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

# FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2015

OR

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

For the transition period from _____ to _____

Commission file number: 001-36288

## AKARI THERAPEUTICS, PLC

*(Exact name of registrant as specified in its charter)*

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

**76 Wimpole Street**
**London, W1G 8LY**
**United Kingdom**
*(Address of principal executive offices and Zip Code)*

Registrant's telephone number, including area code: **+44-203-318-3004**

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, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☐ Accelerated filer ☐

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

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

As of November 16, 2015, the registrant had 1,177,693,383 ordinary shares outstanding.

**AKARI THERAPEUTICS, PLC**

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PART I - FINANCIAL INFORMATION

Item 1. Financial Statements.

**AKARI PHARMACEUTICALS, Plc**

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(In U.S. Dollars)

**AKARI THERAPEUTICS, Plc**

COMBINED AND CONSOLIDATED BALANCE SHEETS
As of September 30, 2015 and December 31, 2014
(in U.S. Dollars, except share data)

| **Assets** | September 30, 2015 (Unaudited) | December 31, 2014 |
|---|---|---|
| Current Assets: | | |
| Cash and cash equivalents | $ 78,772,888 | $ 3,327,468 |
| Prepaid expenses and other current assets | 166,141 | 7,781 |
| Total Current Assets | 78,939,029 | 3,335,249 |
| | | |
| Restricted deposit | 142,079 | - |
| Property and Equipment, net | 34,932 | - |
| Patent Acquisition Costs, net | 58,099 | 59,417 |
| Total Assets | $ 79,174,139 | $ 3,394,666 |
| | | |
| **Liabilities and Shareholders' Equity** | | |
| | | |
| Current Liabilities: | | |
| Accounts payable | 3,753,518 | 555,528 |
| Accounts payable - related party | - | 39,236 |
| Accrued expenses | 3,845,928 | 42,999 |
| Loans payable - shareholders | 3,031,304 | 533,605 |
| Liability related to stock options and warrants | 27,165,905 | - |
| Total Current Liabilities | 37,796,655 | 1,171,368 |
| | | |
| Other long-term liability | 46,038 | - |
| Total liabilities | 37,842,693 | 1,171,368 |
| | | |
| Commitments and Contingencies | | |
| | | |
| Shareholders' Equity: | | |
| Share capital of GBP .01 par value Authorized: 5,000,000,000 shares; Issued and outstanding: 1,177,693,383 and 722,345,600 at September 30, 2015 and December 31, 2014, respectively | 18,340,894 | 11,210,804 |
| Additional paid-in capital | 86,062,364 | 2,445,494 |
| Accumulated other comprehensive income | 197,091 | 46,081 |
| Accumulated deficit | (63,268,903) | (11,479,081) |
| Total Shareholders' Equity | 41,331,446 | 2,223,298 |
| Total Liabilities and Shareholders' Equity | $ 79,174,139 | $ 3,394,666 |

See notes to combined and consolidated financial statements.

**AKARI THERAPEUTICS, Plc**

COMBINED AND CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS - UNAUDITED
For the Three and Nine Months Ended September 30, 2015 and September 30, 2014
(in U.S. Dollars)

| | Three Months Ended | | Nine Months Ended | |
|---|---|---|---|---|
| | September 30, 2015 | September 30, 2014 | September 30, 2015 | September 30, 2014 |
| Operating Expenses: | | | | |
| Research and development costs | $ 1,313,265 | $ 162,575 | $ 3,869,395 | $ 539,965 |
| General and administrative expenses | 2,730,434 | 55,454 | 3,140,945 | 274,195 |
| Excess consideration | 19,283,280 | - | 19,283,280 | - |
| Total Operating Expenses | 23,326,979 | 218,029 | 26,293,620 | 814,160 |
| Loss from Operations | (23,326,979) | (218,029) | (26,293,620) | (814,160) |
| | | | | |
| Other Income (Expense): | | | | |
| Interest income | 1,445 | - | 1,445 | 85 |
| Changes in fair value of warrant liabilities - gains/(losses) | 638,691 | - | 638,691 | - |
| Financing expense | (22,973,138) | - | (22,973,138) | - |
| Exchange loss | (22) | (2,218) | (60,581) | (12,120) |
| Interest expense | (3,054,262) | (2,882) | (3,059,898) | (7,547) |
| Other taxes | (21,425) | - | (42,721) | - |
| Total Other Income (Expense) | (25,408,711) | (5,100) | (25,496,202) | (19,582) |
| | | | | |
| Loss before Income Taxes | (48,735,690) | (223,129) | (51,789,822) | (833,742) |
| | | | | |
| Income Taxes | - | - | - | |
| | | | | |
| Net Loss | (48,735,690) | (223,129) | (51,789,822) | (833,742) |
| | | | | |
| Other Comprehensive Income (Loss): | | | | |
| Foreign Currency Translation Adjustment | (43,262) | (20,391) | 151,010 | (34,379) |
| | | | | |
| Comprehensive Loss | $ (48,778,952) | $ (243,520) | $ (51,638,812) | $ (868,121) |
| | | | | |
| Earnings per common share (basic and diluted) | $ (0.06) | $ (0.00) | $ (0.07) | $ (0.01) |
| | | | | |
| Weighted average common shares (basic and diluted) | 781,738,789 | 73,370,267 | 742,360,887 | 72,968,124 |

See notes to combined and consolidated financial statements.

