have polymorphisms conferring eculizumab resistance. Under the fast track program, the sponsor of a new product candidate may request that the FDA designate the product candidate for a specific indication as a fast track drug concurrent with, or after, the filing of the IND for the product candidate. The FDA must determine if the product 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 other clinical endpoints. A product candidate approved on this basis is generally 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 product 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 NDA or 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 application 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 are identified 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 that may be disseminated about 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 development, 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.

Regulation and Marketing Authorization in the European Union

The process governing approval of medicinal products in the European Union follows essentially the same lines as in the United States and, likewise, generally involves satisfactorily completing each of the following:

- preclinical laboratory tests, animal studies and formulation studies all performed in accordance with the applicable E.U. Good Laboratory Practice regulations;
- submission to the relevant national authorities of a clinical trial application, or CTA, which must be approved before human clinical trials may begin;
- performance of adequate and well-controlled clinical trials to establish the safety and efficacy of the product for each proposed indication;
- submission to the relevant competent authorities of a marketing authorization application, or MAA, which includes the data supporting safety and efficacy as well as detailed information on the manufacture and composition of the product in clinical development and proposed labelling;
- satisfactory completion of an inspection by the relevant national authorities of the manufacturing facility or facilities, including those of third parties, at which the product is produced to assess compliance with strictly enforced current cGMP;
- potential audits of the non-clinical and clinical trial sites that generated the data in support of the MAA; and
- review and approval by the relevant competent authority of the MAA before any commercial marketing, sale or shipment of the product.

Preclinical Studies

Preclinical tests include laboratory evaluations of product chemistry, formulation and stability, as well as studies to evaluate toxicity in animal studies, in order to assess the potential safety and efficacy of the product. The conduct of the preclinical tests and formulation of the compounds for testing must comply with the relevant E.U. regulations and requirements. The results of the preclinical tests, together with relevant manufacturing information and analytical data, are submitted as part of the CTA.

Clinical Trial Approval

Requirements for the conduct of clinical trials in the European Union including Good Clinical Practice, or GCP, are implemented in the Clinical Trials Directive 2001/20/EC and the GCP Directive 2005/28/EC. Pursuant to Directive 2001/20/EC and Directive 2005/28/EC, as amended, a system for the approval of clinical trials in the European Union has been implemented through national legislation of the member states. Under this system, approval must be obtained from the competent national authority of an E.U. member state in which a study is planned to be conducted, or in multiple member states if the clinical trial is to be conducted in a number of member states. To this end, a CTA is submitted, which must be supported by an investigational medicinal product dossier, or IMPD, and further supporting information prescribed by Directive 2001/20/EC and Directive 2005/28/EC and other applicable guidance documents. Furthermore, a clinical trial may only be started after a competent ethics committee has issued a favorable opinion on the clinical trial application in that country.

In April 2014, a new Clinical Trials Regulation, (EU) No 536/2014 was adopted which will replace the current Clinical Trials Directive 2001/20/EC. To ensure that the rules for clinical trials are identical throughout the European Union, the new E.U. clinical trials legislation was passed as a “regulation” that is directly applicable in all E.U. member states. All clinical trials performed in the European Union are required to be conducted in accordance with the Clinical Trials Directive 2001/20/EC until the new Clinical Trials Regulation (EU) No 536/2014 becomes applicable, which is scheduled to be in 2018.

The new Regulation (EU) No 536/2014 aims to harmonize, simplify and streamline the approval of clinical trials in the European Union. The main characteristics of the Regulation include:

- A streamlined application procedure via a single entry point, the E.U. portal.
- A single set of documents to be prepared and submitted for the application as well as simplified reporting procedures that will spare sponsors from submitting broadly identical information separately to various bodies and different member states.
- A harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts. Part I is assessed jointly by all member states concerned. Part II is assessed separately by each member state concerned.
- Strictly defined deadlines for the assessment of clinical trial application.
- The involvement of the ethics committees in the assessment procedure in accordance with the national law of the member state concerned but within the overall timelines defined by the Regulation (EU) No 536/2014.

Marketing Authorization

Authorization to market a product in the member states of the European Union proceeds under one of four procedures: a centralized authorization procedure, a mutual recognition procedure, a decentralized procedure or a national procedure.

Centralized Authorization Procedure

The centralized procedure enables applicants to obtain a marketing authorization that is valid in all E.U. member states based on a single application. Certain medicinal products, including products developed by means of biotechnological processes, must undergo the centralized authorization procedure for marketing authorization, which, if granted by the European Commission, is automatically valid in all 28 E.U. member states. The EMA and the European Commission administer this centralized authorization procedure pursuant to Regulation (EC) No 726/2004.

Pursuant to Regulation (EC) No 726/2004, this procedure is mandatory for:

- medicinal products developed by means of one of the following biotechnological processes:
 - recombinant DNA technology;
 - controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes including transformed mammalian cells; and
 - hybridoma and monoclonal antibody methods;
- advanced therapy medicinal products as defined in Article 2 of Regulation (EC) No. 1394/2007 on advanced therapy medicinal products;
- medicinal products for human use containing a new active substance that, on the date of effectiveness of this regulation, was not authorized in the European Union, and for which the therapeutic indication is the treatment of any of the following diseases:
 - acquired immune deficiency syndrome;
 - cancer;
 - neurodegenerative disorder;
 - diabetes;
 - auto-immune diseases and other immune dysfunctions; and
 - viral diseases; and
- medicinal products that are designated as orphan medicinal products pursuant to Regulation (EC) No 141/2000.

The centralized authorization procedure is optional for other medicinal products if they contain a new active substance or if the applicant shows that the medicinal product concerned constitutes a significant therapeutic, scientific or technical innovation or that the granting of authorization is in the interest of patients in the European Union.

Administrative Procedure

Under the centralized authorization procedure, the EMA's Committee for Human Medicinal Products, or CHMP, serves as the scientific committee that renders opinions about the safety, efficacy and quality of medicinal products for human use on behalf of the EMA. The CHMP is composed of experts nominated by each member state's national authority for medicinal products, with expert appointed to act as Rapporteur for the co-ordination of the evaluation with the possible assistance of a further member of the Committee acting as a Co-Rapporteur. After approval, the Rapporteur(s) continue to monitor the product throughout its life cycle. The CHMP has 210 days to adopt an opinion as to whether a marketing authorization should be granted. The process usually takes longer in case additional information is requested, which triggers clock-stops in the procedural timelines. The process is complex and involves extensive consultation with the regulatory authorities of member states and a number of experts. When an application is submitted for a marketing authorization in respect of a drug that is of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation, the applicant may pursuant to Article 14(9) Regulation (EC) No 726/2004 request an accelerated assessment procedure. If the CHMP accepts such request, the time-limit of 210 days will be reduced to 150 days but it is possible that the CHMP can revert to the standard time-limit for the centralized procedure if it considers that it is no longer appropriate to conduct an accelerated assessment. Once the procedure is completed, a European Public Assessment Report, or EPAR, is produced. If the opinion is negative, information is given as to the grounds on which this conclusion was reached. After the adoption of the CHMP opinion, a decision on the MAA must be adopted by the European Commission, after consulting the E.U. member states, which in total can take more than 60 days.

Conditional Approval

In specific circumstances, E.U. legislation (Article 14(7) Regulation (EC) No 726/2004 and Regulation (EC) No 507/2006 on Conditional Marketing Authorisations for Medicinal Products for Human Use) enables applicants to obtain a conditional marketing authorization prior to obtaining the comprehensive clinical data required for an application for a full marketing authorization. Such conditional approvals may be granted for product candidates (including medicines designated as orphan medicinal products) if (1) the risk-benefit balance of the product candidate is positive, (2) it is likely that the applicant will be in a position to provide the required comprehensive clinical trial data, (3) the product fulfills unmet medical needs and (4) the benefit to public health of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data are still required. A conditional marketing authorization may contain specific obligations to be fulfilled by the marketing authorization holder, including obligations with respect to the completion of ongoing or new studies, and with respect to the collection of pharmacovigilance data. Conditional marketing authorizations are valid for one year, and may be renewed annually, if the risk-benefit balance remains positive, and after an assessment of the need for additional or modified conditions and/or specific obligations. The timelines for the centralized procedure described above also apply with respect to the review by the CHMP of applications for a conditional marketing authorization.

Marketing Authorization under Exceptional Circumstances

Under Article 14(8) Regulation (EC) No 726/2004, products for which the applicant can demonstrate that comprehensive data (in line with the requirements laid down in Annex I of Directive 2001/83/EC, as amended) cannot be provided (due to specific reasons foreseen in the legislation) might be eligible for marketing authorization under exceptional circumstances. This type of authorization is reviewed annually to reassess the risk-benefit balance. The fulfillment of any specific procedures/obligations imposed as part of the marketing authorization under exceptional circumstances is aimed at the provision of information on the safe and effective use of the product and will normally not lead to the completion of a full dossier/approval.

Market Authorizations Granted by Authorities of E.U. Member States

In general, if the centralized procedure is not followed, there are three alternative procedures as prescribed in Directive 2001/83/EC:

- The decentralized procedure allows applicants to file identical applications to several E.U. member states and receive simultaneous national approvals based on the recognition by E.U. member states of an assessment by a reference member state.
- The national procedure is only available for products intended to be authorized in a single E.U. member state.
- A mutual recognition procedure similar to the decentralized procedure is available when a marketing authorization has already been obtained in at least one E.U. member state.

A marketing authorization may be granted only to an applicant established in the European Union.

Pediatric Studies

Prior to obtaining a marketing authorization in the European Union, applicants have to demonstrate compliance with all measures included in an EMA-approved Paediatric Investigation Plan, or PIP, covering all subsets of the paediatric population, unless the EMA has granted a product-specific waiver, a class waiver, or a deferral for one or more of the measures included in the PIP. The respective requirements for all marketing authorization procedures are set forth in Regulation (EC) No 1901/2006, which is referred to as the Pediatric Regulation. This requirement also applies when a company wants to add a new indication, pharmaceutical form or route of administration for a medicine that is already authorized. The Pediatric Committee of the EMA, or PDCO, may grant deferrals for some medicines, allowing a company to delay development of the medicine in children until there is enough information to demonstrate its effectiveness and safety in adults. The PDCO may also grant waivers when development of a medicine in children is not needed or is not appropriate, such as for diseases that only affect the elderly population.

Before a marketing authorization application can be filed, or an existing marketing authorization can be amended, the EMA determines that companies actually comply with the agreed studies and measures listed in each relevant PIP.

Periods of Authorization and Renewals

A marketing authorization is valid for five years in principle and the marketing authorization may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the competent authority of the authorizing member state. To this end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least six months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization is valid for an unlimited period, unless the European Commission or the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal. Any authorization which is not followed by the actual placing of the drug on the E.U. market (in case of centralized procedure) or on the market of the authorizing member state within three years after authorization ceases to be valid (the so-called sunset clause).

Orphan Drug Designation and Exclusivity

The European Commission, following an evaluation by the EMA's Committee for Orphan Medicinal Products designated CoversinTM, as an orphan medicinal product for PNH and GBS. Pursuant to Regulation (EC) No 141/2000 and Regulation (EC) No. 847/2000, the European Commission can grant such orphan medicinal product designation to products for which the sponsor can establish that it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 people in the European Union, or a life threatening, seriously debilitating or serious and chronic condition in the European Union and that without incentives it is unlikely that sales of the drug in the European Union would generate a sufficient return to justify the necessary investment. In addition, the sponsor must establish that there is no other satisfactory method approved in the European Union of diagnosing, preventing or treating the condition, or if such a method exists, the proposed orphan drug will be of significant benefit to patients.

Orphan drug designation is not a marketing authorization. It is a designation that provides a number of benefits, including fee reductions, regulatory assistance, and the possibility to apply for a centralized E.U. marketing authorization, as well as ten years of market exclusivity following a marketing authorization. During this market exclusivity period, neither the EMA, the European Commission nor the member states can accept an application or grant a marketing authorization for a "similar medicinal product." A "similar medicinal product" is defined as a medicinal product containing a similar active substance or substances as those contained in an authorized orphan medicinal product and that is intended for the same therapeutic indication. The market exclusivity period for the authorized therapeutic indication may be reduced to six years if, at the end of the fifth year, it is established that the orphan designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity. In addition, a competing similar medicinal product may in limited circumstances be authorized prior to the expiration of the market exclusivity period, including if it is shown to be safer, more effective or otherwise clinically superior to the already approved orphan drug. Furthermore, a product can lose orphan designation, and the related benefits, prior to us obtaining a marketing authorization if it is demonstrated that the orphan designation criteria are no longer met.

Regulatory Data Protection

E.U. legislation also provides for a system of regulatory data and market exclusivity. According to Article 14(11) of Regulation (EC) No 726/2004, as amended, and Article 10(1) of Directive 2001/83/EC, as amended, upon receiving marketing authorization, new chemical entities approved on the basis of complete independent data package benefit from eight years of data exclusivity and an additional two years of market exclusivity. Data exclusivity prevents regulatory authorities in the European Union from referencing the innovator's data to assess a generic (abbreviated) application. During the additional two-year period of market exclusivity, a generic marketing authorization can be submitted, and the innovator's data may be referenced, but no generic medicinal product can be marketed until the expiration of the market exclusivity. The overall ten-year period will be extended to a maximum of 11 years if, during the first eight years of those ten years, the marketing authorization holder, or MAH, obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. Even if a compound is considered to be a new chemical entity and the innovator is able to gain the period of data exclusivity, another company nevertheless could also market another version of the drug if such company obtained marketing authorization based on an MAA with a complete independent data package of pharmaceutical test, preclinical tests and clinical trials. However, products designated as orphan medicinal products enjoy, upon receiving marketing authorization, a period of ten years of orphan market exclusivity—see also *Orphan Drug Designation and Exclusivity*. Depending upon the timing and duration of the E.U. marketing authorization process, products may be eligible for up to five years' supplementary protection certificates, or SPCs, pursuant to Regulation (EC) No 469/2009. Such SPCs extend the rights under the basic patent for the drug.

Regulatory Requirements After a Marketing Authorization has been Obtained

If we obtain authorization for a medicinal product in the European Union, we will be required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products:

Pharmacovigilance and other requirements

We will, for example, have to comply with the E.U.'s stringent pharmacovigilance or safety reporting rules, pursuant to which post-authorization studies and additional monitoring obligations can be imposed. Other requirements relate, for example, to the manufacturing of products and APIs in accordance with good manufacturing practice standards. E.U. regulators may conduct inspections to verify our compliance with applicable requirements, and we will have to continue to expend time, money and effort to remain compliant. Non-compliance with E.U. requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, can also result in significant financial penalties in the European Union. Similarly, failure to comply with the E.U.'s requirements regarding the protection of individual personal data can also lead to significant penalties and sanctions. Individual E.U. member states may also impose various sanctions and penalties in case we do not comply with locally applicable requirements.

Manufacturing

The manufacturing of authorized drugs, for which a separate manufacturer's license is mandatory, must be conducted in strict compliance with the EMA's Good Manufacturing Practices, or GMP, requirements and comparable requirements of other regulatory bodies in the European Union, which mandate the methods, facilities and controls used in manufacturing, processing and packing of drugs to assure their safety and identity. The EMA enforces its current GMP requirements through mandatory registration of facilities and inspections of those facilities. The EMA may have a coordinating role for these inspections while the responsibility for carrying them out rests with the member states competent authority under whose responsibility the manufacturer falls. Failure to comply with these requirements could interrupt supply and result in delays, unanticipated costs and lost revenues, and could subject the applicant to potential legal or regulatory action, including but not limited to warning letters, suspension of manufacturing, seizure of product, injunctive action or possible civil and criminal penalties.

Marketing and Promotion

The marketing and promotion of authorized drugs, including industry-sponsored continuing medical education and advertising directed toward the prescribers of drugs and/or the general public, are strictly regulated in the European Union under Directive 2001/83/EC. The applicable regulations aim to ensure that information provided by holders of marketing authorizations regarding their products is truthful, balanced and accurately reflects the safety and efficacy claims authorized by the EMA or by the competent authority of the authorizing member state. Failure to comply with these requirements can result in adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties.

Patent Term Extension

In order to compensate the patentee for delays in obtaining a marketing authorization for a patented product, a supplementary certificate, or SPC, may be granted extending the exclusivity period for that specific product by up to five years. Applications for SPCs must be made to the relevant patent office in each E.U. member state and the granted certificates are valid only in the member state of grant. An application has to be made by the patent owner within six months of the first marketing authorization being granted in the European Union (assuming the patent in question has not expired, lapsed or been revoked) or within six months of the grant of the patent (if the marketing authorization is granted first). In the context of SPCs, the term "product" means the active ingredient or combination of active ingredients for a medicinal product and the term "patent" means a patent protecting such a product or a new manufacturing process or application for it. The duration of an SPC is calculated as the difference between the patent's filing date and the date of the first marketing authorization, minus five years, subject to a maximum term of five years.

A six month pediatric extension of an SPC may be obtained where the patentee has carried out an agreed pediatric investigation plan, the authorized product information includes information on the results of the studies and the product is authorized in all member states of the European Union.

Foreign Regulation

In addition to regulations in the United States and European Union, 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 or EMA approval for a product, we must obtain approval by the comparable regulatory authorities of foreign countries 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 or EMA approval.

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 product 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.

Legal Proceedings

We are not involved in any material legal proceedings.

Employees

As of December 31, 2016, we had fifteen full-time employees and two full-time equivalent consultants.

C. Organizational Structure

Our corporate structure consists of Akari Therapeutics PLC and three subsidiaries, one of which is an indirect subsidiary. The following is a list of our subsidiaries:

<u>Name of Subsidiary</u>	<u>Jurisdiction</u>	<u>Activity</u>	<u>% Holding</u>
Volution Immuno Pharmaceuticals SA	Switzerland	Research & Development	100%
Celsus Therapeutics Inc.	Delaware, USA	Inactive	100%
Morria Biopharma Ltd	Israel	Inactive	100%

D. Property, Plant and Equipment

We do not currently own any property. We currently lease 4,900 square feet of office space in New York, New York, for approximately \$25,000 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 \$11,000 per month. The lease for this property expires in March 2019.

Item 4A. UNRESOLVED STAFF COMMENTS

None.

Item 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

A. Operating Results

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our combined and consolidated financial statements and related notes appearing elsewhere in this Annual Report on Form 20-F. 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 3D "Risk Factors" in this Annual Report on Form 20-F.

Overview

We are a clinical-stage biopharmaceutical company focused on developing inhibitors of acute and chronic inflammation, specifically the complement system, the eicosanoid system and the bioamine system for the treatment of rare and orphan diseases. Each of these systems has scientifically well-supported causative roles in the diseases we are targeting. We believe that blocking early mediators of inflammation will prevent initiation and continual amplification of the processes that cause certain diseases.

All of our molecules are derived from ticks which have undergone 300 million years of natural selection to produce inhibitors that bind tightly to key highly-conserved inflammatory mediators, are generally well tolerated in humans, and remain fully functional when a host is repeatedly exposed to the molecule.

Our lead product candidate, Coversin™, which is a second-generation 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), and independently also inhibits LTB4 activity, both elements that are co-located as part of the immune/inflammatory response. Coversin is a recombinant small protein (16,740 Da) derived from a protein originally 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 pioneered by Alexion Pharmaceuticals (Nasdaq: ALXN) following approval by the U.S. Food and Drug Administration, or FDA, approval in 2007 of their drug Soliris® (eculizumab) to treat PNH. Soliris® is currently the only drug approved to treat two complement-related orphan indications, paroxysmal nocturnal haemoglobinuria, or PNH, and atypical Hemolytic Uremic Syndrome, or aHUS, and had annual sales of \$2.8 billion in 2016. Eculizumab is a humanized monoclonal antibody, administered by twice monthly intravenous infusion (IV).

Our initial clinical targets for Coversin are PNH, aHUS, and Guillain Barré syndrome, or GBS. We are also targeting patients with polymorphisms of the C5 molecule which interfere with correct binding of eculizumab, making these patients resistant to treatment with that drug. In addition to disease targets where complement dysregulation is the key driver, we are also targeting a range of inflammatory diseases where the inhibition of both C5 and LTB4 are implicated.

Other compounds in our pipeline include engineered versions of Coversin that potentially decrease the frequency of administration, improve potency, or allow for specific tissue targeting, as well as new proteins targeting LBT4 alone, as well as bioamine inhibitors (for example, anti-histamines). In general, these inhibitors act as ligand binding compounds, which may provide additional benefit versus other modes of inhibition. For example, off target effects are less likely with ligand capture. One example of this benefit is seen with LTB4 inhibition through ligand capture. LTB4 acts to amplify the inflammatory signal by bringing and activating white blood cells to the area of inflammation. Compounds that have targeted the production of leukotrienes will inhibit both the production of pro-inflammatory as well as anti-inflammatory leukotrienes—often diminishing the potential benefit of the drug on the inflammatory system. Coversin has demonstrated that, by capturing LTB4, it is limited to disrupting the white blood cell activation and attraction aspects, without interfering with the anti-inflammatory benefits of other leukotrienes.

To date, we have demonstrated: (i) full complement inhibition and marked lactate dehydrogenase reduction in a PNH patient with eculizumab resistance and who has now been self-administering Coversin daily for over one year pursuant to an approved clinical protocol in the Netherlands; (ii) 100% inhibition of complement C5 activity by Coversin with once daily subcutaneous injections during our Phase Ib clinical trial in healthy volunteers; (iii) that Coversin inhibits PNH red blood cell lysis *in vitro*; 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 both our Phase Ib healthy volunteer study and our 28-day safety study in non-human primates.

In the fourth quarter of 2016, we commenced enrollment for a 90 day open-label Phase II, single arm trial in patients with PNH in 5 centers in the European Union. To date, five patients have been enrolled. This trial is designed to test the safety and efficacy of Coversin in patients with PNH who have not received any other complement blocking therapies. Patients who complete the trial will have the option to continue self-administration with Coversin in an open-label long term safety study. We expect to provide interim results from the Phase II trial in April, 2017. Assuming results from this trial confirm the safety and efficacy of Coversin in PNH, we expect to begin our Phase III program before the end of 2017.

Coversin has received orphan drug status from the FDA and EMA for PNH and GBS. Orphan drug designation provides the sponsor certain benefits and incentives, including a period of marketing exclusivity if regulatory approval of the drug is ultimately received for the designated indication. The receipt of orphan drug designation status does not change the regulatory requirements or process for obtaining marketing approval and designation does not mean that marketing approval will be received. We intend to apply in the future for further orphan drug designation in indications we deem appropriate.

On March 29, 2017, we received notice from the FDA of fast track designation for the investigation of Coversin for treatment of PNH in patients who have polymorphisms conferring eculizumab resistance. The fast track program was created by the FDA to facilitate the development and expedite the review of new drugs which show promise in treating a serious or life-threatening disease and address an unmet medical need. Drugs that receive this designation benefit from more frequent communications and meetings with FDA to review the drug's development plan including the design of the proposed clinical trials, use of biomarkers and the extent of data needed for approval. Drugs with fast track designation may qualify for priority review to expedite the FDA review process, if relevant criteria are met.

Coversin 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 we believe will provide considerable benefits in terms of patient convenience. We believe that the subcutaneous formulation of Coversin may accelerate recruitment for our clinical trials, and, as an alternative to intravenous infusion, may accelerate patient uptake if Coversin is approved by regulatory authorities for commercial sale. Patient surveys contracted by us suggest that a majority of patients would prefer to self-inject daily than undergo intravenous infusions.

On September 18, 2015, we completed our acquisition, or the Acquisition, of all of the capital stock of Volution Immuno Pharmaceuticals SA, or Volution, from RPC Pharma Limited, or RPC, Volution's sole shareholder, in exchange for ordinary shares, par value £0.01, or Ordinary Shares, 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 American Depositary Shares, or 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).

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 (as 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 (loss) per share have been retrospectively adjusted in the Combined and Consolidated 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, or the "Financing", at a price of \$18.945 per restricted ADS, which represented approximately 33.3% of our outstanding Ordinary Shares after giving effect to the Acquisition and the Financing. We incurred \$5.4 million of share issuance costs for net proceeds of \$69.6 million.

Critical Accounting Policies and Use of Estimates

The preparation of the combined and consolidated financial statements in conformity with United States generally accepted accounting principles, or U.S. GAAP, 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.

Share-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 Combined and 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 Combined and Consolidated Statements of Comprehensive Income (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 share price volatility, which we calculate based on the historical volatility of peer companies. 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 share 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 stock-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 Ordinary Shares 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 changes in fair value of options and warrants liabilities.

Warrants and RPC Options

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 Combined and Consolidate Statement of Comprehensive Loss as changes in fair value of option/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 share price volatility of our Ordinary Shares. 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. At December 31, 2016, the fair value of the warrants was \$34,838. The change in fair value of the warrants for the year ended December 31, 2016, was a decrease of \$650,303 and was recognized as a change in fair value of option and warrant liabilities in the Combined and Consolidated Statement of Comprehensive Loss.

In connection with a short-term working capital loan from shareholders of approximately \$3 million, the shareholders were granted options in RPC, equivalent to 15% of the current outstanding equity issued by RPC. The RPC options were accounted for in accordance with ASC 718, “*Compensation-Stock Compensation*”. The fair value of the RPC options is estimated using the fair value of Akari Ordinary Shares times RPC’s ownership in Akari Ordinary Shares times 15% and was initially valued at approximately \$26 million. These options do not relate to the share capital of Akari. The exact terms of these options have not been finalized. During the year ended December 31, 2015, 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 the statement of comprehensive loss as a credit to the loan discount. At December 31, 2015, the fair value of the options was \$15,711,017. At December 31, 2016, the fair value of the options was \$7,627,790. The change in fair value of the options in the year ended December 31, 2016, was a decrease of \$8,083,047 and was recognized as a change in fair value of option and warrant liabilities in the Combined and Consolidated Statement of Comprehensive Loss.

At December 31, 2016, the fair value of the options and warrants was \$7,662,808.

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 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 (loss) income. Gains or losses from foreign currency transactions and the remeasurement of intercompany balances are included in foreign currency exchange gains/(losses).

Results of Operations

For the Years Ended December 31, 2016 and December 31, 2015

Research and development expenses

Research and development expenses for the year ended December 31, 2016 were approximately \$17,306,000 compared to approximately \$5,800,000 for the year ended December 31, 2015. This 198% or \$11,506,000 increase was due to higher expenses of approximately \$8,175,000 for manufacturing, \$1,859,000 for clinical trial expenses, \$914,000 for consulting expense, \$576,000 for personnel expenses, \$221,000 for regulatory expenses, \$119,000 for toxicology studies and \$119,000 for stock-based non-cash compensation expense offset by a research and development tax credit of \$578,000.

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, 2016 were approximately \$9,941,000 compared to approximately \$5,502,000 for the year ended December 31, 2015. This 81% or \$4,439,000 increase was primarily due to higher expenses of approximately \$2,851,000 for stock-based non-cash compensation expense, \$1,480,000 of personnel expenses, \$564,000 of board expenses and \$356,000 of rent expenses, offset by \$750,000 of compensation expense in 2015.

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 approximately \$19,283,000 was calculated as the difference between the fair value of the consideration 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 Combined and Consolidated Statements of Comprehensive Loss in the year ended December 31, 2015 due to the fact that Goodwill could not be justified and was considered fully impaired.

Other Income (expenses)

Other income for the year ended December 31, 2016 was approximately \$9,106,000 compared to other expense of \$14,733,000 for the year ended December 31, 2015. This change was primarily attributed to approximately \$22,974,000 of financing expense related to recording of the stock option liability, \$3,054,000 of interest expense in 2015 and \$2,675,000 of higher income related to the change in the fair value of the stock option and warrant liabilities in 2015 than in 2016.

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 approximately \$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 approximately \$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 approximately \$19,283,000 was calculated as the difference between the fair value of the consideration 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 Combined and Consolidated Statements of Comprehensive Loss in the year ended December 31, 2015 due to the fact that Goodwill could not be justified and was considered fully impaired.

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.

B. Liquidity and Capital Resources

At December 31, 2016, we had \$44,120,775 in cash and cash equivalents and short-term investments. In addition, as of December 31, 2016, we had accumulated losses in the total amount of \$74,937,610. Since inception, we have funded our operations primarily through the sale of equity securities and debt financing. 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. In connection with the private placement, we incurred \$5.4 million of share issuance costs for net proceeds of \$69.6 million.

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 shareholders' equity and working capital. We believe our current cash and cash equivalents and short-term investments are sufficient to fund future operations for at least the next twelve months. 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 3D under the heading "Risk Factors" of our Annual Report on Form 20-F for the year ended December 31, 2016.

We are constantly addressing our liquidity and intend to 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 will require additional capital in order to complete the clinical development of and to commercialize our product candidates and our pre-clinical product candidates.

Net cash used in operating activities was \$24,625,000 during the year ended December 31, 2016 compared to \$4,966,000 during the year ended December 31, 2015. Net cash flow used in operating activities was primarily attributed to our ongoing research activities to support Coversin, including manufacturing, clinical trial and preclinical activities.

Net cash used in investing activities was \$10,067,000 during the year ended December 31, 2016. This is cash used to purchase office equipment and short-term investments offset by maturities of short-term securities compared to \$1,392,000 provided by investing activities during the year ended December 31, 2015 primarily related to cash acquired from acquisition.

Net cash provided by financing activities was \$69,044,000 during the year ended December 31, 2015. This is primarily from net proceeds from issuance of shares and shareholder loans offset by the repayment of shareholder loans. In the year ended December 31, 2016, we had no financing activity.

C. Research and Development, Patents and Licenses

Our research and development expenditures were approximately \$17,306,000, \$5,799,000 and \$1,616,000 for the years ended December 31, 2016, 2015 and 2014, respectively. Most of such research and development expenditures were in the form of payments to third parties to carry out our manufacturing, pre-clinical and clinical research activities.

We incurred the following research and development expenses for the years ended December 31, 2016, 2015 and 2014:

	Years ended December 31, (in \$000's)		
	2016	2015	2014
Direct Expenses:			
Coversin	\$ 12,087	\$ 2,437	\$ 547
Clinical trials	1,982	41	11
Other	2,161	1,087	329
Total direct expenses	16,230	3,565	887
Indirect Expenses:			
Staffing	1,062	621	232
Other indirect	14	1,613	497
Total indirect expenses	1,076	2,234	729
Total Research and Development	\$ 17,306	\$ 5,799	\$ 1,616

D. Trend Information

We are a development stage company and it is not possible for us to predict with any degree of accuracy the outcome of our research, development or commercialization efforts. As such, it is not possible for us to predict with any degree of accuracy any significant trends, uncertainties, demands, commitments or events that are reasonably likely to have a material effect on our net sales or revenues, income from continuing operations, profitability, liquidity or capital resources, or that would cause financial information to not necessarily be indicative of future operating results or financial condition. However, to the extent possible, certain trends, uncertainties, demands, commitments and events are identified in the preceding subsections of this Item 5.

E. Off-balance Sheet Arrangements

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

F. Contractual Obligations

The following table summarizes our significant contractual obligations as of December 31, 2016:

<i>Contractual Obligations</i>	Total	Less than 1 year	1 – 3 years	3-5 years	More than 5 years
Lease of office space (1)(2)	\$ 1,152,087	\$ 441,719	\$ 710,368	\$ -	\$ -
Total	\$ 1,152,087	\$ 441,719	\$ 710,368	\$ -	\$ -

- (1) In March 2014, we entered into a lease agreement for offices in London which was amended January 1, 2016. The amended lease term commenced on December 1, 2014 and expires in March 2019. We have minimum rental payments of approximately \$11,000 plus VAT for each month for our UK offices. The lease can be cancelled early by either party upon 3 months' notice.
- (2) We also have a five-year lease for offices in the United States effective July 2014. Minimum rental payments range from approximately \$25,000 per month to approximately \$29,000 per month. The lease expires in August 2019.

Item 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

A. Directors and Senior Management

The following table presents the names of the current members of our board of directors and executive officers.

Name	Age	Position
James Hill, M.D.	71	Class A Director
Stuart Ungar, M.D.	73	Class A Director
David Byrne	57	Class A Director
Donald Williams	58	Class A Director
Robert Ward	59	Class A Director
Gur Roshwalb, M.D.	48	Class B Director — Chief Executive Officer
Clive Richardson	52	Class B Director — Chief Operating Officer
Ray Prudo	72	Class C Director — Executive Chairman of the Board
Dov Elefant	49	Chief Financial Officer
Robert Shaw	63	General Counsel and Secretary

Biographical information of the members of our board of directors and executive officers is set forth below.

James Hill, M.D., age 71, has served as a member of our board of directors since September 2015. Prior to joining our board of directors, Dr. Hill was a non-executive director and Chairman of Genetix Group Plc from 2001 to 2009, an AIM listed company providing scientists with intelligent solutions for cell imaging and analysis. Previously Dr. Hill was a director and Senior Vice President of Corporate Affairs with SmithKline Beecham, from 1994 to 2001, with global responsibility for Investor Relations, Government Affairs, Communication and was a member of the corporate management team which oversaw corporate strategy. Dr. Hill's prior experience was in the field of strategic product development working closely with research and development and the global markets. Dr. Hill qualified in medicine at Guys Hospital and became a fellow to The Royal Colleges of Physicians in both London and Edinburgh and was earlier awarded a Hunterian Professorship by The Royal College of Surgeons in England.

Stuart Ungar, M.D., age 73, has served as a member of our board of directors since September 2015. Dr. Ungar is currently a member of our board of directors. After pursuing post-graduate studies in Internal Medicine and research in neuro-pharmacology at The Royal Post-Graduate Medical School, UK, Dr. Ungar was in practice as an Internist at The Princess Grace Hospital, London. Following fifteen years of practice he, jointly with Dr. Raymond Prudo, founded The Doctors Laboratory PLC (TDL), a general pathology laboratory, which provided analytical services to clinicians and pharmaceutical organizations throughout the United Kingdom and abroad. During his tenure as Chairman and Board Director, The Doctors Laboratory PLC grew from a start-up to become one of the largest pathology laboratories in the United Kingdom. It was sold to Sonic Healthcare, a quoted Australian PLC in 2002. Dr. Ungar studied medicine and biochemistry in the University of London at the Royal Free Hospital School of Medicine. As a post-graduate he was admitted to The Royal College of Physicians of the United Kingdom. Dr. Ungar is a Life Fellow of The Royal Society of Medicine and a founder and former Vice-President of The Independent Doctors Federation.

David Byrne, age 57, has served as a member of our board of directors since June 2016. Mr. Byrne is currently Group Chief Executive Officer of Sonic Healthcare UK Group, the United Kingdom's largest NGO clinical diagnostics organization, a position that he has held since 1997. Mr. Byrne is also the CEO of The Doctors Laboratory which is a subsidiary of Sonic. Mr. Byrne also currently serves as a Main Board Director for CIS Healthcare Limited and served as a Main Board Finance Director for Clinisys Solutions Ltd from 2000 to 2007. He is a UK Chartered Certified Accountant with over 25 years' experience in corporate finance and developing early stage biotechnology and medical services companies.

Donald Williams, age 58, has served as a member of our board of directors since June 2016. Mr. Williams is a 35-year veteran of the public accounting industry who retired in 2014. Mr. Williams spent 18 years as a partner at Ernst & Young and the last seven years as a partner at Grant Thornton. Mr. Williams' career focused on private and public companies in the technology and life sciences sectors. During the last seven years at Grant Thornton, he served as the National Leader of Grant Thornton's Life Sciences Practice and the Managing Partner of the San Diego Office. He was the lead partner for both Ernst & Young and Grant Thornton on multiple initial public offerings; secondary offerings; private and public debt financings; as well as numerous mergers and acquisitions. Mr. Williams serves as a director of Alphatec Holdings, Inc., Impedimed Limited, Marina Biotech, Inc. and Proove Biosciences, Inc. Mr. Williams served on the board of directors and is past President and Chairman of the San Diego Venture Group and has served on the board of directors of various charitable organizations in the communities in which he has lived. Mr. Williams is a graduate of Southern Illinois University with a B.S. degree.

Robert E. Ward, age 59, has served as a member of our board of directors since October 2016. Mr. Ward has served as President and Chief Executive Officer and a member of the Board of Directors of Radius Health, Inc. (NasdaqGM: RDUS) since December 2013. Prior to joining Radius, Mr. Ward was Vice President for Strategy and External Alliances for the New Opportunities iMed at AstraZeneca, a biopharmaceutical company, from 2011 to 2013. In addition, he served as Co-Chair of the Joint Development Committees in AstraZeneca's drug development partnerships with Alcon and Galderma. Prior to AstraZeneca, from 2010 to 2011, Mr. Ward was the Managing Director of Harriman Biopartners, LLC, a biopharmaceutical company, and from 2006 to 2010 he was the Vice President of Corporate Development for NPS Pharmaceuticals, a pharmaceutical company. Mr. Ward received a B.A. in Biology and a B.S. in Physiological Psychology, both from the University of California, Santa Barbara; an M.S. in Management from the New Jersey Institute of Technology; and an M.A. in Immunology from The Johns Hopkins University School of Medicine.

Gur Roshwalb, M.D., age 48, has served as our Chief Executive Officer since March 2013 and joined our board of directors in June 2014. Prior to joining Akari, from April 2008 to February 2012, Dr. Roshwalb was employed by Venrock, a leading venture capital firm, where he most recently served as a Vice President investing in both private and public healthcare companies. At Venrock, Dr. Roshwalb was involved in the valuation, diligence and deal structuring of numerous pharmaceutical and biotechnology companies. Prior to Venrock, Dr. Roshwalb was a senior equity analyst at Piper Jaffray from June 2004 to March 2008 where he published research on specialty pharmaceutical companies. Dr. Roshwalb was in private practice in New York and Board Certified in Internal Medicine before joining the investment community. He received an MBA from the NYU Stern School of Business, and an MD from the Albert Einstein College of Medicine.

Clive Richardson, age 52, has served as our Chief Operating Officer and member of our board of directors since September 2015. Mr. Richardson is currently Head of Operations for Volution, a position he has held since January 2014 as a consultant. Prior his current position, Mr. Richardson served as consultant to Volution's predecessor company, Varleigh Immuno Pharmaceuticals, since inception in 2007. Prior to working for Volution and Varleigh, Mr. Richardson served as a member of the board of directors for a range of international healthcare companies, including CIS Healthcare Ltd. and Clinisys Ltd. Mr. Richardson was formerly Head of Equities Research for Investec Bank, and worked as a strategy consultant for L.E.K. Consulting. Mr. Richardson holds an M.A. in Zoology from Trinity College, Oxford University.

Ray Prudo, M.D. age 72, has served as our Executive Chairman since September 2015. Dr. Prudo has been an active investor and developer of healthcare companies for 25 years. Dr. Prudo is the Founder, Chairman, and Chief Executive Officer of Volution and its predecessor company, Varleigh Immuno Pharmaceuticals, since inception in 2007. He is currently a board member of several UK healthcare companies. Dr. Prudo holds an MBBS from the University of London, and an FRCP(C) from the Royal College of Physicians and Surgeons of Canada.

Dov Elefant, age 49, has served as our Chief Financial Officer since January 2012. From March 2011 until January 2012, he was Chief Financial Officer of Althera Medical Ltd. and from March 2009 to February 2011 he performed consulting services to a number of companies. He was also the Corporate Controller, from March 2007 to February 2009 for Lev Pharmaceuticals, which was acquired by ViroPharma in 2008, Controller and Vice President of Finance and Administration at EpiCept Corporation from December 1999 to March 2007, Assistant Controller at Tetragenex Pharmaceuticals from November 1998 to October 1999 and held other accounting and finance roles from March 1991 to October 1998. Mr. Elefant holds a B.S. in accounting from Yeshiva University.

Robert M. Shaw, age 63, has served as our General Counsel & Secretary since February 2016. Prior to joining Akari, he was General Counsel at Kenyon & Kenyon LLP, a law firm in New York, New York from 2010 to 2016. Prior to 2010, he held the following positions: Vice President, Acting General Counsel, and Secretary at KV Pharmaceutical Company in St. Louis, Missouri (2008 to 2010), Senior Vice President, General Counsel and Secretary at Pliva, Inc. in East Hanover, New Jersey (2004 to 2008); Executive Vice President, Chief Administrative Officer, General Counsel and Secretary at Savient Pharmaceuticals, Inc. in East Brunswick, New Jersey (1998 to 2004). From 1979 to 1998, he held various positions at BASF Corporation, Hoechst Celanese Corporation, and law firms in New York and Pennsylvania. Mr. Shaw holds a B.A. in Chemistry from Amherst College and a J.D. from the School of Law at Washington University in St. Louis.

B. Compensation

Summary Compensation Table

The following table shows the compensation paid or accrued during the last two fiscal years ended December 31, 2016 and 2015 to (1) our Executive Chairman, (2) our Chief Executive Officer, (3) our Chief Financial Officer, (4) our Chief Operating Officer, and (5) our General Counsel and Secretary.

Name and Principal Position	Year	Salary (\$)	Bonus (\$)	Stock Awards (\$)	Option Awards (\$) ⁽¹⁾	Non-Equity Incentive Plan Compensation (\$)	Nonqualified Deferred Compensation Earnings (\$)	All Other Compensation (\$)	Total (\$)
Ray Prudo, Executive Chairman ⁽²⁾	2016	200,000	150,000	—	—	—	—	—	350,000
	2015	56,986	—	—	—	—	—	—	56,986
Gur Roshwalb, M.D., Chief Executive Officer	2016	375,000	187,500	—	—	—	—	18,750 ⁽⁵⁾	581,250
	2015	357,292	86,625	—	6,863,034	—	—	—	7,306,951
Dov Elefant, Chief Financial Officer	2016	200,000	62,500	—	—	—	—	10,000 ⁽⁵⁾	272,500
	2015	200,000	37,500	—	857,879	—	—	—	1,095,379
Clive Richardson, Chief Operating Officer ⁽³⁾	2016	282,178	129,167	—	—	—	—	34,815 ⁽⁶⁾	446,160
	2015	79,792	—	—	3,431,517	—	—	—	3,511,309
Robert Shaw, General Counsel and Secretary ⁽⁴⁾	2016	218,750	—	—	178,061	—	—	10,925 ⁽⁵⁾	407,736
	2015	—	—	—	—	—	—	—	—

(1) These amounts represent the aggregate grant date fair value for option awards for fiscal years 2016 and 2015, respectively, computed in accordance with FASB ASC Topic 718. A discussion of the assumptions used in determining grant date fair value may be found in our Financial Statements, included in our Annual Report on Form 20-F for the years ended December 31, 2016 and 2015.

- (2) Dr. Prudo was appointed as our Executive Chairman in connection with the Acquisition.
- (3) Mr. Richardson was appointed as our Chief Operating Officer in connection with the Acquisition.
- (4) Mr. Shaw was appointed as our General Counsel in February 2016 and Company Secretary in March 2016.
- (5) Consists of company contributions to a 401K plan.
- (6) Consists of company contributions to a pension plan of \$33,225 and life insurance premiums of \$1,590.

Narrative Disclosure to Summary Compensation Table

Ray Prudo. On September 21, 2015, in connection with the Acquisition, we entered into an agreement with our Executive Chairman and director, Ray Prudo. The agreement was effective as of September 18, 2015. Under the agreement, Dr. Prudo will hold office as Chairman and Class C Director for a three year term and thereafter will seek reappointment in accordance with our Articles of Association. Dr. Prudo's appointment is subject to early termination in accordance with the Articles of Association or if he ceases to be a director.

Dr. Prudo's current annual salary is \$206,000. Upon termination of Dr. Prudo's appointment, he shall be entitled to any accrued but unpaid base salary and expense reimbursement. Under the agreement, Dr. Prudo is required to maintain the confidentiality of our confidential information.

In a separately entered into agreement with Dr. Prudo on September 2015, Dr. Prudo is entitled to an additional cash payment each calendar year in the discretion of our board of directors based on Dr. Prudo's performance. Dr. Prudo's annual cash bonus is currently set at 60% of base salary.

Gur Roshwalb, M.D. On September 21, 2015, in connection with the Acquisition, we entered into an executive employment agreement with our Chief Executive Officer and director, Gur Roshwalb. The employment agreement was effective as of September 18, 2015, and has a term of one year with automatic renewals for successive one-year periods unless terminated by either party upon three-months' notice prior to the expiration of the current term. We are entitled to terminate the employment agreement immediately upon notice in the case of termination for cause or Dr. Roshwalb's death or disability and upon 30 days' prior written notice for any other reason. Dr. Roshwalb is entitled to terminate the employment agreement with or without good reason upon 30 days' prior written notice. Dr. Roshwalb is required to resign as a director upon termination for any reason.

Dr. Roshwalb's current annual base salary is \$450,000 which is subject to review on an annual basis. Dr. Roshwalb is also entitled to an annual cash bonus with a target of 40% of base salary, provided that the actual amount of such bonus may be greater or less than the target amount. The employment agreement also provides that Dr. Roshwalb is entitled to a stock option grant to purchase 32,543,700 Ordinary Shares (equivalent to 325,437 ADSs). This option was granted under our 2014 Equity Incentive Compensation Plan, or the 2014 Plan, on September 21, 2015, has a ten-year term, is exercisable at a price equal to \$0.3221 per share (or \$32.21 per ADS) and vests ratably on a semi-annual basis over four years, with a minimum 25% vesting, subject to acceleration in the case of change of control or non-renewal of the employment agreement. The employment agreement further provides that Dr. Roshwalb shall receive no additional compensation for his service on the board of directors.

Upon termination of Dr. Roshwalb's employment by us for cause or by Dr. Roshwalb without good reason or in the case of Dr. Roshwalb's disability or death then he shall be entitled to any accrued but unpaid base salary and expense reimbursement.

Upon termination of Dr. Roshwalb's employment without cause or by Dr. Roshwalb for good reason, in addition to any accrued but unpaid base salary and expense reimbursement, he shall be entitled to receive an amount equal to 12 months of base salary in effect before the employment terminates, plus the greater of the actual or target annual performance bonus to which Dr. Roshwalb may have been entitled to for the year in which the employment terminates. Upon termination of Dr. Roshwalb's employment upon non-renewal of the term, in addition to any accrued but unpaid base salary and expense reimbursement, he shall be entitled to receive an amount equal to 12 months of base salary in effect before the employment terminates. In each such instance of termination, Dr. Roshwalb shall also be entitled to an amount equal to our share of the medical insurance premium that we pay for Dr. Roshwalb under our health care plan for 12 months following the date of termination.

Upon termination of Dr. Roshwalb's employment by us without cause or by Dr. Roshwalb for good reason within one year of a change of control in addition to any accrued but unpaid base salary and expense reimbursement, he shall be entitled to receive an amount equal to 18 months of base salary in effect before the employment terminates, plus one and a half times the target annual performance bonus to which Dr. Roshwalb may have been entitled to for the year in which the employment terminates; provided our valuation in a change of control transaction is greater than our valuation at the time of the Acquisition. In such instance, Dr. Roshwalb shall also be entitled to an amount equal to our share of the medical insurance premium that we pay for Dr. Roshwalb under our health care plan for 18 months following the date of termination.

The employment agreement also contains restrictive covenants for our benefit and Dr. Roshwalb is required to maintain the confidentiality of our confidential information.

Dov Elefant. On September 21, 2015, in connection with the Acquisition, we entered into an executive employment agreement with our Chief Financial Officer, Dov Elefant. The employment agreement was effective as of September 18, 2015, and has a term of one year with automatic renewals for successive one-year periods unless terminated by either party upon three-months' notice prior to the expiration of the current term. We are entitled to terminate the employment agreement immediately upon notice in the case of termination for cause or Mr. Elefant's death or disability and upon 30 days' prior written notice for any other reason. Mr. Elefant is entitled to terminate the employment agreement with or without good reason upon 30 days' prior written notice.

Mr. Elefant's current annual base salary is \$240,000 which is subject to review on an annual basis. Mr. Elefant is also entitled to an annual cash bonus with a target of 25% of base salary, provided that the actual amount of such bonus may be greater or less than the target amount. The employment agreement also provides that Mr. Elefant is entitled to a stock option grant to purchase 4,067,963 Ordinary Shares (equivalent to 40,679 ADSs). This option was granted under our 2014 Plan on September 21, 2015, has a ten-year term, is exercisable at a price equal to \$0.3221 per share (or \$32.21 per ADS) and vests ratably on a semi-annual basis over four years, subject to acceleration in the case of change of control or non-renewal of the employment agreement.

Upon termination of Mr. Elefant's employment by us for cause or by Mr. Elefant without good reason or in the case of Mr. Elefant's disability or death then he shall be entitled to any accrued but unpaid base salary and expense reimbursement.

Upon termination of Mr. Elefant's employment without cause or by Mr. Elefant for good reason, in addition to any accrued but unpaid base salary and expense reimbursement, he shall be entitled to receive an amount equal to 12 months of base salary in effect before the employment terminates, plus the greater of the actual or target annual performance bonus to which Mr. Elefant may have been entitled to for the year in which the employment terminates. Upon termination of Mr. Elefant's employment upon non-renewal of the term, in addition to any accrued but unpaid base salary and expense reimbursement, he shall be entitled to receive an amount equal to 12 months of base salary in effect before the employment terminates. In each such instance of termination, Mr. Elefant shall also be entitled to an amount equal to our share of the medical insurance premium that we pay for Mr. Elefant under our health care plan for 12 months following the date of termination.