**AKARI THERAPEUTICS, Plc**

COMBINED AND CONSOLIDATED STATEMENT OF CHANGES IN SHAREHOLDER' EQUITY
As of and for the Nine Months Ended September 30, 2015

(in U.S. Dollars)

| | *Akari Therapeutics, Plc (Formerly Celsus Therapeutics)* Share Capital | | Additional Paid-in | Accumulated Other Comprehensive | Accumulated | |
|---|---|---|---|---|---|---|
| | Shares | Amount | Capital | Income | Deficit | Total |
| Shareholders' Equity, January 1, 2015 | 722,345,600 | 11,210,804 | $ 2,445,494 | $ 46,081 | $ (11,479,081) | 2,223,298 |
| Issuance of share capital related to 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 | 63,437,683 | - | - | 69,581,758 |
| Issuance of share capital for advisory fees | 3,830,400 | 59,448 | 690,552 | - | - | 750,000 |
| Stock based compensation | - | - | 76,062 | - | - | 76,062 |
| Comprehensive Loss | - | - | | 151,010 | (51,789,822) | (51,638,812) |
| Shareholders' Equity, September 30, 2015 | 1,177,693,383 | $ 18,340,894 | $ 86,062,364 | $ 197,091 | $ (63,268,903) | $ 41,331,446 |

See notes to combined and consolidated financial statements.

**AKARI THERAPEUTICS, Plc**

COMBINED AND CONSOLIDATED STATEMENTS OF CASH FLOWS - UNAUDITED
As of and for the Nine Months Ended September 30, 2015 and 2014
(in U.S. Dollars )

| | Nine Months Ended September 30, 2015 | September 30, 2014 |
|---|---|---|
| Cash Flows from Operating Activities: | | |
| Net loss | $ (51,789,822) | (833,742) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation | 4,424 | 1,455 |
| Stock based compensation | 76,062 | - |
| 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 warrants | (638,691) | - |
| Changes in operating assets and liabilities: | | |
| Decrease (increase) in assets: | | |
| Prepaid expenses and other assets | 1,475,903 | (3,099) |
| Increase (decrease) in liabilities: | | |
| Accounts payable and accrued expenses | 6,638,855 | 26,540 |
| Other liabilities | 439 | - |
| Total adjustments | 53,594,714 | 24,896 |
| Net Cash Provided By (Used in) Operating Activities | 1,804,892 | (808,846) |
| | | |
| Cash Flows from Investing Activities: | | |
| Cash received from reverse acquisition | 1,410,577 | - |
| Net Cash Provided by Investing Activities | 1,410,577 | - |
| | | |
| Cash Flows from Financing Activities: | | |
| Proceeds from stockholder loans | 3,031,304 | - |
| Payments of stockholder loans | (508,713) | (7,205) |
| Proceeds from issuance of shares | 75,000,000 | 237,090 |
| Net issuance costs | (5,418,242) | - |
| Proceeds from stock subscription | - | 112,300 |
| Net Cash Provided by Financing Activities | 72,104,349 | 342,185 |
| | | |
| Effect of Exchange Rates on Cash and Cash Equivalents | 125,602 | (34,379) |
| | | |
| Net Increase in Cash and Cash Equivalents | 75,445,420 | (501,040) |
| Cash and Cash Equivalents, beginning | 3,327,468 | 553,654 |
| Cash and Cash Equivalents, end | $ 78,772,888 | $ 52,614 |
| | | |
| Supplemental Disclosures of Cash Flow Information: | | |
| Cash paid during the year for: | | |
| Interest | $ 22,662 | $ 12 |

See notes to combined and consolidated financial statements.

## NOTE 1 - Nature of Business

Akari Pharmaceuticals, Plc, (the "Company" or "Akari"), formerly Celsus Therapeutics Plc ("Celsus"), is incorporated in the United Kingdom. The Company is a clinical stage biotechnology company, and is focused on developing anti-complement and anti-inflammatory molecules as treatments for a wide range of rare and orphan conditions in the autoimmune and inflammatory diseases sectors.

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

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

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

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

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

**NOTE 1 - Nature of Business (cont.)**

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

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

**NOTE 2 - Summary of Significant Accounting Policies**

**Basis of Presentation -** The accompanying combined and consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP") for interim financial information and the rules and regulations of the U.S. Securities and Exchange Commission ("SEC). Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. These financial statements have been prepared on the same basis as the Company's annual financial statements and, in the opinion of management, reflect all adjustments including normal and recurring adjustments which the Company considers necessary for the fair presentation of financial information. The results of operations and comprehensive loss for the three and nine months ended September 30, 2015 are not necessarily indicative of expected results for the full fiscal year or any other period.