Upon termination of Mr. Elefant's employment by us without cause or by Mr. Elefant for good reason within one year of a change of control in addition to any accrued but unpaid base salary and expense reimbursement, he shall be entitled to receive an amount equal to 18 months of base salary in effect before the employment terminates, plus one and a half times the target annual performance bonus to which Mr. Elefant may have been entitled to for the year in which the employment terminates; provided our valuation in a change of control transaction is greater than our valuation at the time of the Acquisition. In such instance, Mr. Elefant shall also be entitled to an amount equal to our share of the medical insurance premium that we pay for Mr. Elefant under our health care plan for 18 months following the date of termination.

The employment agreement also contains restrictive covenants for our benefit and Mr. Elefant is required to maintain the confidentiality of our confidential information.

Clive Richardson. On September 21, 2015, in connection with the Acquisition, we entered into an executive employment agreement with our Chief Operating Officer and director, Clive Richardson. The employment agreement was effective as of September 16, 2015 and shall continue in effect until terminated by either party upon at least six months' prior written notice.

Mr. Richardson's current annual base salary of £252,000 which is subject to review on an annual basis. Mr. Richardson is also entitled to an annual cash bonus with a target of 40% of base salary, provided that the actual amount of such bonus may be greater or less than the target amount. The employment agreement also provides that Mr. Richardson is entitled to a stock option grant to purchase 16,271,850 Ordinary Shares (equivalent to 162,718 ADSs). This option was granted under our 2014 Plan on September 21, 2015, has a ten-year term, is exercisable at a price equal to \$0.3221 per share (or \$32.21 per ADS) and vests ratably on a semi-annual basis over four years, with a minimum 25% vesting, subject to acceleration in the case of change of control or non-renewal of the employment agreement.

Upon termination of Mr. Richardson's employment by us for cause, then he shall be entitled to any accrued amounts due at the date of termination. In other instances of termination of Mr. Richardson's employment, he shall be entitled to receive an amount equal to 18 months of base salary in effect before the employment terminates, plus one and a half times the target annual performance bonus to which Mr. Richardson may have been entitled to for the year in which the employment terminates; provided our valuation in a change of control transaction is greater than our valuation at the time of the Acquisition..

The employment agreement also contains restrictive covenants for our benefit and Mr. Richardson is required to maintain the confidentiality of our confidential information.

Robert Shaw. On March 23, 2016, we entered into an executive employment agreement with our General Counsel and Secretary, Robert Shaw which was subsequently amended on February 15, 2017. The employment agreement has a term of one year with automatic renewals for successive one-year periods unless terminated by either party upon three-months' notice prior to the expiration of the current term. We are entitled to terminate the employment agreement immediately upon notice in the case of termination for cause or Mr. Shaw's death or disability and upon 30 days' prior written notice for any other reason. Mr. Shaw is entitled to terminate the employment agreement with or without good reason upon 30 days' prior written notice.

Mr. Shaw's current annual base salary is \$256,250 which is subject to review on an annual basis. From February 15, 2017, Mr. Shaw is also entitled to an annual cash bonus with a target of 30% of base salary, provided that the actual amount of such bonus may be greater or less than the target amount. The employment agreement also provides that Mr. Shaw is entitled to a stock option grant to purchase 1,800,000 Ordinary Shares (equivalent to 18,000 ADSs). This option was granted under our 2014 Plan on March 23, 2016, has a ten-year term, is exercisable at a price equal to \$.0141 per share (or \$14.10 per ADS) and vests ratably on a semi-annual basis over four years, subject to acceleration in the case of change of control or non-renewal of the employment agreement.

Upon termination of Mr. Shaw's employment by us for cause or by Mr. Shaw without good reason or in the case of Mr. Shaw's disability or death then he shall be entitled to any accrued but unpaid base salary and expense reimbursement.

Upon termination of Mr. Shaw's employment without cause, by Mr. Shaw for good reason or upon non-renewal of the term, in each case occurring after February 15, 2017, in addition to any accrued but unpaid base salary and expense reimbursement, he shall be entitled to receive an amount equal to 75% of (i) 12 months of base salary in effect before the employment terminates, plus (ii) the greater of the actual or target annual performance bonus to which Mr. Shaw may have been entitled to for the year in which the employment terminates. In each such instance of termination, Mr. Shaw shall also be entitled to an amount equal to our share of the medical insurance premium that we pay for Mr. Shaw under our health care plan for 9 months following the date of termination.

Upon termination of Mr. Shaw's employment by us without cause or by Mr. Shaw for good reason, in each case occurring after February 15, 2017, within one year of a change of control in addition to any accrued but unpaid base salary and expense reimbursement, he shall be entitled to receive an amount equal to 18 months of base salary in effect before the employment terminates, plus one and a half times the target annual performance bonus to which Mr. Shaw may have been entitled to for the year in which the employment terminates; provided our valuation in a change of control transaction is greater than our valuation at the time of the Acquisition. In such instance, Mr. Shaw shall also be entitled to an amount equal to our share of the medical insurance premium that we pay under our health care plan for 18 months following the date of termination.

The employment agreement also contains restrictive covenants for our benefit and Mr. Shaw is required to maintain the confidentiality of our confidential information.

Outstanding Equity Awards at Fiscal Year-End

The following table provides information regarding all outstanding equity awards for (1) our Executive Chairman, (2) our Chief Executive Officer, (3) our Chief Financial Officer, (4) our Chief Operating Officer, and (5) our General Counsel and Secretary, as of December 31, 2016:

Name	Option Awards		Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Options (#)	Option Exercise Price (\$)	Option Expiration Date
	Number of Securities Underlying Unexercised Options (#) Exercisable ⁽¹⁾	Number of Securities Underlying Unexercised Options (#) Unexercisable ⁽¹⁾			
Ray Prudo	—	—	—	—	—
Gur Roshwalb, M.D.	560,000 ⁽²⁾	—	—	2.00	9/24/2023
	100,000 ⁽³⁾	—	—	2.00	9/24/2023
	120,000 ⁽⁴⁾	—	—	0.75	2/5/2024
	10,169,906 ⁽⁵⁾	22,373,794	—	0.3221	9/21/2025
Dov Elefant	40,000 ⁽⁶⁾	—	—	1.56	1/11/2022
	100,000 ⁽³⁾	—	—	2.00	7/1/2023
	40,000 ⁽⁴⁾	—	—	0.75	2/5/2024
	1,271,238 ⁽⁵⁾	2,796,725	—	0.3221	9/21/2025
Clive Richardson	5,084,953 ⁽⁵⁾	11,186,897	—	0.3221	9/21/2025
Robert Shaw	225,000 ⁽⁷⁾	1,575,000	—	0.141	3/23/2026

- (1) Amounts represent options to purchase Ordinary Shares.
- (2) These options were granted on September 24, 2013, and were fully exercisable on September 18, 2015.
- (3) These options were granted on September 24, 2013, and were fully exercisable on July 1, 2014.
- (4) These options were granted on February 2, 2014, and were fully exercisable on May 31, 2014.
- (5) These options were granted on September 21, 2015, in connection with the Acquisition, and are exercisable over a four-year period with one-sixteenth of the options granted vesting every three months beginning September 21, 2015, through 2019.
- (6) These options were granted on July 1, 2013, and were fully exercisable on July 1, 2014.
- (7) These options were granted on March 23, 2016 and are exercisable over a four-year period with one-eighth of the options granted vesting every six months beginning March 23, 2016, through 2020.

Director Compensation

Our director compensation program is administered by our board of directors with the assistance of the compensation committee. The compensation committee conducts an annual review of director compensation and makes recommendations to the board with respect thereto.

Based on the recommendation of our compensation committee, our board of directors adopted an amended and restated non-employee director compensation policy on November 19, 2015 which was subsequently amended on June 29, 2016. On January 26, 2017, our board approved a 3% increase in cash compensation. As a result, our non-employee directors will be compensated for service on our board of directors as follows in 2017:

- an annual retainer for service on the board of directors of \$37,080;

- an annual retainer for service a member of the audit committee, compensation committee, nominating and governance committee and the research and development committee of \$5,150;
- for the chairman of the compensation committee, and nominating and governance committee, an annual retainer of \$10,300;
- for the chairperson of the audit committee, an annual retainer of \$15,450;
- for service on the board, an annual grant of a stock option to purchase 1,300,000 Ordinary Shares (equivalent to 13,000 ADSs) or Annual Stock Option; the grant is made each year on the date of the Company's Annual General Meeting of shareholders, or AGM, on the date of the first meeting of the board held following the AGM, or on any date following such AGM as may be recommended by the compensation committee and approved by the Board;
- for each new non-employee director that is appointed to the board of directors, an initial grant of a stock option to purchase 1,300,000 Ordinary Shares (equivalent to 13,000 ADSs), or Initial Stock Option Grant; if the non-employee director was not previously appointed to the board and is first elected at the Company's AGM, the grant shall be made on the date of the Company's AGM, on the date of the first meeting of the board held following the AGM, or on any date following such AGM as may be recommended by the compensation committee and approved by the board; if the non-employee director is appointed to the board in advance of the next AGM and will stand for election at that AGM, the grant shall be made at the meeting of the board at which he or she is appointed and, if not made at such meeting, shall be made promptly following such meeting by written unanimous consent of the board; and if the non-employee director is first appointed to the board in advance of the next AGM and will not stand for election at that AGM, the number of shares in the grant and the vesting schedule shall be determined by the compensation committee, taking into account the term of the appointment and the grant shall be made at the meeting of the board at which he or she is appointed and, if not made at such meeting, shall be made promptly following such meeting by written unanimous consent of the board;
- unless otherwise specified by the board or the compensation committee at the time of grant, each Annual Stock Option granted under this policy shall (i) vest in full on the date of the next AGM following the date of grant, subject to the non-employee director's continued service on the Board; (ii) have an exercise price equal to the fair market value of the Company's Ordinary Shares as determined in the 2014 Plan on the grant date; (iii) terminate ten years after the grant date, (iv) become fully vested immediately prior to a change of control and (v) contain such other terms and conditions as set forth in the form of option agreement approved by the board or the compensation committee prior to the grant date; and
- unless otherwise specified by the board or the compensation committee at the time of grant, each Initial Stock Option Grant for newly appointed or elected directors granted under the non-employee director compensation policy shall (i) vest ratably in three equal installments with the first installment vesting on the date of the first AGM following the date of the grant, and with the second and third installments vesting, respectively, on the dates of the second and third AGMs following the date of the grant, subject to the non-employee director's continued service on the board; (ii) have an exercise price equal to the fair market value of the Company's Ordinary Shares as determined in the 2014 Plan on the grant date; (iii) terminate ten years after the grant date, (iv) become fully vested immediately prior to a change of control and (v) contain such other terms and conditions as set forth in the form of option agreement approved by the board or the compensation committee prior to the grant date; and
- each of these options shall be granted under our 2014 Plan, terminate ten years after the grant date and become fully vested immediately prior to a change of control.

All directors are eligible to receive reimbursement for reasonable out-of-pocket expenses incurred in connection with attendance at meetings of our board of directors, and our non-employee directors are also eligible to receive reimbursement, upon approval of the board of directors or a committee thereof, for reasonable out-of-pocket expenses incurred in connection with attendance at various conferences or meetings with our management.

The following table sets forth information regarding the total compensation awarded to, earned by or paid to each of our non-employee directors during the year ended December 31, 2016 for their service on our board of directors. Dr. Prudo, our Executive Chairman, Dr. Roshwalb, our Chief Executive Officer, and Clive Richardson, our Chief Operating Officer, did not receive any additional compensation for their service as a director during 2016. The compensation that we pay to the foregoing persons is discussed in the "Summary Compensation Table" above.

<u>Name</u>	<u>Fees Earned or Paid in Cash (\$)</u>	<u>Option Awards (\$)⁽¹⁾</u>	<u>Total (\$)</u>
James Hill, M.D. ⁽²⁾	58,249	126,226	184,475
Stuart Ungar ⁽³⁾	50,770	126,226	176,996
David Byrne ⁽⁴⁾	21,683	278,636	300,319
Donald Williams ⁽⁵⁾	25,500	248,898	274,398
Robert Ward ⁽⁶⁾	10,880	69,062	79,942
Mark S. Cohen ^{(7) (8)}	60,749	195,287	256,036
Allan Shaw ⁽⁹⁾	25,290	-	25,290

- (1) These amounts represent the aggregate grant date fair value of options granted to each director during the year ended December 31, 2016 computed in accordance with ASC Topic 718. A discussion of the assumptions used in determining grant date fair value may be found in our Audited Financial Statements, included in our Annual Report on Form 20-F for the fiscal year ended December 31, 2016.
- (2) As of December 31, 2016, options to purchase an aggregate of 2,600,000 Ordinary Shares (equivalent to 26,000 ADSs) were outstanding, of which 587,518 Ordinary Shares (equivalent to 5,875 ADSs) were exercisable.
- (3) As of December 31, 2016, options to purchase an aggregate of 2,600,000 Ordinary Shares (equivalent to 26,000 ADSs) were outstanding, of which 574,185 Ordinary Shares (equivalent to 5,741 ADSs) were exercisable.
- (4) Mr. Byrne was appointed as a Class A director on April 20, 2016. As of December 31, 2016, options to purchase an aggregate of 2,600,000 Ordinary Shares (equivalent to 26,000 ADSs) were outstanding, none of which were exercisable.
- (5) Mr. Williams was appointed as a Class A director on June 29, 2016. As of December 31, 2016, options to purchase an aggregate of 2,600,000 Ordinary Shares (equivalent to 26,000 ADSs) were outstanding, none of which were exercisable.
- (6) Mr. Ward was appointed as a Class A director on October 13, 2016. As of December 31, 2016, options to purchase an aggregate of 1,300,000 Ordinary Shares (equivalent to 13,000 ADSs) were outstanding, none of which were exercisable.
- (7) Mr. Cohen resigned as a Class C director on October 13, 2016. As of December 31, 2016, options to purchase an aggregate of 4,401,500 Ordinary Shares (equivalent to 44,015 ADSs) were outstanding, of which 4,401,500 Ordinary Shares (equivalent to 44,015 ADSs) were exercisable. In connection with Mr. Cohen's resignation, we and Mr. Cohen agreed that Mr. Cohen's (i) outstanding unvested stock options from November 25, 2015 and June 29, 2016 in the amounts of 1,028,722 and 1,300,000 ordinary shares, respectively, shall be fully vested as of October 13, 2016, and (ii) vested options (including those whose vesting accelerated pursuant to the preceding clause) shall continue to be exercisable for a period ending on the earlier of (1) 10 years following the respective dates of grant of such options, or (2) three months following the Company's 2018 AGM. In addition, we agreed to (i) grant Mr. Cohen an additional option to purchase 1,300,000 fully vested ordinary shares (equivalent to 13,000 ADS) at an exercise price of \$0.080621 per share (or \$8.0621 per ADS) and which can be exercised until three months following the 2018 AGM, and (ii) pay Mr. Cohen, in quarterly installments, \$45,750 for the balance of director fees that he would have earned through the 2017 AGM and an additional \$61,000 that he would have earned in director fees from the 2017 AGM to the 2018 AGM.
- (8) Does not include payments of an aggregate of \$18,542 for intellectual property legal services and expenses for third parties in 2016 made to Pearl Cohen Zedek Latzer Baratz LLP, of which Mr. Cohen is a senior partner.
- (9) Mr. Shaw's term as a Class A director expired on June 29, 2016. As of December 31, 2016, all previously granted options to Mr. Shaw expired without exercise.

C. Board Practices

Our Articles of Association, as amended, provide that our business is to be managed by the board of directors (subject to any directions made by the members of the Company by special shareholder resolution). Our board of directors is divided into three classes for purposes of election (Class A Directors, who serve a one year term before being subject to re-election at the Company's annual general meeting; Class B Directors, who serve a two year term before being subject to re-election at the annual general meeting; and Class C Directors who serve a three year term before being subject to re-election at the annual general meeting, provided also that in any two year period, a majority of the board must stand for re-election). Our board of directors currently consists of eight members: James Hill, M.D., Stuart Ungar, M.D., David Byrne, Donald Williams and Robert Ward currently serve as Class A directors, with a term ending at the 2017 annual general meeting; Gur Roshwalb, M.D. and Clive Richardson currently serve as Class B directors, with a term ending at the 2017 annual general meeting; and Ray Prudo, currently serves as a Class C director, with a term ending at the 2018 annual general meeting. Ray Prudo serves as Executive Chairman of our board of directors.

Subject to certain exceptions, the rules of Nasdaq permit a foreign private issuer to follow its home country practice in lieu of listing requirements of Nasdaq. The committees of our board of directors consist of an audit committee, a compensation committee and a nominating and corporate governance committee.

Audit Committee

Our audit committee currently consists of three members, appointed by the board of directors: Donald Williams, James Hill, M.D. and David Byrne, all of whom are independent within the meaning of SEC corporate governance rules of independence for purposes of the audit committee. Mr. Williams is the chairman of our audit committee. Our board of directors has determined that Mr. Williams is the audit committee financial expert.

Compensation Committee

Our compensation committee currently consists of three members, appointed by the board of directors: James Hill, M.D., Stuart Ungar, M.D. and David Byrne, all of whom are independent within the meaning of SEC corporate governance rules of independence for purposes of the compensation committee. Dr. Hill is the chairman of our compensation committee.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee currently consists of three members, appointed by our board of directors: Robert Ward, James Hill, M.D., and Stuart Ungar, M.D., all of whom are independent within the meaning of SEC corporate governance rules of independence for purposes of the nominating and corporate governance committee. Mr. Ward is the chairman of our nominating and corporate governance committee.

None of our non-employee directors have any service contracts with Akari or any of our subsidiaries that provide for benefits upon termination of employment.

D. Employees

As of December 31, 2016, we had fifteen full-time employees and a further two full-time equivalent consultants. Six of our employees and one consultant were engaged in research and development and nine employees and one consultant were engaged in management, administration and finance. Eleven are located in England and six are located in the United States.

None of our employees are members of labor unions.

E. Share Ownership

Information with respect to share ownership of members of our board of directors and executive officers is included in “Item 7. Major Shareholders and Related Party Transactions”

Option Plans

2014 Plan

In order to retain qualified individuals, the Board previously established the 2007 Stock Option Plan. We currently have issued options representing 736,500 Ordinary Shares under the 2007 Stock Option Plan.

On June 19, 2014, our board of directors approved the 2014 Equity Incentive Plan, or the 2014 Plan. The shareholders approved the 2014 Plan on June 19, 2014. The purpose of the 2014 Plan is to enable us to continue to attract and retain professional personnel for the purposes of executing our clinical development plan. The material terms of the 2014 are set forth below.

The option plan is administered by our 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 736,500 Ordinary Shares shall be added to the 2014 Plan pursuant to subsection (ii). Options may be granted at any time. As of March 30, 2017, options to purchase 78,635,698 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.

On January 23, 2017, the compensation committee approved a UK Sub-Plan of the 2014 Plan which offers UK residents the opportunity to acquire interests in us in a similar manner to that offered to US employees. The UK Sub-Plan requires that only employees may receive grants, and that all options granted under the UK Sub-Plan must be designated as “non-tax-advantaged Options” under UK law. Options granted under the UK Sub-Plan are exercisable pursuant to the terms of their award and are subject to the terms of the 2014 Plan generally, except where otherwise stated. The UK Sub-Plan differs from the 2014 Plan only in UK-specific provisions regarding a valid disposition to survivors and compliance with local UK laws regarding securities, treatment as compensation, tax matters, data privacy, and third party rights.

Grants to non-employee directors who are based in the UK or who are UK resident taxpayers are made pursuant to the 2014 Plan in accordance with the UK Appendix to the Amended and Restated Non-Employee Director Compensation Policy which was approved by the compensation committee on January 23, 2017. The UK Appendix, as with the Sub-Plan for employees, differs from the Non-Employee Director Compensation Policy by providing specific UK-specific provisions. All options granted to UK non-employee directors or resident taxpayers are, as with the Sub-Plan for employees, designated as “non-tax-advantaged options” under UK law, exercisable pursuant to the terms of the award and the 2014 Plan, and provide for UK specific provisions regarding survivorship, securities, compensation, tax, data privacy, and third party rights laws.

In addition, on January 26, 2017, our board of directors approved a CSOP Sub Plan as recommended to the board by the compensation committee. The CSOP Sub-Plan modifies the 2014 Plan to qualify as a Schedule 4 CSOP Scheme as defined under the UK’s Income Tax (Earnings & Pensions) Act 2003, or ITEPA. The purpose of the CSOP Sub-Plan is to allow options granted to UK resident employees and directors to qualify as a Schedule 4 CSOP Scheme under governing law and to therefore qualify for certain tax advantages under ITEPA. CSOP options are effectuated by the execution of a deed of grant by the Company evidencing shares, option exercise price, restrictions, and other terms or conditions. Grants are limited under the CSOP Sub-Plan such that an employee cannot hold more than £30,000 in value, measured as of grant date. In the event of redundancy, retirement, a relevant transfer within the meaning of the Protection of Employment regulations, or a cease of control (as defined in Section 719 ITEPA) under governing UK law, the recipient may exercise any CSOP option that has become exercisable but has not yet been exercised for a period of six months. A Change of Control under UK law will similarly permit option exercise.

2007 Stock Option Plan

On August 28, 2007, our board of directors approved the 2007 Stock Option Plan, or the 2007 Stock Option Plan, as 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 5,865,000 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 30, 2017, options to purchase 736,500 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.

Equity Award Grant Policy

Based on the recommendation of the compensation committee, our board of directors adopted an Equity Award Grant Policy on January 26, 2017, which sets forth policies for us to follow when we grant stock options, shares of restricted stock, restricted stock units or other equity based awards to employees of the Company or its subsidiaries.

The grants are divided into annual grants, made on the last business day in March, new hire grants, to our new hires, and performance grants to existing employees in recognition of performance. The policy standardizes employee grants and delegates authority to the Executive Chairman and CEO to make grants other than (a) grants of more than 1,000,000 Ordinary Shares or share-equivalents to one individual on one date; (b) new hire or performance grants to a person who is reasonably expected to be an executive officer or director upon hire or promotion; (c) any grant which would exceed 1,000,000 Ordinary Shares or share equivalents to any one individual in a calendar year; or (d) any grant with an exercise price less than fair market value on the date. These non-delegated grants remain in the sole authority of the compensation committee.

Pricing will be based on the closing market price on the NASDAQ Capital Market for all such grants. All new hire grants must be made by a writing sent to the recipient stating the terms and conditions and clarifying that the equity award is subject to approval, whether by the delegated authority pursuant to the policy or by the compensation committee or the board itself.

Item 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

A. Major Shareholders

The following table sets forth certain information with respect to the beneficial ownership of our Ordinary Shares as of March 30, 2017 (except where otherwise indicated) for:

- each person, or group of affiliated persons, who are known by us to beneficially own more than 5% of our outstanding Ordinary Shares;
- each member of our board of directors
- each of our other executive officers; and
- all of our directors and executive officers as a group.

The number of shares beneficially owned by each entity, person, director or executive officer is determined under the rules of the SEC and the information is not necessarily indicative of beneficial ownership for any other purpose. Under such rules, beneficial ownership includes any shares as to which the individual has the sole or shared voting power or investment power and also any shares that the individual has the right to acquire within 60 days of March 30, 2017, through the exercise of any option or other right. Unless otherwise indicated, each person has sole investment and voting power, or shares such powers with his or her spouse, with respect to the shares set forth in the following table.

Ordinary Shares that may be acquired by an individual or group within 60 days of March 30, 2017, pursuant to the exercise of options or warrants, are deemed to be outstanding for the purpose of computing the percentage ownership of such individual or group, but are not deemed to be outstanding for the purpose of computing the percentage ownership of any other person shown in the table. The percentage of ownership is based on 1,177,693,383 shares of Ordinary Shares outstanding on March 30, 2017, adjusted as required by the rules promulgated by the SEC to determine beneficial ownership. Akari does not know of any arrangements, including any pledge by any person of securities of Akari, the operation of which may at a subsequent date result in a change of control of Akari. Unless otherwise noted, the address of each director and executive officer of Akari is: c/o Akari Therapeutics, Plc, 24 West 40th Street, 8th Floor, New York, New York, 10018.

	Number of Ordinary Shares Beneficially Owned ⁽¹⁾	Percentage of Ordinary Shares Beneficially
<u>Directors and Executive Officers</u>		
Ray Prudo	722,345,600 ⁽¹⁾	61.3%
Clive Richardson	6,101,944 ⁽²⁾	*
James Hill, M.D.	587,518 ⁽³⁾	*
Stuart Ungar, M.D.	574,185 ⁽⁴⁾	*
Gur Roshwalb, M.D.	13,159,326 ⁽⁵⁾	1.1%
Dov Elefant	1,705,486 ⁽⁶⁾	*
David Byrne	433,333 ⁽⁷⁾	*
Donald Williams	—	*
Robert Ward	—	*
Robert M. Shaw	450,000 ⁽⁸⁾	*
<i>All directors and officers as a group (10 persons)</i>	745,357,392	62.1%
<u>5% or More Shareholders</u>		
RPC Pharma Limited ⁽⁹⁾	722,345,600	61.3%
Deerfield Management Company, L.P.	115,070,000 ⁽¹⁰⁾	9.8%

* Represents beneficial ownership of less than 1% of our outstanding Ordinary Shares.

- (1) Represents the entire holdings of RPC Pharma Limited. Dr. Prudo has voting and dispositive control over the Ordinary Shares held by RPC Pharma Limited and owns approximately 71% of RPC's outstanding shares (including option grants), including 10.64% of RPC's outstanding shares held in trust for Dr. Ungar. Dr. Prudo disclaims beneficial ownership except to the extent of his actual pecuniary interest in such shares.
- (2) Consists of options to purchase 6,101,944 Ordinary Shares (equivalent to 61,019 ADSs) at an exercise price of \$0.3221 per share (or \$32.21 per ADS), which expire on September 21, 2025.
- (3) Consists of options to purchase 231,278 Ordinary Shares (equivalent to 2,312 ADSs) at an exercise price of \$0.3221 per share (or \$32.21 per ADS), which expire on September 21, 2025 and 356,240 Ordinary Shares (equivalent to 3,562 ADSs) at an exercise price of \$0.1917 per share (or \$19.17 per ADS), which expire on November 25, 2025. Does not include shares held by RPC Pharma Limited of which he has a pecuniary interest. Dr. Hill disclaims beneficial ownership of the shares held by RPC Pharma Limited.
- (4) Consists of options to purchase 211,278 Ordinary Shares (equivalent to 2,112 ADSs) at an exercise price of \$0.3221 per share (or \$32.21 per ADS), which expire on September 21, 2025 and 362,907 Ordinary Shares (equivalent to 3,629 ADSs) at an exercise price of \$0.1917 per share (or \$19.17 per ADS), which expire on November 25, 2025. Does not include shares held by RPC Pharma Limited of which he has a pecuniary interest. Dr. Ungar disclaims beneficial ownership of the shares held by RPC Pharma Limited.

- (5) Includes options to purchase 12,203,888 Ordinary Shares (equivalent to 122,038 ADSs) at an exercise price of \$0.3221 per share (or \$32.21 per ADS), which expire on September 21, 2025, 120,000 Ordinary Shares (equivalent to 1,200 ADSs) at an exercise price of \$0.75 per share (or \$75.00 per ADS), which expire on February 5, 2024 and 660,000 Ordinary Shares (equivalent to 6,600 ADSs) at an exercise price of \$2.00 per share (or \$200.00 per ADS), which expire on September 24, 2023.
- (6) Includes options to purchase 40,000 Ordinary Shares (equivalent to 400 ADSs) at an exercise price of \$1.56 per share (or \$156.00 per ADS), which expire on January 11, 2022, 100,000 Ordinary Shares (equivalent to 1,000 ADSs) at an exercise price of \$2.00 per share (or \$200.00 per ADS), which expire on July 1, 2023, 40,000 Ordinary Shares (equivalent to 400 ADSs) at an exercise price of \$0.75 per share (or \$75.00 per ADS), which expire on February 5, 2024 and 1,525,486 Ordinary Shares (equivalent to 15,254 ADSs) at an exercise price of \$0.3221 per share (or \$32.21 per ADS), which expire on September 21, 2025.
- (7) Consists of options to purchase 433,333 Ordinary Shares (equivalent to 4,333 ADSs) at an exercise price of \$0.18 per share (or \$18.00 per ADS), which expire on April 22, 2026. Does not include shares held by RPC Pharma Limited of which he has a pecuniary interest. Mr. Byrne disclaims beneficial ownership of the shares held by RPC Pharma Limited.
- (8) Consists of options to purchase 450,000 Ordinary Shares (equivalent to 4,500 ADSs) at an exercise price of \$0.141 per share (or \$14.10 per ADS), which expire on March 23, 2026.
- (9) The principal business office of RPC Pharma Limited is c/o Landmark Fiduciare (Suisse) SA, 6 Place des Eaux-Vives, P.O. Box 3461, Geneva, V8 1211, Switzerland.
- (10) Consists of (i) 57,535,000 Ordinary Shares (equivalent to 575,350 ADSs) directly held by Deerfield Private Design Fund III, L.P. (the “Private Design Shares”) which are indirectly beneficially owned by Deerfield Mgmt. III, L.P., its general partner, Deerfield Management Company, L.P., its investment advisor, and James E. Flynn, and (ii) 57,535,000 Ordinary Shares (equivalent to 575,350 ADSs) directly held by Deerfield Special Situations Fund, L.P. which are indirectly beneficially owned by Deerfield Mgmt., L.P., its general partner, Deerfield Management Company, L.P., its investment advisor, and James E. Flynn (the “Special Situations Shares”). As the sole member of the respective general partners of Deerfield Mgmt. III, L.P. and Deerfield Management Company, L.P., Mr. Flynn is the sole natural person possessing beneficial ownership over the Private Design Shares. As the sole member of the respective general partners of Deerfield Mgmt., L.P. and Deerfield Management Company, L.P., Mr. Flynn is the sole natural person possessing beneficial ownership over the Special Situations Shares. The business address for Deerfield Private Design Fund III, L.P. and Deerfield Special Situations Fund, L.P. is 780 Third Avenue, 37th floor, New York, NY 10017.

Deutsche Bank Trust Company Americas, or Deutsche Bank, is the holder of record for the company’s ADR program, pursuant to which each ADS represents 100 Ordinary Shares. As of March 30, 2017, Deutsche Bank held 1,172,831,700 Ordinary Shares representing 99.6% of the issued share capital held at that date. To our knowledge, as of March 30, 2017, we had approximately 13 holders of record with addresses in the United States. As a result, the number of holders of record or registered holders in the United States is not representative of the number of beneficial holders or of the residence of beneficial holders.

To our knowledge, there has been no significant change in the percentage ownership held by the principal shareholders listed above since September 18, 2015.

B. Related Party Transactions

The following discloses, since January 1, 2016, certain related party transactions involving us. The descriptions provided below are summaries of the terms of such agreements, do not purport to be complete and are qualified in their entirety by the complete agreements.

Employment and Consulting Agreements

We have or have had employment, consulting or related agreements with each member of our senior management and employee-directors. See “Item 6. Directors, Senior Management and Employees—Compensation”.

Office Lease

We lease our UK office space from The Doctors Laboratory, or TDL, and have incurred expenses of approximately \$142,000 and \$10,000 plus VAT during the years ended December 31, 2016 and December 31, 2015, respectively. David Byrne, a non-employee director of ours is also the CEO of TDL.

C. Interests of Experts and Counsel.

Not applicable.

Item 8. FINANCIAL INFORMATION

A. Consolidated Statements and Other Financial Information

See “Item 18. Financial Statements,” which contains our financial statements prepared in accordance with United States GAAP.

B. Legal Proceedings

We are not involved in any material legal proceedings.

C. Dividend Policy

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 Ordinary Shares or ADSs will depend upon any future appreciation in their value. There is no guarantee that our Ordinary Shares or ADSs will appreciate in value or even maintain the price at which our shareholders have purchased their shares.

D. Significant Changes

A discussion of the significant changes in our business can be found under “Item 4. Information on the Company—A. History and Development of the Company.”

Item 9. THE OFFER AND LISTING

A. Offering and Listing Details

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 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
Annual:		
2016	\$ 19.75	\$ 6.71
2015	\$ 62.00	\$ 4.00
2014	\$ 119.00	\$ 45.80
2013 (from February 19, 2013)	\$ 25.00	\$ 7.10
Quarterly:		
First Quarter 2017 (through March 30, 2017)	\$ 8.80	\$ 6.22
Fourth Quarter 2016	\$ 9.75	\$ 6.71
Third Quarter 2016	\$ 13.81	\$ 7.93
Second Quarter 2016	\$ 19.75	\$ 12.20
First Quarter 2016	\$ 19.28	\$ 7.63
Fourth Quarter 2015	\$ 24.00	\$ 13.50
Third Quarter 2015	\$ 46.70	\$ 4.90
Second Quarter 2015	\$ 8.66	\$ 4.00
First Quarter 2015	\$ 62.00	\$ 7.21
Monthly:		
March (through March 30, 2017)	\$ 8.25	\$ 6.22
February 2017	\$ 8.00	\$ 6.40
January 2017	\$ 8.80	\$ 6.80
December 2016	\$ 8.46	\$ 6.71
November 2016	\$ 9.75	\$ 7.08
October 2016	\$ 9.45	\$ 8.05
September 2016	\$ 10.06	\$ 7.93

On March 30, 2017, the last reported sales price of our ordinary shares on the NASDAQ Capital Market was \$7.00 per ADS.

B. Plan of Distribution

Not applicable.

C. Markets

See “—Offer and Listing Details” above.

D. Selling Shareholders

Not applicable.

E. Dilution

Not applicable.

F. Expenses of the Issue

Not applicable.

Item 10. ADDITIONAL INFORMATION

A. Share Capital

Not applicable.

B. Memorandum and Articles of Association

The information called for by this item has been reported previously in our Registration Statement on Form F-1 (File No. 333-192783), filed with the SEC on December 12, 2013, as amended, under the heading "Description of Share Capital" and is incorporated by reference into this Annual Report.

C. Material Contracts

Set forth below are summaries of material agreements to which we are a party, other than contracts entered into in the ordinary course of business, that have been in effect since March 1, 2015. In addition to the agreements described below, we also enter into agreements with clinical research organizations, or CROs, for the conduct of our clinical trials. The descriptions provided below do not purport to be complete and are qualified in their entirety by the complete agreements, which are attached as exhibits to this Annual Report.

Share Exchange Agreement

Pursuant the terms of the Share Exchange Agreement, dated as of July 10, 2015, or Exchange Agreement, by and between us and RPC Pharma Limited, or RPC, on September 18, 2015, RPC exchanged all of the capital stock of Volution Immuno Pharmaceuticals SA or Volution, for 722,345,600 of our Ordinary Shares.

Under the terms and subject to the satisfaction of the conditions described in the Exchange Agreement, we acquired the entire issued share capital of Volution, with Volution becoming our wholly-owned subsidiary on September 18, 2015. Following the Acquisition, the name of the combined company was changed from Celsus Therapeutics, Plc to Akari Therapeutics, Plc.

Lock-Up Agreement

As a condition to the closing of the Acquisition, RPC agreed to enter into a lock-up agreement, pursuant to which RPC agreed not to sell or transfer, or engage in swap or similar transactions with respect to, our Ordinary Shares, including, as applicable, shares received in the Acquisition and issuable upon exercise of certain warrants and options from the completion of the Acquisition until 180 days from the completion of the Acquisition.

Relationship Agreement

As a condition to the closing of the Acquisition, we and RPC entered into a Relationship Agreement, which provided, subject to closing of the Acquisition, the right for RPC to appoint the following number of directors to our board of directors in relation to the percentage of our Ordinary Shares held in aggregate by RPC from time to time: (i) two class A directors if RPC holds 25% or more of our Ordinary Shares; (ii) one class A director if RPC holds 10% or more but less than 25% of our Ordinary Shares; and (iii) no directors if RPC holds less than 10% of our Ordinary Shares.

Additionally, where such right to appoint a director falls away, RPC is obliged to procure the resignation of the relevant director as soon as practicably possible thereafter at no cost to us. Unless otherwise agreed by our board of directors, the directors appointed by RPC shall be class A directors.

Volution's Related Party Transactions

Pursuant to short term loan agreements entered into with Ray Prudo, the Chairman of our board of directors, on October 15, 2014 and November 10, 2014, Volution borrowed an aggregate of approximately \$405,018 from Ray Prudo at an interest rate of \$4.5% per annum. Volution repaid Ray Prudo the entire principal amount outstanding, plus interest in the amount of approximately \$4,052, on April 17, 2015.

On July 3, 2015, under the terms of a contribution agreement among RPC and the shareholders of Volution, the Volution shareholders contributed all of their Volution shares to RPC, which resulted in Volution becoming a wholly owned subsidiary of RPC.

Volution and certain shareholders of Volution, including Ray Prudo who is the Chairman of our board of directors and a director of both Volution and RPC, entered into a working capital advance agreement, pursuant to which such shareholders agreed to make available up to \$4,000,000 in the aggregate, to Volution for working capital purposes. All amounts advanced under the agreement accrued interest at a rate of 3% per annum and matured shortly after completion of the Acquisition.

Employment and Consulting Agreements

See “Item 6. Directors, Senior Management and Employees—Compensation—Employment and Consulting Agreements”.

D. Exchange Controls

There are currently no U.K. laws, decrees or regulations that restrict the export or import of capital, including, but not limited to, foreign exchange controls, or that affect the remittance of dividends or other payments to non-U.K. residents or to U.S. holders of our securities except as otherwise set forth in “Taxation” below. There are no limitations under our Memorandum and Articles of Association restricting voting or shareholding.

E. Taxation

The following summary contains a description of certain United Kingdom and United States federal income tax consequences of the acquisition, ownership and disposition of our Ordinary Shares or ADSs to a U.S. holder of our Ordinary Shares or ADSs. The summary is based upon the tax laws of the United Kingdom and the United States and the respective regulations thereunder as of the date hereof, which are subject to change.

For purposes of this description, a “U.S. Holder” includes any beneficial owner of our Ordinary Shares or ADSs that is, for U.S. federal income tax purposes:

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

A “Non-U.S. Holder” is any beneficial owner of our Ordinary Shares or ADSs that is not a U.S. Holder.

This section does not purport to be a comprehensive description of all of the tax considerations that may be relevant to any particular investor. This discussion assumes that you are familiar with the tax rules applicable to investments in securities generally, and with any special rules to which you may be subject. In particular, the discussion deals only with investors that will hold our Ordinary Shares or ADSs as capital assets, and does not address the tax treatment of investors that are subject to special rules, such as banks, financial institutions, insurance companies, dealers or traders in securities or currencies, persons that elect mark-to-market treatment, tax-exempt entities (including 401 pensions plans), real estate investment trusts, regulated investment companies, grantor trusts, individual retirement and other tax-deferred accounts, persons that received our ordinary or ADS shares as compensation for the performance of services, persons who own, directly, indirectly through non-U.S. entities or by attribution by application of the constructive ownership rules of section 958(b) of the United States Internal Revenue Code of 1986, or Code, 10% or more of our voting shares or ADS, persons that are residents of the U.K. for U.K. tax purposes or that conduct a business or have a permanent establishment in the U.K., persons that hold our Ordinary Shares or ADSs as a position in a straddle, hedging, conversion, integration, constructive sale or other risk reduction transaction, certain former citizens or long-term residents of the U.S., partnerships and their partners and persons whose functional currency is not the U.S. dollar. This discussion is based on laws, treaties, judicial decisions, and regulatory interpretations in effect on the date hereof, all of which are subject to change, as well as, in the United States, the Internal Revenue Code of 1986, as amended, or the Code, administrative pronouncements, judicial decisions, and final, temporary and proposed Treasury regulations, all as of the date hereof, any of which is subject to change, possibly with retroactive effect.

If a partnership holds Ordinary Shares or ADSs, the tax treatment of a partner will generally depend upon the status of the partner and upon the activities of the partnership.

We will not seek a ruling from the U.S. Internal Revenue Service, or IRS, with regard to the U.S. federal income tax treatment of an investment in our Ordinary Shares or ADSs, and we cannot assure you that the IRS will agree with the conclusions set forth below.

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

United Kingdom tax considerations

Taxation of dividends

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

Taxation of Capital Gains

Subject to the comments in the following paragraph, a holder of our Ordinary Shares or ADSs who, for U.K. tax purposes, is not resident nor in the U.K. will not be liable for U.K. taxation on capital gains realized on the disposal of our Ordinary Shares or ADS unless at the time of the disposal:

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

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

Inheritance Tax

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

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

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

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

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

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

An agreement to transfer ADSs should not give rise to SDRT. SDRT would generally be payable on an unconditional agreement to transfer shares in registered form at 0.5% of the amount or value of the consideration for the transfer, but is repayable if, within six years of the date of the agreement, an instrument transferring the shares is executed or, if the SDRT has not been paid, the liability to pay the tax (but not necessarily interest and penalties) would be cancelled.

HMRC now accepts that stamp duty/SDRT is not payable on issues of UK shares and securities to depositary receipt issuers and clearance services anywhere in the world. HMRC still contends however that stamp duty/SDRT at 1.5% is payable on transfers (by sale or otherwise) of shares and securities to depositary receipt systems or clearance services that are not an integral part of an issue of share capital.

United States federal income taxation considerations

Ownership of ADSs

For U.S. federal income tax purposes, a holder of ADSs generally will be treated as the owner of the ordinary shares represented by such ADSs. Gain or loss will generally not be recognized on account of exchanges of ordinary shares for ADSs, or of ADSs for ordinary shares. References to ordinary shares in the discussion below are deemed to include ADSs, unless context otherwise requires.

U.S. Taxation of Distributions

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

Subject to applicable holding period (which generally requires our Ordinary Shares to be held for at least 61 days without protection from the risk of loss during the 121-day period beginning 60 days before the ex-dividend date) and other limitations, the U.S. Dollar amount of dividends received on our Ordinary Shares or ADSs by certain non-corporate U.S. Holders are currently subject to taxation at a maximum rate of 20% if the dividends are "qualified dividends" and certain other requirements are met. Dividends paid on our Ordinary Shares or ADSs will be treated as qualified dividends if: (i) we are eligible for the benefits of the Treaty or the Ordinary Shares or ADSs are readily tradable on an established U.S. securities market and (ii) we were not, in the year prior to the year in which the dividend was paid, and are not, in the year in which the dividend is paid, a passive foreign investment company, or PFIC. Our ADSs are listed on the NASDAQ Capital Market, which is an established securities market in the United States, and we expect the ADSs to be readily tradable on the NASDAQ Capital Market. However, there can be no assurance that the ADSs will be considered readily tradable on an established securities market in the United States in later years. The Company, which is incorporated under the laws of England and Wales, believes that it qualifies as a resident of the United Kingdom for the purposes of, and is eligible for the benefits of, the Convention between the Government of the United States of America and the Government of the United Kingdom of Great Britain and Northern Ireland for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with Respect to Taxes on Income and Capital Gains, signed on July 24, 2001, or the U.S.-U.K. Tax Treaty, although there can be no assurance in this regard. Further, the IRS has determined that the U.S.-U.K. Tax Treaty is satisfactory for purposes of the qualified dividend rules and that it includes an exchange-of-information program. Based on the foregoing, we expect to be considered a qualified foreign corporation under the Code. Accordingly, dividends paid by us to non-corporate U.S. holders with respect to shares that meet the minimum holding period and other requirements are expected to be treated as "qualified dividend income." However, dividends paid by us will not qualify for the 20% maximum U.S. federal income tax rate if we are treated, for the tax year in which the dividends are paid or the preceding tax year, as a "passive foreign investment company" for U.S. federal income tax purposes, as discussed below. Although we currently believe that distributions on our Ordinary Shares or ADSs that are treated as dividends for U.S. federal income tax purposes should constitute qualified dividends, no assurance can be given that this will be the case. U.S. Holders should consult their tax advisors regarding the tax rate applicable to dividends received by them with respect to our Ordinary Shares or ADSs, as well as the potential treatment of any loss on a disposition of our Ordinary Shares or ADSs as long-term capital loss regardless of the U.S. Holders' actual holding period for our Ordinary Shares or ADSs.

We have not maintained and do not plan to maintain calculations of earnings and profits under U.S. federal income tax principles. Accordingly, it is unlikely that U.S. Holders will be able to establish whether a distribution by us is in excess of our and accumulated earnings and profits (as computed under U.S. federal income tax principles). Thus, it is expected that any distribution will be reported as a dividend, even if that distribution would otherwise be treated as a non-taxable return of capital or as capital gain under the rules described above. The amount of any distribution of property other than cash will be the fair market value of that property on the date of distribution.

The U.S. Treasury Department has announced its intention to issue rules regarding when and to what extent holders of ADSs will be permitted to rely on certifications from issuers to establish that dividends paid on shares to which such ADSs relate are treated as qualified dividends. Because such procedures have not yet been issued, it is not clear whether we will be able to comply with them.

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

U.S. Taxation upon Sale or Other Disposition

Subject to the discussion under “Passive Foreign Investment Company Considerations” below, gain or loss realized by a U.S. Holder on the sale or other disposition of our Ordinary Shares or ADSs will be subject to U.S. federal income taxation as capital gain or loss in an amount equal to the difference between the U.S. Holder’s adjusted tax basis in our Ordinary Shares or ADSs and the amount realized on the disposition. Such gain or loss generally will be treated as long-term capital gain or loss if our Ordinary Shares or ADSs have been held for more than one year at the time of the sale or disposition. Any such gain or loss realized will generally be treated as U.S. source gain or loss. In the case of a non-corporate U.S. Holder, long-term capital gains are currently eligible for federal income tax at preferential rates. The deductibility of capital losses is subject to significant limitations.

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

The maximum individual rate for long-term capital gain is currently 20%.

Medicare Tax

Individuals, estates and trusts are subject to a Medicare tax of 3.8% on “net investment income,” which includes dividends, interest, and capital gain from the sale of investment securities, adjusted for certain deductions properly allocated to such investment income. The Medicare tax will apply to the lesser of such net investment income or the excess of the taxpayer’s adjusted gross income (with certain modifications) over a specified amount. The specified amount is \$250,000 for married individuals filing jointly, \$125,000 for married individuals filing separately, and \$200,000 for single individuals. U.S. Holders should consult with their own tax advisers regarding the application of the net investment income tax to them as a result of their investment in our ADSs or Ordinary Shares.

Passive foreign investment company rules

Based on the nature of our present business operations, assets and income, we believe that for the year 2016, we are not a PFIC. However, no assurance can be given that changes will not occur in our business operations, assets and income that might cause us to be treated as a PFIC at some future time.

We would be a PFIC for U.S. federal income tax purposes in any taxable year if 75% or more of our gross income would be passive income, or on average at least 50% of the gross value of our assets is held for the production of, or produces, passive income. In making the above determination, we are treated as earning our proportionate share of any income and owning our proportionate share of any asset of any company in which we are considered to own, directly or indirectly, 25% or more of the shares by value. If we were considered a PFIC at any time when a U.S. Holder held our Ordinary Shares or ADSs, we generally should continue to be treated as a PFIC with respect to that U.S. Holder, and the U.S. Holder generally will be subject to special rules with respect to (a) any gain realized on the disposition of our Ordinary Shares or ADSs and (b) any “excess distribution” by us to the U.S. Holder in respect of our Ordinary Shares or ADSs. Generally, a distribution during a taxable year to a U.S. Holder with respect to Ordinary Shares would be treated as an “excess distribution” to the extent that the distribution plus all other distributions received (or deemed to be received) by the U.S. Holder during the taxable year with respect to such Ordinary Shares, is greater than 125% of the average annual distributions received by the U.S. Holder with respect to such Ordinary Shares during the three preceding years (or during such shorter period as the U.S. Holder may have held the Ordinary Shares or ADSs). Under the PFIC rules: (i) the gain or excess distribution would be allocated ratably over the U.S. Holder’s holding period for our Ordinary Shares or ADSs, (ii) the amount allocated to the taxable year in which the gain or excess distribution was realized or to any year before we became a PFIC would be taxable as ordinary income and (iii) the amount allocated to each other taxable year would be subject to tax at the highest tax rate in effect in that year and an interest charge generally applicable to underpayments of tax would be imposed in respect of the tax attributable to each such year. Because a U.S. Holder that is a direct (and in certain cases indirect) shareholder of a PFIC is deemed to own its proportionate share of interests in any lower-tier PFICs, U.S. Holders should be subject to the foregoing rules with respect to any of our subsidiaries characterized as PFICs, if we are deemed a PFIC.

In the event we were treated as a PFIC, the tax consequences under the default PFIC regime described above could be avoided by either a “mark-to-market” or “qualified electing fund” election. If our Ordinary Shares or ADSs are considered “marketable stock,” a U.S. Holder may elect to “mark-to-market” its ADSs. A U.S. holder making a mark-to-market election (if the eligibility requirements for such an election were satisfied) generally would not be subject to the PFIC rules discussed above, except with respect to any portion of the holder’s holding period that preceded the effective date of the election. Instead, such U.S. Holder would generally include in income any excess of the fair market value of the Ordinary Shares or ADSs at the close of each tax year over its adjusted basis in the Ordinary Shares or ADSs. If the fair market value of the Ordinary Shares or ADSs had depreciated below the U.S. Holders adjusted basis at the close of the tax year, the U.S. Holder may generally deduct the excess of the adjusted basis of the Ordinary Shares or ADSs over its fair market value at that time. However, such deductions generally would be limited to the net mark-to-market gains, if any, that the U.S. Holder included in income with respect to such Ordinary Shares or ADSs in prior years. Income recognized and deductions allowed under the mark-to-market provisions, as well as any gain or loss on the disposition of Ordinary Shares or ADSs with respect to which the mark-to-market election is made, is treated as ordinary income or loss (except that loss is treated as capital loss to the extent the loss exceeds the net mark-to-market gains, if any, that a U.S. Holder included in income with respect to such Ordinary Share or ADSs in prior years). Gain or loss from the disposition of Ordinary Shares or ADSs (as to which a “mark-to-market” election was made) in a year in which we are no longer a PFIC, will be capital gain or loss. Our Ordinary Shares or ADSs should be considered “marketable stock” if they traded at least 15 days during each calendar quarter of the relevant calendar year in more than de minimis quantities. Any such mark to market election would not be available for a lower-tier PFIC. Alternatively, a U.S. Holder making a valid and timely “qualified electing fund” or “QEF” election generally would not be subject to the default PFIC regime discussed above. Instead, for each PFIC year to which such an election applied, the electing U.S. Holder would be subject to U.S. federal income tax on the electing U.S. Holder’s pro rata share of our net capital gain and ordinary earnings, regardless of whether such amounts were actually distributed to the electing U.S. Holder. Any gain on sale or other disposition of a U.S. Holder’s Ordinary Shares or would be treated as capital, and the interest penalty will not be imposed. However, because we do not intend to prepare or provide the information that would permit the making of a valid QEF election, that election will not be available to U.S. holders.