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

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

The financial statements of Varleigh, which was the predecessor business to the Company, have been combined through the date of its dissolution on September 14, 2014.

All intercompany transactions have been eliminated.

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

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

**Use of Estimates -** The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and judgments that may affect the reported amounts of assets, liabilities, equity, revenue, expenses and related disclosure of contingent assets and liabilities. Management's estimates and judgments include assumptions used in the impairment and useful lives of intangible assets, 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, accounts payable, and loans payable shareholders approximate fair value due to their short-term maturities.

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

**Cash and Cash Equivalents** - The Company considers all highly-liquid investments with original maturities of 90 days or less at the time of acquisition to be cash equivalents. The Company had no cash equivalents at September 30, 2015 and December 31, 2014.

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

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

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

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

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

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

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

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

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

**Research and Development Expenses -** Costs associated with research and development are expensed as incurred. Research and development expenses include, among other costs, costs incurred by outside laboratories and other accredited facilities in connection with clinical trials and preclinical studies. Research and development expense for the nine months ended September 30, 2015 and September 30, 2014 amounted to $3,869,395 and $539,965, respectively.

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

**Stock-Based Compensation Expense -**

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

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

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

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

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

(in U.S. Dollars)

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

The following table provides details with respect to changes in accumulated other comprehensive income (AOCI), which is comprised of foreign currency translation adjustments, as presented in the combined balance sheets for the nine months ended September 30, 2015:

| | |
|---|---|
| Balance January 1, 2015 | $ 46,081 |
| Net current period other comprehensive income | 151,010 |
| Balance September 30, 2015 | $ 197,091 |

**New Accounting Pronouncements –**
Not Adopted - In August 2014, the FASB issued Accounting Standard Update No. 2014-15, Disclosure of Uncertainties About an Entity's Ability to Continue as a Going Concern. The amendments require management to perform interim and annual assessments of an entity's ability to continue as a going concern and provides guidance on determining when and how to disclose going concern uncertainties in the financial statements. The standard applies to all entities and is effective for annual and interim reporting periods ending after December 15, 2016, with early adoption permitted. The Company is currently evaluating the impact on its financial statements and disclosures.

**NOTE 3 – Reverse Acquisition**

We completed our acquisition as discussed in Note 1. Based on the terms of the Acquisition and since the Volution securityholders owned approximately 91.68% of the fully-diluted capitalization of the Company immediately following the closing of the Acquisition, Volution is considered to be the acquiring company for accounting purposes, and the transaction has been accounted for as a reverse acquisition under the acquisition method of accounting for business combinations in accordance with U.S. GAAP. Accordingly, the assets and liabilities of Celsus have been recorded as of the acquisition closing date at fair value.

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

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

*Purchase Consideration*

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

| | | |
|---|---|---|
| Fair value of Celsus common stock outstanding | $ 20,034,625 | |
| Fair value of Celsus stock options | 277,461 | (2,481,690 options) |
| Fair value of Celsus warrants | 27,054 | (1,782,246 warrants) |
| Total purchase price | $ 20,339,140 | |

(in U.S. Dollars)

**NOTE 3 – Reverse Acquisition (cont.)**

***Allocation of Purchase Consideration - preliminary***

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

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

| | |
|---|---|
| Cash and cash equivalents | $ 1,410,577 |
| Restricted deposit | 142,079 |
| Prepaid expenses and other assets acquired | 1,672,028 |
| Excess consideration | 19,283,280 |
| Liability related to stock options and warrants | (1,800,581) |
| Other assumed liabilities | (368,243) |
| Total | $20,339,140 |

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

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

**NOTE 4 – Patent Acquisition Costs**

Patent acquisition costs, net, are the asset costs of purchased patents that and are amortized over the useful life of the patent determined to be 22 years, at September 30, 2015 and December 31, 2014 consisted of the following:

| | September 30, 2015 | December 31, 2014 |
|---|---|---|
| Patent acquisition and related costs | $ 96,784 | $ 95,192 |
| Less: Accumulated amortization | (38,685) | (35,775) |
| | $ 58,099 | $ 59,417 |

Amortization of patent acquisition costs for the nine months ended September 30, 2015 and September 30, 2014 was $2,293 and $1,891, respectively.