U.S. Holders are urged to consult their tax advisors about the PFIC rules, including the advisability, procedure and timing of making a mark-to-market election and the U.S. Holder’s eligibility to file such an election (including whether our Ordinary Shares or ADSs are treated as “marketable stock” for such purpose). A U.S. Holder will be required to file Internal Revenue Service Form 8621 if such U.S. Holder owns our Ordinary Shares or ADSs in any year in which we are classified as a PFIC.

Information reporting and backup withholding

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

A non-U.S. Holder generally will not be subject to information reporting or backup withholding with respect to dividends on our Ordinary Shares or ADSs, unless payment is made through a paying agent (or office) in the United States or through certain U.S.-related financial intermediaries. However, a Non-U.S. Holder generally may be subject to information reporting and backup withholding with respect to the payment within the United States of dividends on our Ordinary Shares or ADSs, unless such non-U.S. Holder provides a taxpayer identification number, certifies under penalties of perjury as to its foreign status, or otherwise establishes an exemption.

U.S. individuals (and, under proposed regulations, certain entities) that hold certain specified foreign financial assets, including stock in a foreign corporation, with values in excess of certain thresholds are required to file with their U.S. federal income tax return Form 8938, on which information about the assets, including their value, is provided. Taxpayers who fail to file the form when required are subject to penalties. An exemption from reporting applies to foreign assets held through certain financial institutions. Investors are encouraged to consult with their own tax advisors regarding the possible application of this disclosure requirement to their investment in our Ordinary Shares or ADSs.

Transfer of ADSs

No U.K. stamp duty will be payable on a written instrument transferring an ADS or on a written agreement to transfer an ADS provided that the instrument of transfer or the agreement to transfer is executed and remains at all times outside the United Kingdom. Where these conditions are not met, the transfer of, or agreement to transfer, an ADS could, depending on the circumstances, attract a charge to U.K. stamp duty at the rate of 0.5% of the value of the consideration given in connection with the transfer.

No SDRT will be payable in respect of an agreement to transfer an ADS.

F. Dividends and Paying Agents

Not applicable.

G. Statement by Experts

Not applicable.

H. Documents on Display

We are currently subject to the information and periodic reporting requirements of the Exchange Act, and file periodic reports and other information with the SEC through its electronic data gathering, analysis and retrieval (EDGAR) system. Our securities filings, including this Annual Report and the exhibits thereto, are available for inspection and copying at the public reference facilities of the SEC located at 100 F Street, N.E., Washington, D.C. 20549. You may also obtain copies of the documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street, N.E., Washington, DC 20549. Please call the SEC at 1-800-SEC-0330 for further information on the public reference room. The SEC also maintains a website at <http://www.sec.gov> from which certain filings may be accessed.

As a foreign private issuer, we are exempt from the rules under the Exchange Act related to the furnishing and content of proxy statements, and our officers, directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we are not required under the Exchange Act to file annual, quarterly and current reports and financial statements with the SEC as frequently or as promptly as United States companies whose securities are registered under the Exchange Act.

I. Subsidiary Information

Not applicable.

Item 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT RISK

You should read the following information in conjunction with Item 5, "Operating and Financial Review and Prospects;" Item 3, "Risk Factors;" and our combined and consolidated financial statements, including the related notes thereto, including Note 2, both of which are included elsewhere in this document. The following discussion about our financial risk management activities includes "forward-looking statements" that involve risks and uncertainties. Actual results could differ materially from those projected in these forward-looking statements.

Risk Management Framework

We are exposed to a variety of risks, including changes in foreign currency exchange risk and interest rates.

Currency Exchange Rate Sensitivity

The results of our operations are subject to currency transactional risk. Operating results and financial position are reported in local currencies and then translated into United States dollars at the applicable exchange rate for preparation of our combined and consolidated financial statements. The fluctuation of the U.S. dollar in relation to the British Pound, Euro and Swiss Franc will therefore have an impact upon profitability of our operations and may also affect the value of our assets and the amount of shareholders' equity.

Our functional currency is the United States dollar and our activities are predominantly executed using both the U.S. dollar, Euro and British Pound. We have done a limited number of financings, and we are not subject to significant operational exposures due to fluctuations in these currencies. We have not entered into any agreements, or purchased any instruments, to hedge any possible currency risks at this time.

Interest Rate Sensitivity

We currently have no short-term or long-term debt requiring interest payments. This does not require us to consider entering into any agreements or purchasing any instruments to hedge against possible interest rate risks at this time. Our interest-earning investments are short-term. Thus, any reductions in future income or carrying values due to future interest rate declines are believed to be immaterial.

Item 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

A. Debt Securities

Not applicable.

B. Warrants and Rights

Not applicable.

C. Other Securities

Not applicable.

D. American Depositary Shares

Deutsche Bank Trust Company Americas, as depositary, will register and deliver the ADSs. Each ADS will represent ownership of one hundred (100) Ordinary Shares deposited with State Street Bank & Trust Company, having its principal office at 525 Ferry Road, Crewe Toll, Edinburgh, EH5 2AW Scotland, as custodian for the depositary. Each ADS will also represent ownership of any other securities, cash or other property which may be held by the depositary. The depositary's corporate trust office at which the ADSs will be administered is located at 60 Wall Street, New York, NY 10005, USA. The principal executive office of the depositary is located at 60 Wall Street, New York, NY 10005, USA.

Fees and Charges

As a holder ADSs, you will be required to pay the following service fees to the depositary bank:

<u>Service:</u>	<u>Fee:</u>
Issuance of ADSs, including issuances resulting from a distribution of shares or rights or other property	Up to \$0.05 per ADS issued
Cancellation of ADSs, including in the case of termination of the deposit agreement	Up to \$0.05 per ADS cancelled
Distribution of cash dividends or other cash distributions	Up to \$0.05 per ADS held
Distribution of ADSs pursuant to share dividends, free share distributions or exercise of rights	Up to \$0.05 per ADS held
Distribution of securities other than ADSs or rights to purchase ADSs additional ADSs	A fee equivalent to the fee that would be payable if securities distributed to you had been Ordinary Shares and the Ordinary Shares had been deposited for issuance of ADSs
Depositary services	Up to \$0.05 per ADS held on the applicable record date(s) established by the depositary bank
Transfer of ADRs	\$1.50 per certificate presented for transfer

As an ADS holder, you will also be responsible to pay certain fees and expenses incurred by the depositary bank and certain taxes and governmental charges such as:

- Fees for the transfer and registration of Ordinary Shares charged by the registrar and transfer agent for the Ordinary Shares in the United Kingdom (i.e., upon deposit and withdrawal of Ordinary Shares).
- Expenses incurred for converting foreign currency into U.S. dollars.
- Expenses for cable, telex and fax transmissions and for delivery of securities.
- Taxes and duties upon the transfer of securities, including any applicable stamp duties, any stock transfer charges or withholding taxes (i.e., when Ordinary Shares are deposited or withdrawn from deposit).
- Fees and expenses incurred in connection with the delivery or servicing of Ordinary Shares on deposit.
- Fees and expenses incurred in connection with complying with exchange control regulations and any other regulatory requirements that are not currently applicable but may arise or become applicable to Ordinary Shares, deposited securities, ADSs and ADRs.
- Any applicable fees and penalties thereon.

The depositary fees payable upon the issuance and cancellation of ADSs are typically paid to the depositary bank by the brokers (on behalf of their clients) receiving the newly issued ADSs from the depositary bank and by the brokers (on behalf of their clients) delivering the ADSs to the depositary bank for cancellation. The brokers in turn charge these fees to their clients. Depositary fees payable in connection with distributions of cash or securities to ADS holders and the depositary services fee are charged by the depositary bank to the holders of record of ADSs as of the applicable ADS record date.

The depositary fees payable for cash distributions are generally deducted from the cash being distributed or by selling a portion of distributable property to pay the fees. In the case of distributions other than cash (i.e., share dividends, rights, etc.), the depositary bank charges the applicable fee to the ADS record date holders concurrent with the distribution. In the case of ADSs registered in the name of the investor (whether certificated or uncertificated in direct registration), the depositary bank sends invoices to the applicable record date ADS holders. In the case of ADSs held in brokerage and custodian accounts (via DTC), the depositary bank generally collects its fees through the systems provided by DTC (whose nominee is the registered holder of the ADSs held in DTC) from the brokers and custodians holding ADSs in their DTC accounts. The brokers and custodians who hold their clients' ADSs in DTC accounts in turn charge their clients' accounts the amount of the fees paid to the depositary banks.

In the event of refusal to pay the depositary fees, the depositary bank may, under the terms of the deposit agreement, refuse the requested service until payment is received or may set off the amount of the depositary fees from any distribution to be made to the ADS holder.

The depositary has agreed to reimburse us for a portion of certain expenses we incur that are related to establishment and maintenance of the American Depositary Receipt, or ADR, program, including investor relations expenses. There are limits on the amount of expenses for which the depositary will reimburse us, but the amount of reimbursement available to us is not related to the amounts of fees the depositary collects from investors. Further, the depositary has agreed to reimburse us certain fees payable to the depositary by holders of ADSs. Neither the depositary nor we can determine the exact amount to be made available to us because (i) the number of ADSs that will be issued and outstanding, (ii) the level of service fees to be charged to holders of ADSs and (iii) our reimbursable expenses related to the program are not known at this time.

Payment of Taxes

You will be responsible for any taxes or other governmental charges payable on your ADSs or on the deposited securities represented by any of your ADSs. The depositary may refuse to register any transfer of your ADSs or allow you to withdraw the deposited securities represented by your ADSs until such taxes or other charges are paid. It may apply payments owed to you or sell deposited securities represented by your ADSs to pay any taxes owed and you will remain liable for any deficiency. If the depositary sells deposited securities, it will, if appropriate, reduce the number of ADSs to reflect the sale and pay to you any net proceeds, or send to you any property, remaining after it has paid the taxes. You agree to indemnify us, the depositary, the custodian and each of our and their respective agents, directors, employees and affiliates for, and hold each of them harmless from, any claims with respect to taxes (including applicable interest and penalties thereon) arising from any tax benefit obtained for you.

PART II

Item 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES

A. Defaults

None.

B. Arrears and Delinquencies

None.

Item 14. MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS

The information called for by this item has been reported previously in our Current Reports on Form 8-K filed with the SEC on August 18, 2015 and September 21, 2015 under the heading "Item 3.03 Material Modification to Rights of Security Holders" and is incorporated by reference into this Annual Report.

Item 15. CONTROLS AND PROCEDURES

(a) 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) of the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this Annual Report on Form 20-F, have concluded that, based on such evaluation, our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate, to allow timely decisions regarding required disclosure.

(b) **Management’s Annual 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, 2016, 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, 2016.

(c) **Attestation Report of Registered Public Accounting Firm**

This report does not include an attestation report of our registered public accounting firm as we are an emerging growth company.

(d) **Changes in Internal Controls over Financial Reporting**

There were no changes in our internal control over financial reporting that occurred during the year ended December 31, 2016 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 16. [RESERVED]

Item 16A. Audit Committee Financial Expert

Our board of directors has determined that Mr. Donald Williams is the audit committee financial expert.

Item 16B. Code of Ethics

We have adopted a code of ethics that applies to all of our employees, including our chief executive officer and chief financial and accounting officer. The text of the code of conduct is posted in the “Investor Relations” section of our website at www.akarix.com. Disclosure regarding any amendments to, or waivers from, provisions of the code of conduct that apply to our directors, principal executive and financial officers will be included in a Current Report on Form 8-K within four business days following the date of the amendment or waiver, unless website posting or the issuance of a press release of such amendments or waivers is then permitted by the rules of the NASDAQ stock market.

Item 16C. Principal Accountant Fees and Services

On December 18, 2015, the audit committee of our board of directors engaged BDO AG as our independent registered public accounting firm and we dismissed Kost, Forer, Gabbay & Kasierer, a member of Ernst & Young Global as our independent registered public accounting firm. On April 5, 2016, the audit committee of our board of directors engaged BDO USA, LLP as our independent registered public accounting firm and we dismissed BDO AG as our independent registered public accounting firm.

BDO AG served as our independent registered public accounting firm and audited our financial statements for the year ended December 31, 2015 and BDO USA, LLP served as our independent registered public accounting firm and audited our financial statements for the year ended December 31, 2016.

	2016	2015
Audit Fees ⁽¹⁾	\$ 180,000	\$ 156,135
Audit-Related Fees ⁽²⁾	—	25,000
Tax Fees ⁽³⁾	—	—
All Other Fees ⁽⁴⁾	—	—
Total	\$ 180,000	\$ 181,135

- (1) Audit fees consisted of audit work performed in the preparation of the combined and consolidated financial statements, interim review procedures as well as work generally only the independent registered public accounting firm can reasonably be expected to provide, such as statutory audits.
- (2) Audit related services relate to work regarding a public listing or offering.
- (3) Tax fees relate to tax compliance planning and advice.
- (4) All Other Fees consist of fees for other permissible work not included within the above category descriptions.

Pre-Approval policies and procedures

The audit committee reviews and pre-approves all audit and non-audit services performed by its independent registered public accounting firm, as well as the fees charged for such services. All fees incurred for the year ended 2016 for services rendered by BDO were approved in accordance with these policies. In its review of non-audit service fees, the audit committee considers, among other things, the possible impact of the performance of such services on the auditor's independence. The audit committee has determined that the non-audit services performed by BDO for the year ended December 31, 2016 were compatible with maintaining the auditor's independence.

Item 16D. Exemptions from the Listing Standards for Audit Committees

Not applicable.

Item 16E. Purchases of Equity Securities by the Issuer and Affiliated Purchasers

Not applicable.

Item 16F. Change in Registrant's Certifying Accountant

Not applicable.

Item 16G. Corporate Governance

We rely on a provision in NASDAQ's Listed Company Manual that allows us to follow English corporate law and the Companies Act 2006 with regard to certain aspects of corporate governance. This allows us to follow certain corporate governance practices that differ in significant respects from the corporate governance requirements applicable to U.S. companies listed on NASDAQ.

In accordance with English corporate law and the Companies Act 2006 and practice and subject to the exemption set forth in Rule 5615 of the Marketplace Rules of the NASDAQ Stock Market, we follow the provisions of the Companies Act, rather than the Marketplace Rules of the Nasdaq Stock Market, with respect to the following requirements:

- We do not follow NASDAQ's requirements to seek shareholder approval for the implementation of certain equity compensation plans, the issuances of ordinary shares under such plans, or in connection with certain private placements of equity securities. In accordance with U.K. law, we are not required to seek shareholder approval to allot ordinary shares in connection with applicable employee equity compensation plans. We will follow U.K. law with respect to any requirement to obtain shareholder approval prior to any private placements of equity securities.

As a foreign private issuer, we are permitted to, and we will, follow home country practice in lieu of the above requirements.

Because we are a foreign private issuer, our directors and senior management are not subject to short-swing profit and insider trading reporting obligations under Section 16 of the U.S. Securities Exchange Act of 1934, as amended, or Exchange Act. They are, however, subject to the obligations to report changes in share ownership under Section 13 of the Exchange Act and related SEC rules.

Item 16H. Mine Safety Disclosures

Not applicable.

PART III

Item 17. FINANCIAL STATEMENTS

We have responded to Item 18 in lieu of this item.

Item 18. FINANCIAL STATEMENTS

Financial Statements are filed as part of this annual report. See page F-1.

Item 19. EXHIBITS

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 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.)
4.8	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).
4.9	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	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.)
10.5	Form of Working Capital Agreement, by and between Volution Immuno Pharmaceuticals SA and the Shareholders named therein. (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+	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.)
10.7	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.)
10.8	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.)
10.09+	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.)
10.10+	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.)
10.11+	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.)
10.12+	Letter Agreement between the Company and Ray Prudo dated September 21, 2015*
10.13+	Side Letter between the Company and Ray Prudo dated September 21, 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.)
10.15+	Executive Employment Agreement, dated March 23, 2016, by and between the Company and Robert Shaw.*
10.16+	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 June 30, 2016.)
10.17+	Amendment No. 1 to Employment Agreement dated February 15, 2017 between the Company and Robert Shaw.*
21.1	List of subsidiaries*
23.1	Consent of registered public accounting firm*
23.2	Consent of registered public accounting firm*
31.1	Certification of Chief Executive Officer*
31.2	Certification of the Chief Financial Officer*
32.1	Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002*
32.2	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.
* Filed herewith

SIGNATURES

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

Akari Therapeutics, PLC

By: /s/ Gur Roshwalb

Name: Gur Roshwalb

Title: Chief Executive Officer

Date: March 31, 2017

AKARI THERAPEUTICS, PLC
COMBINED AND CONSOLIDATED FINANCIAL STATEMENTS
AS OF DECEMBER 31, 2016

U.S. DOLLARS

INDEX

	Page
Report of Independent Registered Public Accounting Firm	F-1
Report of Independent Registered Public Accounting Firm	F-2
Combined and Consolidated Balance Sheets	F-3
Combined and Consolidated Statements of Comprehensive Loss	F-4
Combined and Consolidated Statements of Changes in Shareholders' Equity	F-5
Combined and Consolidated Statements of Cash Flows	F-6
Notes to Combined and Consolidated Financial Statements	F-7 – F-25

Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders
Akari Therapeutics, Plc
London, United Kingdom

We have audited the accompanying consolidated balance sheet of Akari Therapeutics, Plc as of December 31, 2016 and the related consolidated statements of comprehensive loss, shareholders' equity, and cash flows for the year ended December 31, 2016. 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 audit.

We conducted our audit 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 audit 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 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 audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Akari Therapeutics, Plc at December 31, 2016, and the results of its operations and its cash flows for the year ended December 31, 2016, in conformity with accounting principles generally accepted in the United States of America.

/s/ BDO USA, LLP

New York, New York

March 31, 2017



Tel. +41 44 444 35 55
Fax +41 44 444 37 66

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 sheet of Akari Therapeutics, Plc as of December 31, 2015 and the related combined and consolidated statements of comprehensive loss, 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 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
 (in U.S. Dollars, except share data)

	December 31, 2016	December 31, 2015
Assets		
Current Assets:		
Cash and cash equivalents	\$ 34,098,812	\$ 68,919,995
Short-term investments	10,021,963	-
Prepaid expenses and other current assets	1,513,006	728,126
Receivable from related party	-	10,366
Total Current Assets	<u>45,633,781</u>	<u>69,658,487</u>
Restricted cash	142,168	142,079
Property and equipment, net	58,364	40,513
Patent acquisition costs, net	39,365	52,483
Total Assets	<u>\$ 45,873,678</u>	<u>\$ 69,893,562</u>
Liabilities and Shareholders' Equity		
Current Liabilities:		
Accounts payable	\$ 2,214,313	\$ 4,320,588
Accrued expenses	1,837,647	408,222
Liabilities related to options and warrants	7,662,808	16,396,158
Total Current Liabilities	<u>11,714,768</u>	<u>21,124,968</u>
Other long-term liability	56,360	49,069
Total liabilities	<u>11,771,128</u>	<u>21,174,037</u>
Commitments and Contingencies		
Shareholders' Equity:		
Share capital of GBP .01 par value		
Authorized: 5,000,000,000 ordinary shares; issued and outstanding: 1,177,693,383 at December 31, 2016 and 2015, respectively	18,340,894	18,340,894
Additional paid-in capital	90,979,363	87,018,764
Accumulated other comprehensive (loss) income	(280,097)	156,480
Accumulated deficit	(74,937,610)	(56,796,613)
Total Shareholders' Equity	<u>34,102,550</u>	<u>48,719,525</u>
Total Liabilities and Shareholders' Equity	<u>\$ 45,873,678</u>	<u>\$ 69,893,562</u>

See notes to combined and consolidated financial statements.

AKARI THERAPEUTICS, Plc

COMBINED AND CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
For the Years Ended December 31, 2016, 2015 and 2014
(in U.S. Dollars)

	December 31 , 2016	Years Ended December 31, 2015	December 31, 2014
Operating Expenses:			
Research and development costs	\$ 17,306,001	\$ 5,799,076	\$ 1,616,204
General and administrative expenses	9,940,557	5,502,214	303,095
Excess consideration	-	19,283,280	-
Total Operating Expenses	<u>27,246,558</u>	<u>30,584,570</u>	<u>1,919,299</u>
Loss from Operations	<u>(27,246,558)</u>	<u>(30,584,570)</u>	<u>(1,919,299)</u>
Other Income (Expense):			
Interest income	143,195	20,705	91
Changes in fair value of option and warrant liabilities - gains	8,733,350	11,408,231	-
Financing expense	-	(22,973,138)	-
Foreign currency exchange gain (loss)	272,985	(90,588)	(22,909)
Interest expense	-	(3,053,948)	(5,436)
Other expenses	(43,969)	(44,224)	-
Total Other Income (Expense)	<u>9,105,561</u>	<u>(14,732,962)</u>	<u>(28,254)</u>
Net Loss	<u>(18,140,997)</u>	<u>(45,317,532)</u>	<u>(1,947,553)</u>
Other Comprehensive (Loss) Income:			
Foreign Currency Translation Adjustment	<u>(436,577)</u>	<u>110,399</u>	<u>79,438</u>
Comprehensive Loss	<u>\$ (18,577,574)</u>	<u>\$ (45,207,133)</u>	<u>\$ (1,868,115)</u>
Loss per common share (basic and diluted)	<u>\$ (0.02)</u>	<u>\$ (0.05)</u>	<u>\$ (0.02)</u>
Weighted average common shares (basic and diluted)	<u>1,177,693,383</u>	<u>852,088,530</u>	<u>85,515,588</u>

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 Years Ended December 31, 2016, 2015 and 2014
(in U.S. Dollars)

	<i>Varleigh Immuno Pharmaceuticals Ltd</i>		<i>Akari Therapeutics, Plc</i>		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount				
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
Stock-based compensation	-	-	-	-	3,933,222	-	-	3,933,222
Dissolution of subsidiary	-	-	-	-	27,377	-	-	27,377
Comprehensive Loss	-	-	-	-	-	(436,577)	(18,140,997)	(18,577,574)
Shareholders' Equity, December 31, 2016	-	\$ -	1,177,693,383	\$ 18,340,894	\$ 90,979,363	\$ (280,097)	\$ (74,937,610)	\$ 34,102,550

See notes to combined and consolidated financial statements.

AKARI THERAPEUTICS, Plc

COMBINED AND CONSOLIDATED STATEMENTS OF CASH FLOWS
For the Years Ended December 31, 2016, 2015 and 2014
(in U.S. Dollars)

	Year Ended		
	December 31, 2016	December 31, 2015	December 31, 2014
Cash Flows from Operating Activities:			
Net loss	\$ (18,140,997)	\$ (45,317,532)	\$ (1,947,553)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	39,944	10,162	4,942
Stock-based compensation	3,933,222	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	(8,733,350)	(11,408,231)	-
Foreign currency exchange gains	(272,985)	-	-
Changes in operating assets and liabilities:			
(Increase) decrease in assets:			
Prepaid expenses and other current assets	(785,876)	913,788	(8,422)
(Decrease) increase in liabilities:			
Accounts payable and accrued expenses	(671,784)	3,755,173	474,209
Other liabilities	7,291	3,469	-
Total adjustments	(6,483,538)	40,351,949	470,729
Net Cash Used in Operating Activities	(24,624,535)	(4,965,583)	(1,476,824)
Cash Flows from Investing Activities:			
Purchase of property and equipment	(54,750)	(10,560)	-
Cash received from reverse acquisition	-	1,410,577	-
Purchase of short-term investments	(46,120,172)	-	-
Maturities of short-term investments	36,098,209	-	-
Receivable from related party	10,081	(8,219)	-
Net Cash (Used) Provided by Investing Activities	(10,066,632)	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
Share 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	(130,016)	121,893	15,262
Net (Decrease) Increase in Cash and Cash Equivalents	(34,821,183)	65,592,527	2,773,814
Cash and Cash Equivalents, beginning	68,919,995	3,327,468	553,654
Cash and Cash Equivalents, end	\$ 34,098,812	\$ 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.