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

| | |
|---|---|
| 2015 | $ 850 |
| 2016 | 3,400 |
| 2017 | 3,400 |
| 2018 | 3,400 |
| 2019 | 3,400 |
| Thereafter | 43,649 |

(in U.S. Dollars)

## NOTE 5 – Loans Payable - Shareholders

Loans payable – shareholders at September 30, 2015 and December 31, 2014 consisted of the following:

| | September 30, 2015 | December 31, 2014 |
|---|---|---|
| Unsecured demand loan (CHF 100,500) bearing interest at 3.5% per annum | $ - | $ 101,252 |
| Unsecured demand loan (EUR 224,250) bearing interest at 4.5% per annum | - | 275,241 |
| Unsecured demand loan (GBP 100,000) bearing interest at 4.5% per annum | - | 157,112 |
| Unsecured demand loan (GBP 1,998,000) bearing interest at 3.0% per annum | 3,031,304 | - |
| | $ 3,031,304 | $ 533,605 |

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

Interest expense included in the statement of comprehensive loss related to these loans for the nine months ended September 30, 2015 and 2014 amounted to approximately $3,059,000 and $7,500, respectively. The 2014 shareholder loans were repaid in April 2015 and the 2015 loans were repaid in October 2015.

## NOTE 6 – Fair Value Measurements

In accordance with ASC No. 820, “Fair Value Measurements and Disclosures”, the Company measures its liability related to stock options and warrants at fair value. The liability related to stock options and warrants is classified within Level 3 value hierarchy because the liability is based on present value calculations and external valuation models whose inputs include market interest rates, estimated operational capitalization rates, volatilities and illiquidity. Unobservable inputs used in these models are significant.

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

As of September 18, 2015, the Acquisition date, warrants to purchase 5,617,977 ordinary shares had full ratchet anti-dilution protection (which would be triggered by a share or warrant issuance at less than $0.1958 price share or exercise price per share). The issuance of ordinary shares in connection with the Financing (see Note 1) triggered the full ratchet anti-dilution protection resulting in an additional 188,303 ordinary shares issuable upon exercise of such warrants and reducing the exercise price to $0.18945.

(in U.S. Dollars)

**NOTE 6 – Fair Value Measurements (cont.)**

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

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

Fair values were estimated using the following assumptions for the options as of September 30, 2015:

| | |
|---|---|
| Expected dividend yield | 0% |
| Expected volatility | 213.9% |
| Risk-free interest | 0.49% |
| Expected life | 1.51 years |

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

As of September 30, 2015, the fair value of the RPC Pharma Ltd stock options was $26,004,442. The net change in fair value was recognized as financing expense or change in fair value of warrant liabilities in the Company's consolidated statement of comprehensive loss. The Company accounted for the options as a liability in accordance with ASC 815-40-25, "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock" and ASC 815-40-15, "Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock."

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

| | September 30, 2015 | December 31, 2014 |
|---|---|---|
| | Fair value measurements using input type Level 3 | |
| Warrants | $ 1,161,463 | |
| RPC options | $ 26,004,442 | |
| Liability related to stock options and warrants | $ 27,165,905 | $ - |

(in U.S. Dollars)

**NOTE 6 – Fair Value Measurements (cont.)**

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

| | Fair value of liability related to stock options and warrants |
|---|---|
| Balance at December 31, 2014 | - |
| Balance at September 18, 2015 (Acquisition) | 1,800,154 |
| Changes in values of liability related to warrants | (638,691) |
| Value of liability related to stock options - transfer in | 26,004,442 |
| Balance at September 30, 2015 | $ 27,165,905 |

**NOTE 7 – Shareholders' Equity**

**Share Capital** – The Company has 5,000,000,000 shares of authorized capital and 1,177,693,383 shares outstanding as of September 30, 2015.

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

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

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

**Share option plan** –

Upon completion of the Acquisition, the Company assumed the former Celsus 2014 Equity Incentive Plan (the "Plan"). In accordance with the Plan, the number of shares that may be issued upon exercise of options under the Plan, shall not exceed 141,142,420 shares. As of September 30, 2015, 84,797,105 ordinary shares are available for future issuance under the Plan.

(in U.S. Dollars)

**NOTE 7 – Shareholders' Equity (cont.)**

The following is a summary of the Company's stock option activity and related information for employees and directors for the nine months ended September 30, 2015:

| | Number of shares | Weighted average exercise price | Weighted average grant date fair value | Weighted average remaining contractual term (in years) | Aggregate intrinsic value |
|---|---|---|---|---|---|
| Options outstanding as of January 1, 2015 | - | $ - | | - | $ - |
| Changes during the period: | | | | | |
| Assumed in Acquisition | 2,428,227 | $ 1.48 | $ 0.55 | | |
| Granted Following the Acquisition | 53,828,625 | $ 0.32 | $ 0.21 | | |
| | | | | | |
| Options outstanding as of September 30, 2015 | 56,256,852 | $ 0.37 | | 9.9 | $ - |
| | | | | | |
| Exercisable options as of September 30, 2015 | 2,229,891 | $ 1.47 | | 7.0 | $ - |

The following is a summary of the Company's non-vested stock options as of September 30, 2015 and changes during the period:

| | Number of shares | Weighted average grant date fair value |
|---|---|---|
| Non-vested options as of December 31, 2014 | - | $ - |
| Non-vested options assumed in Acquisition | 198,336 | $ 0.25 |
| Non-vested options granted | 53,828,625 | $ 0.21 |
| Non-vested as of September 30, 2015 | 54,026,961 | $ 0.21 |

On September 21, 2015, the Company granted 52,883,513 options to its employees at an exercise price of $0.3221 that vest quarterly over 4 years. In addition, the Company granted 945,112 options to its non-employee directors at an exercise price of $0.3221 that vest in 1 year.

Under the provisions of ASC 718 Compensation – Stock Compensation, the Company is required to measure and recognize compensation expense related to any outstanding and unvested stock options previously granted, and thereafter recognize, in its consolidated financial statements, compensation expense related to any new stock options granted after implementation using a calculated fair value based option-pricing model. The Company uses the Black-Scholes option-pricing model to calculate the fair value of all of its stock options and its assumptions are based on historical and available market information. Below are the assumptions used for the options granted prior to the Acquisition:

(in U.S. Dollars)

**NOTE 7 – Shareholders' Equity (cont.)**

| | 2015 |
|---|---|
| Expected dividend yield | 0% |
| Expected volatility | 73.94%-81.21% |
| Risk-free interest | 1.5%-2.18% |
| Expected life | 5.5-9.01 years |

Below are the assumptions used for the options granted in the quarter ended September 30, 2015:

| | 2015 |
|---|---|
| Expected dividend yield | 0% |
| Expected volatility | 71.28%-72.56% |
| Risk-free interest | 1.51%-1.71% |
| Expected life | 5.5-6.25 years |

The computation of the expected volatility assumption used in the Black-Scholes calculation for grants is based on historical volatilities of a peer group of similar companies in the same industry. The expected life assumptions are based on underlying contracts.

During the nine months ended September 30, 2015, the Company recorded approximately $76,000 in share based compensation expenses. As of September 30, 2015, there was approximately $11,400,000 unrecognized compensation cost related to unvested share-based compensation arrangements granted under the Company's stock option plans.

**Warrants and options to service providers and investors -**

The options and warrants outstanding as of September 30, 2015 that were granted to the Company's service providers are as follows:

| Grant date | Number of options | Exercise Price | Expiration date |
|---|---|---|---|
| August 28, 2007 | 20,475 | $ 1.29 | August 28, 2017 |
| May 27, 2009 | 30,000 | $ 1.56 | May 27, 2019 |
| February 12, 2012 | 309,492 | $ 2.00 | February 12, 2017 |
| April 26, 2012 | 90,000 | $ 2.00 | March 19, 2017 |
| June 27, 2012 | 2,988 | $ 1.75 | June 21, 2022 |
| November 30, 2012 | 90,180 | $ 2.00 | November 30, 2017 |
| January 17, 2013 | 43,035 | $ 2.00 | January 17, 2018 |
| January 31, 2013 | 7,200 | $ 2.00 | January 31, 2018 |
| February 8, 2013 | 3,600 | $ 2.00 | February 28, 2018 |
| August 27, 2014 | 35,000 | $ 0.565 | August 27, 2024 |
| | 631,970 | | |

The warrants outstanding as of September 30, 2015 that were granted in connection with certain financings totaled 1,150,276 with a weighted average exercise price of $1.96.

**NOTE 8 – Related Party Transactions**

**Accounting Services -** An entity related to a shareholder provided accounting and bookkeeping services of approximately $44,000 and $25,000, respectively, to the Company during the nine months ended September 30, 2015 and September 30, 2014.

**NOTE 9 - Commitments and Contingencies**

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

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

(in U.S. Dollars)

**NOTE 9 - Commitments and Contingencies (cont.)**

Future minimum lease payments under the Company's operating leases are as follows as of September 30, 2015:

| | London | United States |
|---|---|---|
| 2015 | $ 5,125 | $ 73,107 |
| 2016 | 20,500 | 297,260 |
| 2017 | 20,500 | 312,909 |
| 2018 | 20,500 | 330,291 |
| 2019 | 5,100 | 225,297 |
| | $ 71,725 | $ 1,238,864 |

For the nine months ended September 30, 2015 and September 30, 2014, the Company incurred rental expense in the amount of approximately $27,000 and $0.