AKARI THERAPEUTICS, Plc

NOTES TO COMBINED AND CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2016 and 2015
(in U.S. Dollars)

NOTE 1 - Nature of Business

Akari Therapeutics, Plc, (the “Company” or “Akari”), formerly Celsus Therapeutics Plc (“Celsus”), is incorporated in the United Kingdom. The Company is a clinical-stage biopharmaceutical company focused on developing inhibitors of acute and chronic inflammation, specifically the complement system, the eicosanoid system and the bioamine system for the treatment of rare and orphan diseases.

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 (as 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 Ordinary Shares. The Company’s earnings (loss) per share have been retrospectively adjusted in the Combined and Consolidated Statements 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 generally accepted accounting principles (“U.S. GAAP”). Accordingly, the assets and liabilities of Celsus have been recorded as of the Acquisition closing date at fair value and the condensed consolidated financial statements reflect the historical financial statements of Volution as the Company’s historical financial statements.

The Company, as defined 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 at a price of \$18.945 per restricted ADS (the “Financing”), which represented approximately 33.3% of the outstanding Ordinary Shares of the Company after giving effect to the Acquisition and the Financing. In connection with the private placement, the Company incurred \$5.4 million of share issuance costs for net proceeds of \$69.6 million.

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.

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.

AKARI THERAPEUTICS, Plc

NOTES TO COMBINED AND CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2016 and 2015
(in U.S. Dollars)

NOTE 1 - Nature of Business (cont.)

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 Consolidation – The Combined and Consolidated Financial Statements include the accounts of the Company, Volution and Volution Immuno Pharmaceuticals Ltd (a private limited company incorporated in England and Wales), its wholly-owned subsidiary, which was incorporated in London on August 22, 2014. On September 6, 2016, Volution Immuno Pharmaceuticals Ltd was dissolved.

All intercompany transactions have been eliminated.

Foreign Currency – The functional currency of the Company 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 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 (loss) income. Gains or losses from foreign currency transactions are included in foreign currency exchange gains (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 in the evaluation of impairment and useful lives of intangible assets (patents), accrued liabilities, deferred income taxes, liabilities related to stock 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, short-term investments, restricted cash, receivable from related party and accounts payable approximate fair value due to their short-term maturities.

The Company's liabilities related to options and warrants relate 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 Statements of Comprehensive Loss and included in changes in fair value of option/warrant liabilities.

AKARI THERAPEUTICS, Plc

NOTES TO COMBINED AND CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2016 and 2015
(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 as of December 31, 2016 and December 31, 2015.

Short-term investments – Short-term investments consist of certificates of deposit that are expected to be converted into cash within one year.

Restricted cash - Restricted cash is collateral for a letter of credit related to the Company's office lease.

Prepaid Expenses and Other Current Assets – Prepaid expenses and other current 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:

	<u>Years</u>
Computers, peripheral, and scientific equipment	3
Office furniture and equipment	3

Depreciation expense for the years ended December 31, 2016, 2015 and 2014 was \$36,898, \$7,040 and \$3,051, respectively.

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 22 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 the Company's 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, the Company estimates are most affected by its understanding of the status and timing of services provided relative to the actual services incurred by the service providers. In the event that the Company does not identify certain costs that have been incurred or it under or over-estimates 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. The Company makes these judgments based upon the facts and circumstances known to us in accordance with U.S. GAAP.

AKARI THERAPEUTICS, Plc

NOTES TO COMBINED AND CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2016 and 2015
(in U.S. Dollars)

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

Research and Development Expenses – Costs associated with research and development are expensed as incurred. Research and development expenses include, among other costs, personnel expenses, costs incurred by outside laboratories, manufacturers' and other accredited facilities in connection with clinical trials and preclinical studies. Research and development expense for the years ended December 31, 2016, 2015 and 2014 was \$17,306,001, \$5,799,076 and \$1,616,204, respectively. The Company accounts for research and development tax credits at the time its realization becomes probable. In September 2016, the Company realized research and development tax credits of \$577,671 that was recorded as a credit to research and development costs in the Combined and Consolidated Statements of Comprehensive Loss.

Stock-Based Compensation Expense – Stock-based compensation expense is recorded using the fair-value based method for all awards granted. Compensation costs for stock options and awards is recorded in earnings (loss) 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. 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 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 changes in fair value of option/warrant liabilities.

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.

Uncertain Tax Positions – The Company follows the provisions of ASC 740 "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, accounting in interim periods, disclosure, and transition. Under ASC 740 "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. As of December 31, 2016 and December 31, 2015, the Company had no uncertain tax positions.

AKARI THERAPEUTICS, Plc

NOTES TO COMBINED AND CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2016 and 2015
(in U.S. Dollars)

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

Earnings (Loss) 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 Ordinary Shares 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 Ordinary Shares 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 (loss) (AOCI), which is comprised of foreign currency translation adjustments, as presented in the balance sheets at December 31, 2016 and 2015:

Balance January 1, 2014	\$	(33,357)
Net current period other comprehensive income		79,438
Balance December 31, 2014		<u>46,081</u>
Net current period other comprehensive income		110,399
Balance December 31, 2015		<u>156,480</u>
Net current period other comprehensive loss		(436,577)
Balance December 31, 2016	\$	<u><u>(280,097)</u></u>

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2014-09, “Revenue from Contracts with Customers” (“ASU 2014-09”), which supersedes nearly all existing revenue recognition guidance under GAAP. The core principle of ASU 2014-09 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration to which an entity expects to be entitled for those goods or services. ASU 2014-09 defines a five step process to achieve this core principle and, in doing so, more judgment and estimates may be required within the revenue recognition process than are required under existing GAAP. On July 9, 2015, the FASB voted to defer the effective date by one year to December 15, 2017 for interim and annual reporting periods beginning after that date. Early adoption of ASU 2014-09 is permitted but not before the original effective date (annual periods beginning after December 15, 2016). When effective, ASU 2014-09 prescribes either of the following transition methods: (i) a full retrospective approach reflecting the application of the standard in each prior reporting period with the option to elect certain practical expedients; or (ii) a retrospective approach with the cumulative effect of initially adopting ASU 2014-09 recognized at the date of adoption (which includes additional footnote disclosures). The Company does not believe the adoption of this standard will have a material impact on our financial position, results of operations or related financial statement disclosures.

AKARI THERAPEUTICS, Plc

NOTES TO COMBINED AND CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2016 and 2015
(in U.S. Dollars)

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

In February 2016, the FASB issued ASU No. 2016-02, *Leases* (ASU 2016-02"). ASU 2016-02 establishes a right-of-use (ROU) model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. The new standard is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. The Company is currently evaluating the impact of its pending adoption of the new standard on the Combine and Consolidated Financial Statements.

In March 2016, the FASB issued ASU No. 2016-09, *Improvements to Employee Share-Based Payment Accounting* ("ASU No. 2016-09"). ASU 2016-09 simplifies various aspects related to how share-based payments are accounted for and presented in the Combined and Consolidated Financial Statements. The amendments include income tax consequences, the accounting for forfeitures, classification of awards as either equity or liabilities and classification on the statement of cash flows. The guidance is effective for annual periods beginning after December 15, 2016, and interim periods within those annual periods. The Company does not believe the adoption of this standard will have a material impact on its financial position, results of operations or related financial statement disclosures.

In August 2016, the FASB issued ASU 2016-15, *Classification of Certain Cash Receipts and Cash Payments*, which addresses eight specific cash flow issues with the objective of reducing the existing diversity in practice, including presentation of cash flows relating to contingent consideration payments, proceeds from the settlement of insurance claims, and debt prepayment or debt extinguishment costs, among other matters. This guidance is effective for fiscal years beginning after December 15, 2018, and interim periods within fiscal years beginning after December 15, 2019. Early adoption is permitted, including adoption in an interim period. If adopted in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes that interim period. Adoption of this guidance is required to be applied using a retrospective transition method to each period presented, unless impracticable to do so. The Company does not believe the adoption of this standard will have a material impact on our financial position, results of operations or related financial statement disclosures.

In October 2016, the FASB issued ASU 2016-16, *Intra-Entity Transfers of Assets Other Than Inventory*. This guidance removes the prohibition in ASC 740 against the immediate recognition of the current and deferred income tax effects of intra-entity transfers of assets other than inventory. This guidance is intended to reduce the complexity of U.S. GAAP and diversity in practice related to the tax consequences of certain types of intra-entity asset transfers, particularly those involving intellectual property. This guidance is effective for annual reporting periods beginning after December 15, 2018, and interim periods within fiscal years beginning after December 15, 2019. Early adoption is permitted. The Company is currently evaluating the impact of this guidance on its consolidated financial statements

In November 2016, the FASB issued ASU, 2016-18, *Restricted Cash*, which requires that restricted cash be included with cash and cash equivalents when reconciling the beginning and ending total amounts shown on the statement of cash flows. This guidance is effective for fiscal years beginning after December 15, 2018, and interim periods within fiscal years beginning after December 15, 2019 and should be applied using a retrospective transition method to each period presented. Early adoption is permitted, including adoption in an interim period. If an entity early adopts the amendments in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes that interim period. The Company has not yet determined the timing of adoption. The Company currently presents changes in restricted cash within investing activities and so the adoption of this guidance will result in changes in net

AKARI THERAPEUTICS, Plc

NOTES TO COMBINED AND CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2016 and 2015
(in U.S. Dollars)

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

cash flows from investing activities and to certain beginning and ending cash and cash equivalent totals shown on Combined and Consolidated Statement of Cash Flows. The Company does not believe the adoption of this standard will have a material impact on its financial position, results of operations or related financial statement disclosures.

NOTE 3 – Reverse Acquisition

The Company completed the 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.

The acquisition consideration for accounting purposes consisted of 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. The 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).

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 Ordinary Shares outstanding	\$	20,034,625	(a)
Fair value of Celsus share options		277,461	(2,516,690 options)
Fair value of Celsus warrants		27,054	(1,782,246 warrants)
Total purchase price	\$	<u>20,339,140</u>	

(a) computed by multiplying 55,636,283 Ordinary Shares of Celsus at Acquisition by the closing stock price on September 18, 2015, of \$0.3601.

Allocation of Purchase Consideration

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.

AKARI THERAPEUTICS, Plc

NOTES TO COMBINED AND CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2016 and 2015
(in U.S. Dollars)

NOTE 3 – Reverse Acquisition (cont.)

The following table summarizes the allocation of the purchase consideration to the assets acquired and liabilities assumed based on their fair values at 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
Liabilities related to options and warrants	(1,800,154)
Other assumed liabilities	(368,670)
	<u>\$ 20,339,140</u>

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 realized and the values assigned to the identifiable tangible and intangible assets acquired and liabilities assumed. The Company recorded this non-cash charge in the Combined and Consolidated Statements of Comprehensive Loss for the year ended December 31, 2015 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 and are amortized over the useful life of the patent determined to be 22 years, as of December 31, 2016 and December 31, 2015 consisted of the following:

	December 31, 2016	December 31, 2015
Patent acquisition and related costs	\$ 92,434	\$ 95,050
Less: Accumulated amortization	(53,069)	(42,567)
	<u>\$ 39,365</u>	<u>\$ 52,483</u>

Amortization of patent acquisition costs for the years ended December 31, 2016, 2015 and 2014 was \$3,046, \$3,122 and \$1,891, respectively.

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

Year Ended	Amount
2017	\$ 2,944
2018	2,944
2019	2,944
2020	2,944
2021	2,944
Thereafter	24,645
	<u>\$ 39,365</u>

AKARI THERAPEUTICS, Plc

NOTES TO COMBINED AND CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2016 and 2015
(in U.S. Dollars)

NOTE 5 – Loans Payable – Shareholders

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 in the consolidated balance sheet for \$26 million reflected in current liabilities in the December 31, 2015 Combined and Consolidated 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 the Combined and Consolidated 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 Combined and Consolidated Statement of Comprehensive Loss.

Interest expense included in the Combined and Consolidated Statements of comprehensive loss related to loans for the years ended December 31, 2016, 2015 and 2014 was \$0, \$3,053,948 and \$5,436, respectively. The shareholder loans from 2014 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, short-term investments, receivable from related party, restricted cash and accounts payable 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.

AKARI THERAPEUTICS, Plc

NOTES TO COMBINED AND CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2016 and 2015
(in U.S. Dollars)

NOTE 6 – Fair Value Measurements (cont.)

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.

	December 31, 2016		December 31, 2015		Fair Value Levels
	Carrying Amount \$	Fair Value \$	Carrying Amount \$	Fair Value \$	
Liability related to RPC options	7,627,970	7,627,970	15,711,017	15,711,017	3
Liability related to warrants	34,838	34,838	685,141	685,141	3

In accordance with ASC No. 820, the Company measures its liabilities related to options and warrants on a recurring basis at fair value. The liabilities related to options and warrants are classified within Level 3 value hierarchy because the liabilities are 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 terms and accordingly are recorded as liabilities.

	December 31, 2016		December 31, 2015		Fair Value Levels	Reference
	Carrying Amount \$	Fair Value \$	Carrying Amount \$	Fair Value \$		
Cash and cash equivalents	34,098,812	34,098,812	68,919,995	68,919,995	1	Note 2
Short-term investment	10,021,963	10,021,963	-	-	1	Note 2
Restricted cash	142,168	142,168	142,079	142,079	1	Note 2
Accounts payable	2,214,313	2,214,313	4,320,588	4,320,588	1	-
Liability related to options and warrants	7,662,808	7,662,808	16,396,158	16,396,158	3	Note 6

On 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, 2016, the fair value of the warrants was \$34,838. The net change in fair value of \$650,303 was recognized as change in fair value of option and warrant liabilities in the Company's Combined Consolidated Statement of Comprehensive Loss. The warrants expire on April 4, 2017.

AKARI THERAPEUTICS, Plc

NOTES TO COMBINED AND CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2016 and 2015
(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 Combined and Consolidated Statements of Comprehensive Loss as a change in fair value of option/warrant liabilities.

The fair value of warrants granted was measured using the Binomial method of valuation. Fair values were estimated using the following assumptions for the warrants:

	December 31,	
	2016	2015
Expected dividend yield	0%	0%
Expected volatility	73.39%	233.0%
Risk-free interest	0.51%	0.75%
Expected life	0.26 years	1.26 years

In June 2015, 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 RPC options were accounted for in accordance with ASC 718, “Compensation – Stock Compensation”. The fair value of the RPC options is estimated using the fair value of Akari Ordinary Shares times RPC’s ownership in Akari Ordinary Shares times 15% and was initially valued at approximately \$26 million. These options do not relate to the share capital of Akari. The exact terms of these options have not been finalized. In September 2015, the Company recorded a liability to share options 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 Combined and Consolidated Statements of Comprehensive Loss as a credit to the loan discount. The remaining \$23 million was recorded as a non-cash financing expense in the Combined and Consolidated Statements of Comprehensive Loss during the quarter-ended September 30, 2015.

As of December 31, 2016, the fair value of the RPC options was \$7,627,970. The fair value of the RPC options for the year ended December 31, 2016 decreased by \$8,083,047 and the change was recognized as change in fair value of option/warrant liabilities in the Combined and Consolidated Statements of Comprehensive Loss. As of December 31, 2015, the fair value of the RPC options was \$15,711,017. The Company accounts for the RPC 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 instruments as of the following dates:

	December 31,	
	2016	2015
	Fair value measurements using input type Level 3	
Warrants	\$ 34,838	\$ 685,141
RPC options	7,627,970	15,711,017
Liabilities related to stock options and warrants	<u>\$ 7,662,808</u>	<u>\$ 16,396,158</u>

AKARI THERAPEUTICS, Plc

NOTES TO COMBINED AND CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2016 and 2015
(in U.S. Dollars)

NOTE 6 – Fair Value Measurements (cont.)

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

	Fair value of liabilities related to stock options and warrants
Balance at December 31, 2014	\$ -
Balance at September 18, 2015 (Acquisition)	<u>1,800,154</u>
Changes in values of liabilities related to options and warrants	(11,408,231)
Value of liability related to options - transfer in	26,004,235
Balance at December 31, 2015	<u>16,396,158</u>
Changes in values of liabilities related to options and warrants	(8,733,350)
Balance at December 31, 2016	<u>\$ 7,662,808</u>

NOTE 7 – Shareholders' Equity

Share Capital – The Company has 5,000,000,000 Ordinary Shares of authorized capital and 1,177,693,383 Ordinary Shares outstanding at December 31, 2016 and 2015.

On September 18, 2015, in connection with the Acquisition, 55,636,283 Ordinary 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 Ordinary 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 Ordinary 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. The Company also paid MTS \$500,000 in cash. These amounts were recorded in general and administrative expenses on the Combined and Consolidated Statements of Comprehensive Loss for the year ended December 31, 2015.

Share option plan –

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 Ordinary Shares. At December 31, 2016, 61,770,222 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 expire ten years after the grant date and typically vest over one to four years.

AKARI THERAPEUTICS, Plc

NOTES TO COMBINED AND CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2016 and 2015
(in U.S. Dollars)

NOTE 7 – Shareholders’ Equity (cont.)

The following is a summary of the Company’s share option activity and related information for employees and directors for the year ended December 31, 2016:

	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, 2016	61,362,198	\$ 0.34		9.7	\$ -
Changes during the period:					
Granted	22,700,000	\$ 0.14	\$ 0.09		
Forfeited	(4,690,000)	\$ 0.21	\$ 0.12		
Options outstanding at December 31, 2016	79,372,198	\$ 0.29		8.7	\$ -
Exercisable options at December 31, 2016	25,486,486	\$ 0.34		8.7	\$ -

The following is a summary of the Company’s non-vested share options at December 31, 2016 and changes during the year ended December 31, 2016:

	Number of shares	Weighted average grant date fair value
Non-vested options at December 31, 2015	58,480,181	\$ 0.21
Options granted	22,700,000	\$ 0.09
Options vested	(22,604,469)	\$ 0.18
Non-vested options forfeited	(4,690,000)	\$ 0.12
Non-vested at December 31, 2016	53,885,712	\$ 0.24

On March 23, 2016, the Company granted 11,000,000 options to its employees at an exercise price of \$0.141 per share that vest semi-annually over four years. On April 22, 2016, the Company granted 1,300,000 options to a director at an exercise price of \$0.18 per share that vest annually over three years. On June 29, 2016, the Company granted 7,800,000 options to its directors at an exercise price of \$0.145 per share, 6,500,000 which will vest in full on the date of the Company’s 2017 Annual General Meeting and 1,300,000 of which will vest over three years. On October 13, 2016, the Company granted 1,300,000 options to a director at an exercise price of \$0.080621 per share which will vest equally over three years on the date of the Company’s 2017-2019 Annual General Meetings, with the first vesting on the date of the Company’s 2017 Annual General Meeting. On October 13, 2016, the Company granted 1,300,000 options to a resigning director at an exercise price of \$ 0.080621 per share which vested immediately upon grant.

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

AKARI THERAPEUTICS, Plc

NOTES TO COMBINED AND CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2016 and 2015
(in U.S. Dollars)

NOTE 7 – Shareholders’ Equity (cont.)

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 share price volatility, which is calculated based on the historical volatility of the Company’s Ordinary Shares. 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 share 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.

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 amounts from one balance sheet date to another to compensation expense. Below are the assumptions used for the options granted during the year:

	December 31,		
	2016	2015	2014
Expected dividend yield	0%	0%	-
Expected volatility	74.18%-80.71%	71.28%-81.79%	-
Risk-free interest	1.03%-1.52%	1.51%-2.27%	-
Expected life	5.5-6.25 years	5.5-10 years	-

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

Exercise price (range) (\$)	Options outstanding at December 31, 2016	Weighted average remaining contractual life (years)	Weighted average exercise price (\$)	Options exercisable at December 31, 2016	Remaining contractual life (years for exercisable options)	Weighted average exercise price (\$)
0.08-0.19	24,313,351	9.31	0.15	6,950,054	9.22	0.15
0.32	53,597,347	8.72	0.32	17,239,932	8.72	0.32
0.60-0.75	290,000	7.20	0.72	290,000	7.20	0.72
0.98-1.56	311,500	3.24	1.31	311,500	3.24	1.31
2.00	860,000	6.73	2.00	695,000	6.73	2.00
	79,372,198			25,486,486		

During the year ended December 31, 2016, the Company recorded approximately \$3,933,000 in stock-based compensation expenses for employees and directors. At December 31, 2016, there was approximately \$8,957,000 of unrecognized compensation cost related to unvested share-based compensation arrangements granted under the Company’s share option plans which the Company expects to recognize over 2.7 years.

AKARI THERAPEUTICS, Plc

NOTES TO COMBINED AND CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2016 and 2015
(in U.S. Dollars)

NOTE 7 – Shareholders’ Equity (cont.)

Warrants to service providers and investors –

The warrants outstanding at December 31, 2016, classified as equity, were issued in connection with several private placements of the Company 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		

NOTE 8 – Related Party Transactions

Accounting Services – An entity related to a shareholder provided accounting and bookkeeping services of approximately \$45,000, \$131,000 and \$25,000, respectively, to the Company during the years ended December 31, 2016, 2015 and 2014, respectively.

Office Lease - A non-employee director of the Company is also the CEO of The Doctors Laboratory (“TDL”). The Company leases its UK office space from TDL and has incurred expenses of approximately \$142,000 and \$10,000 plus VAT during the years ended December 31, 2016 and 2015, respectively (see Note 9).

Other – At December 31, 2015, there was 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 amount is recorded under “Receivable from related party” within current assets on the balance sheet. At December 31, 2016, the balance was \$0.

NOTE 9 - Commitments and Contingencies

Lease commitment – In March 2014, the Company entered into a lease agreement for offices in London which was amended January 1, 2016. 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 (See Note 8).

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 at December 31, 2016:

	London	United States
2017	\$ 128,810	\$ 312,909
2018	128,810	330,291
2019	25,970	225,297
	\$ 283,590	\$ 868,497

For the years ended December 31, 2016 and December 31, 2015, the Company incurred rental expense in the amount of approximately \$445,000 and \$104,000, respectively.

AKARI THERAPEUTICS, Plc

NOTES TO COMBINED AND CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2016 and 2015
(in U.S. Dollars)

NOTE 10 – Earnings Per Share

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

Earnings per share	Years Ended December 31,		
	2016	2015	2014
Company posted	Net loss	Net loss	Net loss
Basic weighted average shares outstanding	1,177,693,383	852,088,530	85,515,588
Dilutive effect of Ordinary Share equivalents	None	None	None
Dilutive weighted average shares outstanding	1,177,693,383	852,088,530	85,515,588

For purposes of the diluted net loss per share calculation, share 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 share equivalents that were excluded from the computation of diluted earnings (loss) per share for the respective periods because the effect would have been anti-dilutive:

	Year Ended December 31, 2016	Year Ended December 31, 2015	Year Ended December 31, 2014
Total share options	79,372,198	61,362,198	-
Total warrants-equity classified	1,782,246	1,782,246	-
Total warrants-liability classified	5,806,280	5,806,280	-
Total share options and warrants	86,960,724	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, 2016 is 20%, reduced from 20.25% from December 31, 2015.

Tax assessment:

The periods open to inquiry by the United Kingdom ("UK") tax authorities are 2015 and 2016. The Company has not been issued final tax assessments since its establishment in Switzerland.

AKARI THERAPEUTICS, Plc

NOTES TO COMBINED AND CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2016 and 2015
(in U.S. Dollars)

NOTE 11 – Taxes (cont.)

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.

At December 31, 2016 and 2015, 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.

The components of loss before income taxes are as follows:

	<u>December 31, 2016</u>	<u>December 31, 2015</u>	<u>December 31, 2014</u>
Domestic (UK)	\$ (17,956,167)	\$ (39,599,123)	\$ (332,663)
Foreign	(184,830)	(5,718,409)	(1,614,890)
Loss before income tax	<u>\$ (18,140,997)</u>	<u>\$ (45,317,532)</u>	<u>\$ (1,947,553)</u>

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

	<u>December 31, 2016</u>	<u>December 31, 2015</u>	<u>December 31, 2014</u>
Current income taxes			
Domestic (UK)	-	-	-
Foreign	-	-	-
Deferred income taxes			
Domestic (UK)	-	-	-
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:

	<u>December 31, 2016</u>	<u>December 31, 2015 (Revised)</u>	<u>December 31, 2014</u>
Net loss before income tax	(18,140,997)	(45,317,532)	(1,947,553)
Statutory rate	20.00%	20.25%	21.50%
Expected income tax recovery	(3,628,199)	(9,176,800)	(418,724)
Impact on income tax expense/recovery from			
Change in valuation allowance	1,336,161	7,447,002	572,139
Permanent differences – excess consideration	-	3,904,864	-
Permanent differences - liability related to options and warrants	(130,061)	(225,748)	-
Change of tax rate from prior year	80,986	15,596	-
Tax rate difference in foreign jurisdictions	2,341,113	(1,964,914)	(153,415)
Income tax expense	<u>-</u>	<u>-</u>	<u>-</u>

AKARI THERAPEUTICS, Plc

NOTES TO COMBINED AND CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2016 and 2015
(in U.S. Dollars)

NOTE 11 – Taxes (cont.)