**NOTE 10 – Earnings Per Share**

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

| | Three Months Ended September 30, | |
|---|---|---|
| **Earnings per share** | 2015 | 2014 |
| Company posted | Net loss | Net loss |
| Basic weighted average shares outstanding | 781,738,789 | 73,370,267 |
| Dilutive effect of common stock equivalents | None | None |
| Dilutive weighted average shares outstanding | 781,738,789 | 73,370,267 |

| | Nine Months Ended September 30, | |
|---|---|---|
| **Earnings per share** | 2015 | 2014 |
| Company posted | Net loss | Net loss |
| Basic weighted average shares outstanding | 742,360,887 | 72,968,124 |
| Dilutive effect of common stock equivalents | None | None |
| Dilutive weighted average shares outstanding | 742,360,887 | 72,968,124 |

(in U.S. Dollars)

**NOTE 10 – Earnings Per Share (cont.)**

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

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

| | Three month Period ended September 30, 2015 | Three month period ended September 30, 2014 | Nine month period ended September 30, 2015 | Nine month period ended September 30, 2014 |
|---|---|---|---|---|
| Total stock options | 56,256,852 | - | 56,256,852 | - |
| Total warrants-equity classified | 1,782,246 | - | 1,782,246 | - |
| Total warrants-liability classified | 5,806,280 | - | 5,806,280 | - |
| Total stock options and warrants | 63,845,378 | - | 63,845,378 | - |

**NOTE 11 – Subsequent Events**

In October 2015, the Company repaid the short-term working capital loans from shareholders in the amount of approximately $3 million.

**Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.**

*You should read this discussion together with the combined and consolidated financial statements, related notes and other financial information included elsewhere in this Quarterly Report on Form 10-Q. The following discussion may contain predictions, estimates and other forward-looking statements that involve a number of risks and uncertainties, including those discussed under "Risk Factors" in this Quarterly Report on Form 10-Q. These risks could cause our actual results to differ materially from any future performance suggested below.*

**Overview**

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

On September 18, 2015, Celsus completed its acquisition of all of the capital stock of Volution Immuno Pharmaceuticals SA ("Volution"), from 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.

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

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

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

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

Scientific understanding of the role of complement C5 inhibition in the treatment of a range of rare diseases related to uncontrolled activation of the complement arm of the immune system is growing. These rare diseases include conditions such as PNH, aHUS, MG, GBS, and Sjögren's syndrome.

Coversin entered clinical development in 2013 when a Phase Ia clinical trial was initiated under a Clinical Trials Authorisation (CTA) issued by the Medicines and Healthcare products Regulatory Agency (MHRA), an executive agency of the Department of Health in the United Kingdom. The primary objective of this single ascending dose, first-in-man study was to explore the safety profile of Coversin. The drug was well tolerated, and no serious or dose-related adverse events were reported. The secondary objective of this Phase Ia clinical trial was to examine the effect of Coversin on complement activity at the highest, therapeutic dose. This showed that the peak onset of action was about nine hours after injection, and that the effect of a single dose persisted for more than 96 hours. The effects were consistent between all subjects and showed 100% inhibition of the complement system (see Phase Ia trial results, at right) within 12 hours. This trial suggested that Coversin is suitable for once daily subcutaneous injection. Confirmation of this and of the optimal repeat dose are expected to be obtained in a Phase Ib repeat dose study to be initiated in the fourth quarter of 2015. Our initial clinical targets will be PNH, GBS, aHUS, and the treatment of patients with polymorphisms of the C5 molecule which interfere with correct binding of eculizumab, making them resistant to treatment with that drug. The latter are expected to be initially treated under compassionate use and named patient protocols until sufficient safety and efficacy data have been accumulated to allow for regulatory approval.

A Phase Ib clinical trial in healthy volunteers is currently expected to be initiated in the fourth quarter of 2015 or early 2016, and we expect to initiate a Phase II trial in PNH patients in the first or early second quarter of 2016. We expect to begin treating PNH patients resistant to eculizumab on a compassionate basis before year-end 2015, and to start Phase II trials in GBS in the first half of 2016 and in aHUS beginning later in 2016. We expect data from the Phase II trial in PNH to be available by year-end 2016. If Coversin achieves satisfactory results in those Phase II clinical trials, we expect to immediately proceed into Phase III pivotal studies in both Europe and the United States. We have decided to discontinue development of Celsus's prior technology. Our reported Results of Operations for the nine months ended September 30, 2015 and September 30, 2014 and the other financial information presented below, are combined from those of both us and our preceding entity, Varleigh Immuno Pharmaceuticals. Volution was formed in October 2013, and operationally overlapped with Varleigh through July 2014, when Varleigh effectively ceased operations before formal dissolution in September 2014.

Our research and development expenses consist primarily of personnel expenses, fees paid to external service providers for formulation and synthesis activities, manufacturing and costs of pre-clinical studies and clinical trials. We primarily use external service providers to manufacture our product candidates for clinical trials and for all of our pre-clinical and clinical development work. We charge all research and development expenses to operations as they are incurred. We expect our research and development expenses to remain our primary expense in the near future as we continue to develop our product candidates. We currently perform our research and development activity mainly through outsourcing to subcontractors. Since inception we have generated significant losses in connection with our research and development, including the pre-clinical and clinical development of our product candidates. At September 30, 2015, we had an accumulated deficit of approximately $63,269,000. Since inception, we have funded our operations primarily through the sale of equity securities and debt financing. We have not yet generated any revenues and we expect to continue to incur net losses and negative cash flows for the foreseeable future. These net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. At September 30, 2015 we had $78,772,888 of cash and cash equivalents available to fund future operations through 2017.