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

	December 31, 2016	December 31, 2015 (Revised)
Deferred tax assets		
Stock-based compensation	994,618	210,573
Stock option and warrant revaluation	1,525,594	3,181,481
Tax loss carry forward	13,370,548	11,162,545
Valuation allowance	(15,890,760)	(14,554,599)
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.

The following changes were made in this Note 11 to correct errors in prior periods:

- At December 31, 2015, the Company’s deferred income tax asset for stock option and warrant revaluation was increased by \$3.1 million, and the valuation allowance for deferred income taxes was increased accordingly.
- the Company re-allocated the deferred tax assets among its various filing jurisdictions and the foreign tax rate differential was reduced accordingly.

In 2016, as a result of a transfer pricing adjustment, the Company has re-allocated the deferred tax assets among its various filing jurisdictions. Due to the different statutory rates in effect in those jurisdictions, the total deferred tax asset has been reduced; however, because the Company continues to have a full valuation allowance against all of its deferred tax assets, this adjustment did not have an impact on its financial statements.

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

	Domestic	Foreign
2017	-	-
2018	-	-
2019	-	-
2020	-	-
2021	-	-
Beyond 2021	38,399,914	21,785,348
Total operating loss carry forwards	38,399,914	21,785,348

At December 31, 2016, the Company had approximately \$38.4 million of UK operating loss carryforwards to reduce future UK taxable income. These carryforwards do not expire. At December 31, 2016, the Company had approximately \$21.8 million of foreign operating loss carryforwards in the US and Switzerland. 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, 2016 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.

AKARI THERAPEUTICS, Plc

NOTES TO COMBINED AND CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2016 and 2015
(in U.S. Dollars)

NOTE 11 – Taxes (cont.)

In August 2016, the Company filed a credit claim for 2015 tax year. The credit claim was in the amount of approximately \$578,000 for the year ended December 31, 2015 and was received in September 2016 and was recorded as a credit to research and development costs in the Combined and Consolidated Statements of Comprehensive Loss. 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 record a related receivable at December 31, 2016.

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, 2015
United States	\$ 28,849	\$ 32,373
United Kingdom	29,515	8,140
Total	<u>\$ 58,364</u>	<u>\$ 40,513</u>

NOTE 13 – Subsequent Events

The Company has evaluated events up to the filing date of these financial statements and determined that no subsequent event activity required disclosure.



**Private & Confidential
Addressee Only**
Ray Prudo
76 Wimpole Street
London W1G 9RT

New York office:
24 West 40th Street, 8th Fl
New York, NY, 10018
Tel: +1-646-350-0702
Fax: +1-646-843-9352

London office:
75 Wimpole Street
London W1G 9RS
Tel: +44 (0) 20 80040270
Fax: +44 (0) 20 3318 3004

21 September 2015

Dear Ray

Chairmanship of Akari Therapeutics, Plc

I am writing to you in view of the forthcoming completion of the share exchange agreement dated 10 July 2015 made between Celsus Therapeutics Plc (the “**Company**”) and RPC Pharma Limited (“**RPC**”), pursuant to which the Company will purchase all capital stock of Volution Immuno Pharmaceuticals SA (“**Volution**”) from RPC, Volution’s sole shareholder, in exchange for ordinary shares of the Company, and the Company will be renamed Akari Therapeutics, Plc (“**Completion**”).

We are pleased to set out the basis on which the Company’s Board of Directors (the “**Board**”) offers to appoint you as Chairman and a director (“**Director**”) of the Company upon Completion, on and subject to the terms set out in this Letter.

Appointment and Status

Your appointment as Chairman and Director of the Company will take effect from, and be conditional upon, Completion (at which time it is envisaged that the Company will change its name to Akari Therapeutics, Plc). It is currently envisaged that Completion will occur on or around 16 September 2015 (and for the avoidance of doubt, if Completion does not take place by 31 December 2015, the terms of this Letter shall be null and void and shall have no effect).

Your appointment will be subject to the Company’s Articles of Association (the “**Articles**”) as amended from time to time, whether by the relationship agreement dated 10 July 2015 made between the Company and RPC (the “**Relationship Agreement**”) or otherwise. Copies of the Articles and Relationship Agreement are enclosed for your information.

We should also make it clear that these terms and conditions constitute a contract for services, and not a contract of employment. This role will supersede any current role you have with Volution and it is a condition of this offer that you resign from any current employment with Volution (conditional upon Completion) in a form acceptable to the Company if so requested. By accepting this offer, you also confirm that you are not subject to any restrictions that could prevent you from holding this office as Chairman and/or Director.

Duties and Responsibilities

In your role as Chairman, subject to changes in prevailing corporate governance practice or future decisions by the Board, you will generally be expected to:

- chair the Company's Board meetings, and attend strategic meetings, general meetings and meetings of the Research & Development Committee (which includes setting the agenda for such meetings);
- attend meetings of other Board Committees as appropriate;
- set the Company's strategic direction, working with the Board;
- promote the highest standards of integrity, probity and corporate governance throughout the Company and its divisions, particularly at Board level;
- ensure, in conjunction with the Chief Executive, that the Board receives accurate, timely and clear information;
- contribute to effective communication with shareholders;
- facilitate the effective contribution of the other non-executive directors and ensure constructive relations between executive and non-executive directors; and
- work closely with the Chief Executive.

You may request all relevant information about the affairs of the Company and its subsidiaries that is reasonably necessary for you to effectively discharge your duties.

As a director, you will be required to act at all times in the best interests of the Company. In accordance with the Companies Act 2006 and any other applicable statute or stock exchange rule, you will also owe certain fiduciary duties to the Company, including (without limitation) duties to:

- act within the powers conferred on you by the Company's Articles and by law;
- promote the success of the Company;
- exercise independent judgement;
- exercise reasonable care, skill and diligence;
- not accept benefits from third parties; and
- avoid conflicts of interest, and declare any interests in proposed transactions or arrangements, with the Company.

It is your responsibility to familiarise yourself with these duties and responsibilities. If you need clarification on any of these points, please let the Company's General Counsel and/or Company Secretary know.

You should carry out these responsibilities in accordance with any prevailing law and regulation, including any applicable stock exchange listing requirements and/or corporate governance obligations. In particular, you will comply with the Company's policies from time to time regarding the dealing of securities and conflicts of interest. Accordingly, you may not engage in any transactions in the Company's securities without first notifying the Company's General Counsel and/or Company Secretary and obtaining his/her prior written approval.

Term

You will initially hold office as a Class C Director for a three-year term, further to Article 19.2.3. Thereafter, you will be required to seek re-appointment on such basis as the Articles may set out from time to time. You should note that you have no right to be re-nominated by the Board.

Notwithstanding the other terms of this Letter, your appointment as Chairman and Director may also be terminated by the Company with immediate effect (without being required to serve notice or make any payment in lieu of notice or other payment) should any of the events set out in Articles 25.1.2, 25.1.3, 25.1.4, 25.1.5 or 25.1.6 occur or if at any time you cease to be a Director.

On termination of your appointment (howsoever arising), you will not be entitled to any compensation for loss of office, and you will only be entitled to such fees as may have accrued to the date of termination (together with reimbursement in the normal way of expenses properly incurred before that date). You will also resign from your office as director of the Company (and any offices you may hold in any of the Company's group companies) as the Board may direct.

Fees and Expenses

Your fee will be US\$200,000 per annum. This shall accrue, and be payable, in equal monthly instalments, subject to deductions of income tax and National Insurance as required by law.

The Company will reimburse you for any reasonable expenses properly incurred in attending the Board and Committee meetings or otherwise on Company business, subject to your provision of receipts or such other documentation as the Company may reasonably require. The Company may also grant you other benefits commensurate with your position from time to time.

Notwithstanding anything contained herein or in any incentive compensation plan, program or arrangement sponsored by the Company, if any incentive or performance-based compensation is awarded to you, it shall be subject to reduction or repayment by reason of a correction or restatement of the Company's financial information if and to the extent such reduction or repayment is required by any applicable law or stock exchange rule.

Attendance

By accepting the appointment, you agree to commit sufficient time for the proper performance of your duties to the Company. This will include attendance at the meetings mentioned above, the AGM and other shareholder meetings, and other *ad hoc* Board and Committee meetings (as required), along with travelling time and generally sufficient time for you to prepare for meetings and to regularly update and refresh your skills and knowledge with regard to your role.

The nature of the role makes it impossible to be specific about the maximum time commitment that will be required by you, but it should average no more than 10 days per month at most. You may be required to devote additional time to the Company in respect of preparation time and any *ad hoc* matters that may arise, particularly when the Company is undergoing periods of increased activity. At certain times it may be necessary to convene additional Board, committee, shareholder or other meetings.

Outside Interests

During the term of your appointment, you should therefore obtain prior written authorisation from the Board before accepting any other directorships or business commitments that could affect the time you are able to devote to your role with the Company, impinge on the proper performance of your responsibilities, or give rise to a conflict of interest with the Company.

You have already disclosed the following commitments/positions to the Board:

- Chairman, CIS Healthcare Ltd.
- Chairman, The Doctors Laboratory Ltd.
- Chairman, Varleigh Dx (UK) Ltd.

If you become aware of any actual or potential conflicts of interest which affect or relate to the Company, whether in relation to these commitments/positions or otherwise, you should immediately inform the Company's General Counsel and/or Company Secretary.

Confidentiality

In your capacity as Chairman and Director, you will become aware of confidential information about the business, affairs, plans and prospects of the Company and its subsidiaries. In common with all other directors, you owe a duty of confidentiality to the Company and its subsidiaries in respect of such information and, notwithstanding any other positions you may hold (whether as a director, adviser, employee, partner, investor, person connected with an investor or otherwise), no such information should be used, divulged or communicated to any person, firm or organisation other than in the proper performance of your duties or with the consent of the Board or as required by a court of competent jurisdiction. This duty of confidentiality will continue to apply after you have ceased to be a director.

I would also draw your attention to the various legal and regulatory requirements that apply to the disclosure of inside information and insider dealing, in particular Regulation FD and Rule 10b-5 under the Securities Exchange Act of 1934, as amended. You should avoid making any statements or carrying out any actions that might risk a breach of these requirements.

Liability

You will have the benefit of the indemnity contained within the Articles for certain liabilities you may incur in the performance of your duties as a director of the Company. The Company also maintains a directors' and officers' liability insurance policy in this regard.

You may take independent professional advice at the Company's reasonable expense where necessary for the proper performance of your duties. In such cases you are encouraged to discuss the issue with one or more of your non-executive colleagues or the Company's General Counsel and/or Company Secretary in advance, and should obtain pre-approval of any such costs.

Administrative Matters

In order to formalise your appointment, we will need certain information from you, so that your appointment can be notified to the NASDAQ Stock Market and Companies House in the UK. Accordingly, I enclose two copies of this Letter and various forms for you to complete and return to the Company if you wish to accept the appointment.

By signing this Letter, you also consent to the Company holding and processing information about you for legal, personnel, administrative and management purposes, including the processing of sensitive personal data (as defined in the Data Protection Act 1998). You consent to the Company making such information available to any of its group companies, third parties who provide products and services to the Company (such as advisers and payroll administrators), regulatory authorities and any other organisations which may have a legitimate need to receive this information. You also consent to the transfer of such information outside the European Economic Area as necessary for the Company's business interests and administration.

Governing Law

This Letter is governed by, and shall be construed in accordance with, the laws of England, and the parties agree to submit to the jurisdiction of the courts of England. It contains the entire agreement and understanding between the parties in relation to the matters set out herein, and replaces all previous negotiations, agreements, arrangements or understandings (whether implied or expressed, orally or in writing) in this regard, which are hereby treated as terminated by mutual consent.

I trust the above is all in order, but please don't hesitate to contact me if you have any questions.

Yours sincerely

/s/ Gur Roshwalb

.....
For and on behalf of Akari Therapeutics, Plc

I agree to the terms and conditions of my appointment as Chairman and director of Akari Therapeutics, Plc with effect from Completion on the basis set out above.

/s/ Ray Prudo

Agreed by Ray Prudo

21/9/2015

Date



**Private & Confidential
Addressee Only**
Ray Prudo
76 Wimpole Street
London W1G 9RT

New York office:
24 West 40th Street, 8th Fl
New York, NY, 10018
Tel: +1-646-350-0702
Fax: +1-646-843-9352

London office:
75 Wimpole Street
London W1G 9RS
Tel: +44 (0) 20 80040270
Fax: +44 (0) 20 3318 3004

21 September 2015

Dear Ray

Side letter: your engagement with Celsus Therapeutics Limited (the “Company”)

As recently discussed, I am writing to confirm the value of your services to the Company as Chairman and director, and our belief that it would be in the best interests of the Company and its ultimate shareholders to enter into the arrangements set out in this Letter, on and subject to its terms.

Accordingly, I am pleased to confirm that you will be eligible to be considered for an additional cash payment (a “**Fee Uplift**”) in each calendar year in respect of which the Board (or appropriate sub-committee) reasonably concludes, in its absolute discretion, that your strategic leadership in the role of Chairman has generated exceptional value for the Company and its ultimate shareholders.

In assessing the amount of any such Fee Uplift, the Board (or appropriate sub-committee) will consider relevant factors, potentially including (without limitation) Company performance and relevant legal obligations, stock exchange rules, and corporate governance requirements. The maximum amount of any Fee Uplift will be as set by the appropriate sub-committee in its absolute discretion for the relevant calendar year. Any Fee Uplift will be paid to you as a US\$ cash payment, less all applicable withholdings required by law.

Payment of any Fee Uplift is conditional upon your ongoing compliance with the terms of your Appointment, and your not having ceased to be Chairman and/or a director of the Company by reason of your resignation or further to Article 25.1.2, 25.1.3, 25.1.4, 25.1.5 and/or 25.1.6 of the Company’s Articles of Association (as amended from time to time) as at the date on which the relevant Fee Uplift is due to be paid. In addition, any payment made to you further to this Letter shall be subject to reduction or repayment by reason of a correction or restatement of the Company’s financial information, if and to the extent such reduction or repayment is required by any applicable law or stock exchange rule.

This Letter supplements the terms of your letter of appointment with the Company dated on or around the date of this Letter (your “**Appointment**”), and defined terms not otherwise defined in this Letter will have the meaning set out in the Appointment. Like your Appointment, this Letter will take effect from, and be conditional upon, Completion, and similarly if Completion does not take place by 31 December 2015, its terms will be null and void and shall have no effect. The terms of your Appointment will continue unchanged save as set out in this Letter.

This Letter is governed by, and shall be construed in accordance with, the laws of England, and the parties agree to submit to the jurisdiction of the courts of England. It contains the entire agreement and understanding between the parties in relation to the matters set out herein, and replaces all previous negotiations, agreements, arrangements or understandings (whether implied or expressed, orally or in writing) in this regard, which are hereby treated as terminated by mutual consent.

I trust the above is all in order, but please don't hesitate to contact me if you have any questions.

Yours sincerely

/s/ Gur Roshwalb

.....

For and on behalf of Akari Therapeutics, Plc

EXECUTIVE EMPLOYMENT AGREEMENT

This Employment Agreement (the "Agreement"), made and entered into this 23rd day of March 2016 by and between Akari Therapeutics PLC, a company organized under the law of England and Wales (the "Company"), and Robert M. Shaw ("Executive").

WHEREAS, the Executive and the Company are currently parties to an offer letter agreement dated February 4, 2016 (the "Prior Agreement"); and

WHEREAS, the Executive's employment by the Company was effective as of February 16, 2016 (the "Employment Date"); and

WHEREAS, Company and the Executive wish to enter into this Agreement and upon full execution, this Agreement will supersede and replace in its entirety the Prior Agreement, (other than the Restrictive Covenant Agreement), and the Prior Agreement shall be of no further force or effect;

NOW, THEREFORE, in consideration of the mutual promises, terms, provisions, and conditions contained herein, the parties agree as follows:

- 1. Role and Duties.** Subject to the terms and conditions of this Agreement, Company shall continue to employ Executive as its General Counsel & Secretary reporting to the Company's Chief Executive Officer ("CEO"). Executive accepts such employment upon the terms and conditions set forth herein, and agrees to perform to the best of Executive's ability the duties normally associated with such position and as determined by Company in its sole discretion. During Executive's employment, Executive shall devote all of Executive's business time and energies to the business and affairs of Company, provided that nothing contained in this Section 1 shall prevent or limit Executive's right to manage Executive's personal investments on Executive's own personal time, including, without limitation the right to make passive investments in the securities of: (a) any entity which Executive does not control, directly or indirectly, and which does not compete with Company, or (b) any publicly held entity so long as Executive's aggregate direct and indirect interest does not exceed two percent (2%) of the issued and outstanding securities of any class of securities of such publicly held entity. During Executive's employment, Executive shall not engage in any other non-Company related business activities of any nature whatsoever (including board memberships) without the Company's prior written consent. In addition, and so long as such activities do not interfere materially with Executive's performance of Executive's duties hereunder, Executive also may participate in civic, charitable and professional activities, but shall not serve in any official capacity, including as a member of a board, without the prior written consent of the Company's Board of Directors (the "Board").

2. **Term of Employment.**

- (a) **Term.** The term of this Agreement shall commence on the date hereof and shall continue until the first anniversary of the Employment Date unless terminated earlier pursuant to Section 2(b) (the initial term as well as any successive terms are hereby referred to herein as the "Term"). The Term shall renew automatically for successive one (1) year periods, unless either party has given written notice three (3) months prior to the expiration of the Term in progress that such party elects not to renew the Term. In the event of non-renewal, this Agreement and the Executive's employment hereunder shall terminate automatically at the close of business on the last day of the then current Term.
- (b) **Termination.** Notwithstanding anything else contained in this Agreement, Executive's employment hereunder shall terminate prior to the end of the Term upon the earliest to occur of the following:
- (i) **Death.** Immediately upon Executive's death;
 - (ii) **Termination by Company.** (A) If because of Executive's Disability, written notice by Company to Executive that Executive's employment is being terminated as a result of Executive's Disability, which termination shall be effective on the date of such notice or such later date as specified in writing by Company; (B) If for Cause, written notice by Company to Executive that Executive's employment is being terminated for Cause which termination shall be effective on the date of such notice or such later date as specified in writing by Company; or (C) If by Company for reasons other than under Section 2(b)(ii)(A) or Section 2(b)(ii)(B), written notice by Company to Executive that Executive's employment is being terminated, which termination shall be effective thirty (30) days after the date of such notice or such later date as specified in writing by Company.
 - (iii) **Termination by Executive.**
 - (A) If for Good Reason, written notice by Executive to Company that Executive is terminating Executive's employment for Good Reason and that sets forth the factual basis supporting the alleged Good Reason, which termination shall be effective thirty (30) days after the date of such notice of termination; provided that if Company has cured the circumstances giving rise to the Good Reason, then such termination shall not be effective; or
 - (B) If without Good Reason, written notice by Executive to Company that Executive is terminating Executive's employment, which termination shall be effective at least thirty (30) days after the date of such notice.

- (iv) Notwithstanding anything in this Section 2(b), Company may at any point terminate Executive's employment for Cause prior to the effective date of any other termination contemplated under this Agreement.
- (c) Definition of "Disability". For purposes of this Agreement, "Disability" shall mean Executive's incapacity or inability to perform Executive's duties and responsibilities as contemplated herein for one hundred twenty (120) days or more within any one (1) year period (cumulative or consecutive), because Executive's physical or mental health has become so impaired as to make it impossible or impractical for Executive to perform the duties and responsibilities contemplated hereunder. Determination of Executive's physical or mental health shall be determined by Company after consultation with a medical expert appointed by mutual agreement between Company and Executive who has examined Executive. Executive hereby consents to such examination and consultation regarding Executive's health and ability to perform as aforesaid.
- (d) Definition of "Cause". Cause" shall include: (i) Executive's willful engagement in dishonesty, illegal conduct or gross misconduct, which is, in each case, is materially injurious to Company or any affiliate; (ii) Executive's deliberate insubordination; (iii) Executive's substantial malfeasance or nonfeasance of duty; (iv) Executive's unauthorized disclosure of confidential information; (v) Executive's embezzlement, misappropriation or fraud, whether or not related Executive's employment with Company; or (vi) Executive's breach of a material provision of any employment, non-disclosure, invention assignment, non-competition, or similar agreement between Executive and Company. In all cases, Company shall provide Executive with written notice of the specific conduct or events that Company believes constitutes Cause and, in case of (ii) and (iii) above, Executive shall have thirty (30) days to effect a cure of the claimed conduct or events.
- (e) Definition of "Good Reason". As used herein, a "Good Reason" shall mean: (i) relocation of Executive's principal business location to a location more than fifty (50) miles from Executive's then-current business location; (ii) a material diminution in Executive's duties, authority or responsibilities; or (iii) a material reduction in the Executive's Base Salary; provided that (A) Executive provides Company with written notice that Executive intends to terminate Executive's employment hereunder for one of the grounds set forth in this Section 2(e) within fifteen (15) days of such ground occurring and setting forth in such notice the factual basis for such ground, (B) if such ground is capable of being cured, the Company has failed to cure such ground within a period of thirty (30) days from the date of such written notice of intent to terminate, and (C) Executive terminates Executive's employment within sixty (60) days from the date of such written notice of intent to terminate. For purposes of clarification, the above-listed conditions shall apply separately to each occurrence of Good Reason and failure to adhere to such conditions in the event of Good Reason shall not disqualify Executive from asserting Good Reason for any subsequent occurrence of Good Reason. For purposes of this Agreement, "Good Reason" shall be interpreted in a manner, and limited to the extent necessary, so that it shall not cause adverse tax consequences for either party with respect to Section 409A ("Section 409A") of the Internal Revenue Code of 1986, as amended (the "Code") and any successor statute, regulation and guidance thereto.

3. **Compensation.**

- (a) **Base Salary.** Company shall pay Executive a base salary (the “Base Salary”) at the annual rate of \$250,000.00. The Base Salary shall be payable in substantially equal periodic installments in accordance with Company’s payroll practices as in effect from time to time. Company shall deduct from each such installment all amounts required to be deducted or withheld under applicable law or under any employee benefit plan in which Executive participates. The CEO and Board, or an appropriate committee thereof, shall review the Base Salary on an annual basis.
- (b) **Compensatory Equity Grant.** Pursuant to approval of the Board or an appropriate committee thereof, Executive shall be granted a stock option for the purchase of 1,800,000 ordinary shares of the Company pursuant to the Akari Therapeutics, PLC Amended and Restated 2014 Equity Incentive Plan (the “Plan”), and after January 1, 2017, Executive may be eligible for additional grants of stock options to purchase ordinary shares of the Company, pursuant to the Plan as then in effect or a successor plan, as determined by the Board in its sole discretion. Each stock option grant shall be, to the maximum extent permissible, treated as an “incentive stock option” within the meaning of Section 422 of the Code, and have an exercise price equal to the fair market value (as defined in the Plan) of the ordinary shares on the date of grant of the stock option. Any option grant to Executive shall vest over a four (4) year period, with 12.5% of such grant vesting semi-annually from the date of the grant, subject to Executive’s continued employment with the Company and the vesting of any option shall vest immediately prior to a Change of Control (or upon the non-renewal of this Agreement for any Term following the initial term of this Agreement. Any option grant shall be evidenced in writing by, and subject to the terms and conditions of the Plan pursuant to which it is granted and the Company’s standard form of option agreement, which agreement shall expire ten (10) years from the date of grant except as otherwise provided in the stock option agreement or the Plan.
- (c) **Paid Time Off.** Executive may take up to four (4) weeks of paid time off per year, to be scheduled to minimize disruption to Company’s operations, pursuant to the terms and conditions of Company’s policy and practices as applied to Company senior executives. Executive’s paid vacation for the 2016 fiscal year shall be prorated based on Executive’s actual period of service during that year.

- (d) Fringe Benefits. Executive shall be entitled to participate in all benefit/welfare plans and fringe benefits provided to Company senior executives. Executive understands that, except when prohibited by applicable law, Company's benefit plans and fringe benefits may be amended by Company from time to time in its sole discretion.
- (e) Professional Associations. The Company will pay Executive's annual membership fees associated with his state bar memberships, and with his memberships in the New York City Bar Association, the New York Intellectual Property Law Association, and the Association of Corporate Counsel, and shall pay the reasonable cost of courses required to meet the Executive's annual requirement of twelve (12) credit hours of continuing legal education to maintain his licenses to practice law.
- (f) Reimbursement of Expenses. Company shall reimburse Executive for all ordinary and reasonable out-of-pocket business expenses incurred by Executive in furtherance of Company's business in accordance with Company's policies with respect thereto as in effect from time to time. Executive must submit any request for reimbursement no later than ninety (90) days following the date that such business expense is incurred. All reimbursements provided under this Agreement shall be made or provided in accordance with the requirements of Section 409A of the Code including, where applicable, the requirement that (i) any reimbursement is for expenses incurred during Executive's lifetime (or during a shorter period of time specified in this Agreement); (ii) the amount of expenses eligible for reimbursement during a calendar year may not affect the expenses eligible for reimbursement in any other calendar year; (iii) the reimbursement of an eligible expense shall be made no later than the last day of the calendar year following the year in which the expense is incurred; and (iv) the right to reimbursement or in kind benefits is not subject to liquidation or exchange for another benefit.
- (g) Indemnification. Executive shall be entitled to indemnification with respect to Executive's services provided hereunder pursuant to English law, the terms and conditions of Company's articles of incorporation, Company's directors and officers liability insurance policy and Company's standard indemnification agreement for officers as executed by Company and Executive.