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

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

**Critical Accounting Policies and Use of Estimates**

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

**JOBS Act**

On April 5, 2012, the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, was enacted. Section 107 of the JOBS Act provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. In other words, an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We chose to "opt out" of the extended transition period related to the exemption from new or revised accounting standards, and as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies. This election is irrevocable. Additionally, we are continuing to evaluate the benefits of relying on other exemptions and reduced reporting requirements provided by the JOBS Act.

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

**Stock-Based Compensation and Fair Value of Ordinary Shares**

We account for stock-based compensation in accordance with ASC 718 and ASC 505, that require the measurement and recognition of compensation expense based on estimated fair values for all share-based payment awards made to employees, directors and non-employees. ASC 718 requires companies to estimate the fair value of equity-based payment awards on the measurement date using an option-pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as an expense over the requisite service periods in our consolidated statement of operations.

We recognize compensation expenses for the value of our awards granted based on the straight-line method over the requisite service period of each of the awards, net of estimated forfeitures. ASC 718 requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Estimated forfeitures are based on actual historical pre-vesting forfeitures.

We selected the Black-Scholes-Merton ("Black-Scholes") option-pricing model as the most appropriate fair value method for our stock-options awards and values stock based on the market value of the underlying shares at the date of grant. The option-pricing model requires a number of assumptions. The computation of expected volatility is based on realized historical stock price volatility of peer companies. The expected term of options granted is based on the "Simplified" method acceptable by ASC 718. For non-employees, the expected term assumption is based on the contractual term. The risk free interest rate assumption is the implied yield currently available on the U.S. Treasury yield zero-coupon issues with a remaining term equal to the expected life of the Company's 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.

We apply ASC 718 and ASC 505-50, "Equity-Based Payments to Non-Employees" with respect to options and warrants shares issued to non-employees. ASC 718 requires the use of option valuation models to measure the fair value of the options and warrants at the measurement date. Since the exercise price of some of the options and warrants is denominated in a currency that is different from our functional currency, we account for such warrants as a liability.

**Warrants**

In connection with the issuance of certain warrants, we applied ASC 470-20, "Debt with Conversion and Other Options" ("ASC 470-20 "). In accordance with ASC 470-20, we first allocated the proceeds received to the warrant, freestanding liability instrument that is measured at fair value at each reporting date, based on its fair value, with changes in the fair values being recognized in our statement of comprehensive loss as changes in fair value of warrant liabilities. The fair value of the warrants granted was valued by using the Binomial method of valuation. The anti-dilution rights of the warrants were calculated by using the Binomial method of valuation put option using the same parameters as the warrants call option. The computation of expected volatility is based on realized historical stock price volatility of peer companies. The expected term is based on the contractual term. The risk free interest rate assumption is the implied yield currently available on U.S. Treasury yield zero-coupon issues with a remaining term equal to the expected life of the options. The dividend yield assumption is based on our historical experience and expectation of no future dividend payouts and may be subject to substantial change in the future. We have historically not paid cash dividends and have no foreseeable plans to pay cash dividends in the future. The fair value of the warrants on September 18, 2015 (Acquisition date) was $1,800,154. The change in fair value in the quarter ended September 30, 2015 was a decrease of $638,691 and was recognized as changes in fair value of warrant liabilities in the statement of comprehensive loss. In connection with a short-term working capital loan of approximately $3 million that included options in RPC Pharma Ltd, equivalent to 15% of the current outstanding equity issued by RPC Pharma Ltd, we estimated the fair value of the stock options on September 30, 2015 was approximately $26 million. We recorded a non-cash liability to stock options and warrants for $26 million, allocated $3 million as a loan discount, $23 million as a non-cash financing expense and recorded interest expense in the amount of $3 million in statement of comprehensive loss as a credit to the loan discount. On September 30, 2015, the fair value of the stock options and warrants was $27,165,905.

**Functional Currency**

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

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

**Results of Operations**

***For the Three Months Ended September 30, 2015 and September 30, 2014***

*Research and development expenses*

Research and development expenses for the quarter ended September 30, 2015 were $1,313,265 compared to $162,575 for the quarter ended September 30, 2014. This 708% or $1,150,690 increase was due to higher expenses of for manufacturing and clinical trial activities of approximately $1,142,000, $5,000 of insurance expenses and $4,000 of salary 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 quarter ended September 30, 2015 were $2,730,434 compared to $55,454 for the quarter ended September 30, 2014. This 4,824% or $2,674,980 increase was primarily due to higher expenses of legal, consulting, professional and accounting expenses of approximately $1,750,000, $750,000 of compensation expenses for advisory services related to the Acquisition, $77,000 of stock-based compensation expense, $40,000 of travel related expenses related to the Acquisition and the Financing, $26,000 of insurance expenses, $20,000 of salary expenses and $12,000 of rent expenses.