4. **Payments Upon Termination.**

- (a) **“Accrued Obligations”** means: (i) the portion of Executive’s Base Salary that has accrued, including vacation time, prior to any termination of Executive’s employment with Company and has not yet been paid; and (ii) the amount of any expenses properly incurred by Executive on behalf of Company prior to any such termination and not yet reimbursed. Executive’s entitlement to any other compensation or benefit under any plan of Company shall be governed by and determined in accordance with the terms of such plans, except as otherwise specified in this Agreement.
- (b) **Termination by Company for Cause, by Executive Without Good Reason, or as a Result of Executive’s Disability or Death.** If Executive’s employment hereunder is terminated by Company for Cause, by Executive without Good Reason, as a result of Executive’s Disability or death, then Company shall pay the Accrued Obligations to Executive promptly following the effective date of such termination and shall have no further obligations to Executive.
- (c) **Termination by Company without Cause, by Executive for Good Reason or Upon Expiration of the Term.** In the event that after the first anniversary of the Employment Date, (i) Executive’s employment is terminated by action of the Company other than for Cause; (ii) Executive terminates Executive’s employment for Good Reason; or (ii) due to non-renewal of any Term following the initial term of this Agreement, then, in addition to the Accrued Obligations, Executive shall receive the following, subject to the terms and conditions described in Section 4(e) (including Executive’s execution of a release of claims):
- (A) **Severance Payments.** An amount equal to Executive’s annual Base Salary at the rate in effect as of the termination date, less all customary and required taxes and employment-related deductions. The severance payment provided for in this Section 4(c)(A) shall be paid over a 12-month period in accordance with Company’s normal payroll practices (provided such payments shall be made at least monthly), commencing on the first payroll date following the date on which the release of claims required by Section 4(e) becomes effective and non-revocable, but not after sixty (60) days following the effective date of termination from employment; provided, that if the 60th day falls in the calendar year following the year during which the termination or separation from service occurred, then the payments will commence in such subsequent calendar year; provided, further, that if such payments commence in such subsequent year, the first such installment shall include an amount equal to the payments that would have been paid if the payments had commenced in the first month following the termination of employment.

- (B) Benefits Payments. The Company shall pay to Executive an amount equal to the Company's share of the premium paid for Executive while Executive was an active employee for medical insurance coverage under the Company's health care plan (the "Healthcare Subsidy") for a period of twelve (12) months following Executive's termination date. The Healthcare Subsidy shall be paid, less required withholdings, in the same manner and the same time as the payments under Section 4(c)(A) are paid.
 - (C) Payment of the above described severance payments and benefits are expressly conditioned on Executive's execution without revocation of the release of claims under Section 4(e) and return of Company property under Section 6 and continued compliance with the Executive's obligations in the Restrictive Covenant Agreement.
 - (D) In the event that Executive is eligible for the severance payments and benefits under this Section 4(c), Executive shall not be eligible for and shall not receive any of the severance payments and benefits as provided in Section 4(d).
- (d) Termination by Company Without Cause or by Executive for Good Reason Following a Change of Control. In the event that after the first anniversary of the Employment Date a Change of Control occurs and within a period of one (1) year following the Change of Control, either Executive's employment is terminated other than for Cause, or Executive terminates Executive's employment for Good Reason, then, in addition to the Accrued Obligations, Executive shall receive the following, subject to the terms and conditions described in Section 4(e) (including Executive's execution of a release of claims):
- (A) Severance Payment. An amount equal to one and a half times Executive's annual Base Salary at the rate in effect as of the termination date, less all customary and required taxes and employment-related deductions. The severance payment provided for in this Section 4(d)(A) shall be paid over an 18-month period in accordance with Company's normal payroll practices (provided such payments shall be made at least monthly), commencing on the first payroll date following the date on which the release of claims required by Section 4(e) becomes effective and non-revocable, but not after sixty (60) days following the effective date of termination from employment; provided, that if the 60th day falls in the calendar year following the year during which the termination or separation from service occurred, then the payments will commence in such subsequent calendar year; provided further that if such payments commence in such subsequent year, the first such installment shall include an amount equal to the payments that would have been paid if the payments had commenced in the first month following the termination of employment.

- (B) Benefit Payments. The Company shall pay to Executive the Healthcare Subsidy for a period of eighteen (18) months following Executive's termination date. The Healthcare Subsidy shall be paid, less required withholdings, in the same manner and the same time as the payments under Section 4(d)(A) are paid.
- (C) Payment of the above described severance payments and benefits are expressly conditioned on Executive's execution without revocation of the release of claims under Section 4(e) and return of Company property under Section 6 and continued compliance with Executive's obligations in the Restrictive Covenant Agreement.
- (D) In the event that Executive is eligible for the severance payments and benefits under this Section 4(d), Executive shall not be eligible for and shall not receive any of the severance payments and benefits as provided in Section 4(c).

As used herein, a "Change of Control" shall mean the occurrence of any of the following events: (A) The approval by shareholders of the Company of a merger or consolidation of the Company with any other corporation, other than a merger or consolidation which would result in the voting securities of the Company outstanding immediately prior thereto continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity) more than fifty percent (50%) of the total voting power represented by the voting securities of the Company or such surviving entity outstanding immediately after such merger or consolidation; or (B) The approval by the shareholders of the Company of a plan of complete liquidation of the Company or an agreement for the sale or disposition by the Company of all or substantially all of the Company's assets. Except if the Company's valuation is less than that at the time of the exchange transaction on the 16th September 2015, as calculated including any prior distribution of funds, dividends or sales proceeds then a Change of Control shall not be deemed to have occurred for this Section 4(d).

- (e) Execution of Release of Claims. Company shall not be obligated to pay Executive any of the severance payments or benefits described in this Section 4 unless and until Executive has executed (without revocation) a timely release of claims in a form that is acceptable to Company, and which includes standard and reasonable terms regarding items such as mutual non-disparagement, confidentiality, cooperation and the like, which must be provided to Executive within fifteen (15) days following separation from service, and must be effective and irrevocable prior to the 60th day following Executive's separation from service (the "Review Period"), and which shall include a general release of claims against Company and its affiliated entities and each of their officers, directors, employees and others associated with Company and its affiliated entities. If Executive fails or refuses to return such agreement, or revokes the agreement, within the Review Period, Executive's severance payments hereunder and benefits shall be forfeited.
 - (f) Bonus Payments. If at the time that notice of termination is given to which Section 4(c) or Section 4(d) would apply, Executive is entitled under any Company plan to an annual cash bonus, then the target amount of such cash bonus shall be added to the Base Salary in Section 4(c)(A) or Section 4(d)(A), as applicable, and, in the case of Section 4(d)(A), before the multiplier is applied.
 - (g) No Other Payments or Benefits Owed. The payments and benefits set forth in this Section 4 shall be the sole amounts owing to Executive upon termination of Executive's employment for the reasons set forth in Section 4 and Executive shall not be eligible for any other payments or other forms of compensation or benefits. The payments and benefits set forth in Section 4 shall be the sole remedy, if any, available to Executive in the event that Executive brings any claim against Company relating to the termination of Executive's employment under this Agreement.
5. Prohibited Competition and Solicitation. Executive expressly acknowledges that: (a) there are competitive and proprietary aspects of the business of Company; (b) during the course of Executive's employment, Company shall furnish, disclose or make available to Executive confidential and proprietary information and may provide Executive with unique and specialized training; (c) such Confidential Information and training have been developed and shall be developed by Company through the expenditure of substantial time, effort and money, and could be used by Executive to compete with Company; and (d) in the course of Executive's employment, Executive shall be introduced to customers and others with important relationships to Company, and any and all "goodwill" created through such introductions belongs exclusively to Company, including, but not limited to, any goodwill created as a result of direct or indirect contacts or relationships between Executive and any customers of Company. In light of the foregoing acknowledgements and as a condition of employment hereunder, Executive agrees to abide by Company's Confidentiality, Intellectual Property, Non-Competition and Non-Solicitation Agreement as previously entered into by the Executive and the Company on February 4, 2016 (the "Restrictive Covenant Agreement").

6. Property and Records. Upon the termination of Executive's employment hereunder for any reason or for no reason, or if Company otherwise requests, Executive shall: (a) return to Company all tangible business information and copies thereof (regardless how such Confidential Information or copies are maintained), and (b) deliver to Company any property of Company which may be in Executive's possession, including, but not limited to, Blackberry-type devices, smart phones, laptops, cell phones, products, materials, memoranda, notes, records, reports or other documents or photocopies of the same.
7. Code Sections 409A and 280G.
 - (a) 409A. In the event that the payments or benefits set forth in Section 4 of this Agreement constitute "non-qualified deferred compensation" subject to Section 409A of the Code, then the following conditions apply to such payments or benefits:
 - (i) Any termination of Executive's employment triggering payment under Section 4 must constitute a "separation from service" under Section 409A(a)(2)(A)(i) of the Code and Treas. Reg. §1.409A-1(h) before distribution of such benefits can commence. To the extent that the termination of Executive's employment does not constitute a separation of service under Section 409A(a)(2)(A)(i) of the Code and Treas. Reg. §1.409A-1(h) (as the result of further services that are reasonably anticipated to be provided by Executive to Company at the time Executive's employment terminates), any such payments under Section 4 that constitute deferred compensation under Section 409A shall be delayed until after the date of a subsequent event constituting a separation of service under Section 409A(a)(2)(A)(i) of the Code and Treas. Reg. §1.409A-1(h). For purposes of clarification, this Section 7(a) shall not cause any forfeiture of benefits on Executive's part, but shall only act as a delay until such time as a "separation from service" occurs.
 - (ii) Notwithstanding any other provision with respect to the timing of payments under Section 4 if, at the time of Executive's termination, Executive is deemed to be a "specified employee" of Company (within the meaning of Section 409A(a)(2)(B)(i) of the Code), then limited only to the extent necessary to comply with the requirements of Section 409A, any payments to which Executive may become entitled under Section 4 which are subject to Section 409A (and not otherwise exempt from its application) shall be withheld until the first (1st) business day of the seventh (7th) month following the termination of Executive's employment, at which time Executive shall be paid an aggregate amount equal to the accumulated, but unpaid, payments otherwise due to Executive under the terms of Section 4.

- (iii) It is intended that each installment of the payments and benefits provided under Section 4 of this Agreement shall be treated as a separate “payment” for purposes of Section 409A. Neither Company nor Executive shall have the right to accelerate or defer the delivery of any such payments or benefits except to the extent specifically permitted or required by Section 409A.
 - (iv) Notwithstanding any other provision of this Agreement to the contrary, this Agreement shall be interpreted and at all times administered in a manner that avoids the inclusion of compensation in income under Section 409A, or the payment of increased taxes, excise taxes or other penalties under Section 409A. The parties intend this Agreement to be in compliance with Section 409A. Executive acknowledges and agrees that Company does not guarantee the tax treatment or tax consequences associated with any payment or benefit arising under this Agreement, including but not limited to consequences related to Section 409A.
- (b) 280G. If any payment or benefit Executive would receive under this Agreement, when combined with any other payment or benefit Executive receives pursuant to a Change of Control (for purposes of this section, a “Payment”) would: (i) constitute a “parachute payment” within the meaning of Section 280G of the Code; and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the “Excise Tax”), then such Payment shall be either: (A) the full amount of such Payment; or (B) such lesser amount (with cash payments being reduced before stock option compensation) as would result in no portion of the Payment being subject to the Excise Tax, whichever of the foregoing amounts, taking into account the applicable federal, state and local employment taxes, income taxes, and the Excise Tax, results in Executive’s receipt, on an after-tax basis, of the greater amount of the Payment notwithstanding that all or some portion of the Payment may be subject to the Excise Tax.

8. General.

- (a) Notices. Except as otherwise specifically provided herein, any notice required or permitted by this Agreement shall be in writing and shall be delivered as follows with notice deemed given as indicated: (i) by personal delivery when delivered personally; (ii) by overnight courier upon written verification of receipt; (iii) by telecopy or facsimile transmission upon acknowledgment of receipt of electronic transmission; or (iv) by certified or registered mail, return receipt requested, upon verification of receipt.

Notices to Executive shall be sent to:

Executive's last known residential address in Company's records or such other address as Executive may specify in writing, with a copy sent by email to Executive at: rmshaw.nj@gmail.com (the failure of sending a copy by email will not constitute failure to provide notice under this Agreement)

Notices to Company shall be sent to:

24 West 40th Street, 8th Floor
Attention: Chief Executive Officer

or to such other Company representative as Company may specify in writing.

- (b) Modifications and Amendments. The terms and provisions of this Agreement may be modified or amended only by written agreement executed by the parties hereto.
- (c) Waivers and Consents. The terms and provisions of this Agreement may be waived, or consent for the departure therefrom granted, only by written document executed by the party entitled to the benefits of such terms or provisions. No such waiver or consent shall be deemed to be or shall constitute a waiver or consent with respect to any other terms or provisions of this Agreement, whether or not similar. Each such waiver or consent shall be effective only in the specific instance and for the purpose for which it was given, and shall not constitute a continuing waiver or consent.
- (d) Assignment. Company may assign its rights and obligations hereunder to any person or entity that succeeds to all or substantially all of Company's business or that aspect of Company's business in which Executive is principally involved. Executive may not assign Executive's rights and obligations under this Agreement without the prior written consent of Company.
- (e) Governing Law/Dispute Resolution. This Agreement and the rights and obligations of the parties hereunder shall be construed in accordance with and governed by the law of the State of New York, without giving effect to the conflict of law principles thereof. Any legal action or proceeding with respect to this Agreement shall be brought in the courts of the Supreme Court of the State of New York, New York County, or of the United States of America for the Southern District of New York. By execution and delivery of this Agreement, each of the parties hereto accepts for itself and in respect of its property, generally and unconditionally, the non-exclusive jurisdiction of the aforesaid courts.
- (f) Jury Waiver. ANY, ACTION, DEMAND, CLAIM, OR COUNTERCLAIM ARISING UNDER OR RELATING TO THIS AGREEMENT SHALL BE RESOLVED BY A JUDGE ALONE AND EACH OF COMPANY AND EXECUTIVE WAIVES ANY RIGHT TO A JURY TRIAL THEREOF.

- (g) Headings and Captions. The headings and captions of the various subdivisions of this Agreement are for convenience of reference only and shall in no way modify or affect the meaning or construction of any of the terms or provisions hereof.
- (h) Entire Agreement. This Agreement, together with the other agreements specifically referenced herein, embodies the entire agreement and understanding between the parties hereto with respect to the subject matter hereof and supersedes all prior oral or written agreements and understandings relating to the subject matter hereof. No statement, representation, warranty, covenant or agreement of any kind not expressly set forth in this Agreement shall affect, or be used to interpret, change or restrict, the express terms and provisions of this Agreement.
- (i) Counterparts. This Agreement may be executed in two or more counterparts, and by different parties hereto on separate counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. For all purposes a signature by fax shall be treated as an original.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the date first written above.

ROBERT M. SHAW

AKARI THERAPEUTICS PLC

/s/ Robert Shaw
Signature
Address: 24 Meadow Lane
West Long Branch, NJ 07764

By: /s/ Gur Roshwalb
Name: Gur Roshwalb, MD
Title: Chief Executive Officer

**AMENDMENT NO 1 To
EMPLOYMENT AGREEMENT**

Company and Executive agree as follows:

1. Definitions.

- (a) Except as otherwise defined herein, the initially capitalized and fully capitalized terms shall have the meanings ascribed to them in the Agreement.
- (b) "Agreement" means the Executive Employment Agreement made and entered into by and between Company and Executive on March 23, 2016, a copy of which is attached hereto.
- (c) "Amendment" means this amendment to the Agreement.
- (d) "Amendment Date" means February 15, 2017.
- (e) "Company" means Akari Therapeutics PLC (registration number: 05252842) a company organized under the law of England and Wales.
- (f) "Executive" means Robert M. Shaw, residing at 24 Meadow Lane, West Long Branch, New Jersey, 07764 USA.

2. Amendments to the Agreement.

- (a) Section 1 of the Agreement, entitled "Role and Duties":
 - (1) the first sentence is amended to read in its entirety as follows: "Subject to the terms and conditions of this Agreement, as amended, Company shall continue to employ Executive as its General Counsel reporting in that position to the Company's Chief Executive Officer ("CEO"), and Executive shall continue to serve as Company Secretary pursuant to the Company's Articles of Association and, in that position, under the direction of the Chairman of the Company's Board of Directors, it being understood that the two positions constitute one employment and that no further compensation is payable with respect to Executive's appointment as Company Secretary."; and
 - (2) in the second sentence "position" is changed to "positions".
 - (3) The following sentence is added at the end of the paragraph: "Executive shall resign from his position as Company Secretary effective immediately upon the termination of Executive's employment with Company for any reason."

(b) Section 3 of the Agreement, entitled “Compensation”:

(1) the following paragraph “(h)” is added thereto:

“(h) Annual Performance Bonus. Executive shall be eligible to receive an annual cash bonus (the “Annual Performance Bonus”), with the target amount of such Annual Performance Bonus equal to thirty percent (30%) of Executive’s Base Salary in the year to which the Annual Performance Bonus relates, provided that the actual amount of the Annual Performance Bonus may be greater or less than such target amount. The amount of the Annual Performance Bonus shall be determined by the Board or an appropriate committee thereof in its sole discretion, and shall be paid to Executive no later than January 31st of the calendar year immediately following the calendar year in which it was earned. Except as otherwise provided for in this Agreement, Executive must be employed by Company on the date on which the Annual Performance Bonus is paid in order to be eligible for, and to be deemed as having earned, such Annual Performance Bonus. Company shall deduct from the Annual Performance Bonus all amounts required to be deducted or withheld under applicable law or under any employee benefit plan in which Executive participates.”

(c) Section 4 of the Agreement, entitled “Payments Upon Termination”:

(1) in paragraph (c) thereof, entitled “Termination by Company Without Cause, by Executive for Good Reason or Upon Expiration of the Term”:

(A) The first sentence of such paragraph up to subsection (A) is amended to read in its entirety as follows: “In the event that on or after the Amendment Date, (i) Executive’s employment is terminated by action of the Company other than for Cause; (ii) Executive terminates Executive’s employment for Good Reason; or (iii) due to non-renewal of any Term, then, in addition to the Accrued Obligations, Executive shall receive the following, subject to the terms and conditions described in Section 4(e) (including Executive’s execution of a release of claims):”; and

- (B) in subsection (A) of such paragraph (c) entitled “Severance Payments”, the first sentence thereof is amended to read in its entirety as follows: “An amount equal to seventy-five percent (75%) of the sum of (x) Executive’s annual Base Salary at the rate in effect as of the termination date, and (y) the greater of actual or target Annual Performance Bonus to which Executive may have been entitled for the year in which Executive’s employment terminates, in each case less all customary and required taxes and employment-related deductions.”; and the following words in the second sentence: “The severance payment provided for in this Section 4(c)(A) shall be paid over a 12 -month period” are amended to read as follows: “The severance payment provided for in this Section 4(c)(A) shall be paid over a 9-month period”.
 - (C) in subsection (B) of such paragraph (c) entitled “Benefit Payments”, the words “for a period of twelve (12) months” shall be deleted and replaced with “for a period of nine (9) months”
- (2) in paragraph (d) thereof, entitled “Termination by Company Without Cause, or by Executive for Good Reason Following a Change of Control”:
- (A) the following words in the first sentence of such paragraph which are: “In the event that after the first anniversary of the Employment Date a Change of Control occurs and” are amended to read as follows: “In the event that on or after the Amendment Date a Change of Control occurs and”;
 - (B) in subsection (A) of such paragraph entitled “Severance Payments”, the first sentence thereof is amended to read in its entirety as follows: “An amount equal to one and a half times the sum of (x) Executive’s annual Base Salary at the rate in effect as of the termination date, and (y) the target Annual Performance Bonus to which Executive may have been entitled for the year in which Executive’s employment terminates, in each case less all customary and required taxes and employment-related deductions.”
- (3) paragraph (f) thereof, entitled “Bonus Payments”, is deleted in view of the amendments contained herein.

3. Additional Terms.

- (a) This Amendment is effective as of the Amendment Date.
- (b) Except as expressly amended by this Amendment, the Agreement shall remain in full force and effect according to its terms.
- (c) Executive and the Company acknowledge that any and all communications or negotiations between Executive and the Company leading up to and including the execution of this Amendment do not constitute grounds for a Good Reason termination by Executive or a for Cause termination by Company under the Agreement.
- (d) This Amendment may be executed in two or more counterparts, and by different parties hereto on separate counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. For all purposes, a signature sent by email as a pdf shall be treated as an original.

IN WITNESS WHEREOF, Executive and Company have executed this Amendment as of the Amendment Date.

Executive

Company

Akari Therapeutics PLC

/s/ Robert Shaw
Robert M. Shaw

By: /s/ Gur Roshwalb
Name: Gur Roshwalb, M.D., MBA
Title: CEO

Subsidiaries of Akari Therapeutics PLC

The following table sets forth the name and jurisdiction of incorporation of our subsidiaries:

Name of Subsidiary	Jurisdiction of Incorporation
Celsus Therapeutics Inc.	Delaware
Morria Biopharma Ltd.	Israel
Volution Immuno Pharmaceuticals SA	Switzerland

Consent of Independent Registered Public Accounting Firm

Akari Therapeutics, Plc
London, United Kingdom

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-207443), Form S-8 (No. 333-198109 and 333-207444) and the Registration Statements on Post-Effective Amendments to Form F-1 on Form F-3 (Nos. 333-198107, 333-185247, 333-187826 and 333-191880) of Akari Therapeutics, Plc of our report dated March 31, 2017, relating to the consolidated financial statements, which appears in this Form 20-F.

/s/ BDO USA, LLP

BDO USA, LLP
New York, New York
March 31, 2017

Consent of Independent Registered Public Accounting Firm

Akari Therapeutics, Plc
London, United Kingdom

We hereby consent to the incorporation by reference in the Registration Statements on 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. 333-198107, 333-185247, 333-187826 and 333-191880) of our report dated March 23, 2016, with respect to the combined and consolidated financial statements of Akari Therapeutics, Plc. for the year ended December 31, 2015, which appears in this Form 20-F.

Zurich, March 31, 2017

BDO AG

/s/ Christoph Tschumi

/s/ Julian Snow

CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER UNDER SECTION 302 OF THE
SARBANES-OXLEY ACT

I, Gur Roshwalb, certify that:

1. I have reviewed this annual report on Form 20-F 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 company as of, and for, the periods presented in this report;
4. The company'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)) for the company 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 company, 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 company'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 company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and
5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company'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 company'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 company's internal control over financial reporting.

Date: March 31, 2017

/s/ Gur Roshwalb

Gur Roshwalb, Chief Executive Officer

CERTIFICATION OF THE PRINCIPAL FINANCIAL OFFICER UNDER SECTION 302 OF THE

SARBANES-OXLEY ACT

I, Dov Elefant, certify that:

1. I have reviewed this annual report on Form 20-F 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 company as of, and for, the periods presented in this report;
4. The company'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)) for the company 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 company, 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 company'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 company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and
5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company'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 company'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 company's internal control over financial reporting.

Date: March 31, 2017

/s/ Dov Elefant

Dov Elefant, Chief Financial Officer

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER UNDER SECTION 906 OF THE
SARBANES-OXLEY ACT

Pursuant to 18 U.S.C. Section 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Akari Therapeutics, PLC (the "Company") hereby certifies, to such officer's knowledge that:

- (i) the accompanying Annual Report on Form 20-F of the Company for the year ended December 31, 2016 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and
- (ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 31, 2017

/s/ Gur Roshwalb

Gur Roshwalb

Chief Executive Officer

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. Section 1350, and is not being filed for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference to any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER UNDER SECTION 906 OF THE
SARBANES-OXLEY ACT

Pursuant to 18 U.S.C. Section 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Akari Therapeutics, PLC (the "Company") hereby certifies, to such officer's knowledge that:

- (i) the accompanying Annual Report on Form 20-F of the Company for the year ended December 31, 2016 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and
- (ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 31, 2017

/s/ Dov Elefant

Dov Elefant

Chief Financial Officer

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. Section 1350, and is not being filed for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference to any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.