*Excess consideration*

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

*Other expenses*

Other expense for the quarter ended September 30, 2015 was $25,408,710 compared to $5,100 for the quarter ended September 30, 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 (RPC is a private company that is a majority shareholder of the Company) and $21,000 of other taxes, offset by the revaluation of the warrant liabilities of $638,691.

***For the Nine Months Ended September 30, 2015 and September 30, 2014***

*Research and development expenses*

Research and development expenses for the nine months ended September 30, 2015 were $3,869,395 compared to $539,965 for the nine months ended September 30, 2014. This 617% or $3,329,430 increase was due to higher expenses of for manufacturing and clinical trial activities of approximately $3,320,000, $5,000 of insurance expenses and $4,000 of salary expenses.

*General and administrative expenses*

General and administrative expenses for the nine months ended September 30, 2015 were $3,140,945 compared to $274,195 for the nine months ended September 30, 2014. This 1,046% or $2,866,750 increase was primarily due to higher expenses of legal, consulting, professional and accounting expenses and travel related expenses related to the Acquisition and the Financing of approximately $1,931,000, $750,00 of compensation expenses for advisory services related to the Acquisition, $77,000 of stock-based compensation expense, $51,000 of travel related expenses related to the Acquisition and the Financing, $26,000 of insurance expenses, $20,000 of salary expenses and $12,000 of rent expenses.

*Excess consideration*

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

*Other income (expenses)*

Other income for the nine months ended September 30, 2015 was $25,496,201 compared to $19,582 for the nine months ended September 30, 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 (RPC is a private company that is a majority shareholder of the Company), higher foreign exchange losses of approximately $48,000 and $43,000 of other taxes, offset by the revaluation of the warrant liabilities of $638,691.

**Liquidity and Capital Resources**

Net cash provided by operating activities was $1,804,892 during the nine months ended September 30, 2015 compared to $808,846 used by operating activities during the nine months ended September 30, 2014. Net cash flow used in operating activities was primarily attributed to Volution's ongoing research activities to support Coversin, including manufacturing and clinical trial activities, which was offset by the assumption of unpaid accounts payable and accrued expenses as part of the Acquisition.

Net cash provided by investing activities was $1,410,577 in the nine month period ending September 30, 2015. This is cash received from the reverse acquisition. In the nine month period ending September 30, 2014 we had no investment activity. We anticipate that our investment activities will include income generated from our investment in interest bearing securities in the future.

Net cash provided by financing activities was $72,104,349 during the nine months ended September 30, 2015 compared to $342,185 during the nine months ended September 30, 2014. This increase is primarily attributed to the net proceeds of $69,581,758 from the Financing completed after the Acquisition and $3,031,304 net proceeds from stockholder loans offset by $508,713 of repayments of stockholder loans. In October 2015, we repaid the short-term working capital loans from shareholders in the amount of approximately $3 million.

As of September 30, 2015, we had $78,772,888 in cash and cash equivalents, an increase of $75,445,420 from December 31, 2014, inclusive of cash assumed in the Acquisition. As of November 20, 2015, we had approximately $69.6 million in cash and cash equivalents after paying most of our acquisition and financing related expenses subsequent to September 30, 2015. In addition, as of September 30, 2015, we had accumulated losses in the total amount of approximately $63,269,000. Since inception, we have funded our operations primarily through the sale of equity securities and debt financing. We have not yet generated any revenues and we expect to continue to incur net losses and negative cash flows for the foreseeable future. These net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. We believe our current cash and cash equivalents are sufficient to fund future operations through 2017 This forecast of cash resources is forward-looking information that involves risks and uncertainties, and the actual amount of our expenses over the next twelve months could vary materially and adversely as a result of a number of factors, including the risks and uncertainties set forth in Item 1A under the heading "Risk Factors" of this Quarterly Report on Form 10-Q.

We expect that we will need additional financing to support our long-term plans. We expect to finance our cash needs through the sale of equity securities, strategic collaborations and/or debt financings, or through other sources that may be dilutive to existing shareholders. There can be no assurance that we will be able to obtain funding from any of these sources or, if obtained, what the terms of such funding(s) may be, or that any amount that we are able to obtain will be adequate to support our working capital requirements until we achieve profitable operations. We have no current committed sources of additional capital but are constantly assessing market conditions so that we may take advantage of financing opportunities. If we are unable to raise additional funds when needed, we may not be able to develop any new product candidates that we potentially acquire, or we could be required to delay any future development programs and significantly reduce our activities in order to maintain our operations for the next twelve months. Our future capital requirements may depend on many factors that are currently unknown to us, including:

- the timing of initiation, progress, results and costs of clinical trials and pre-clinical studies for any product candidates that we acquire;
- the costs of manufacturing;
- the costs of raw materials in order to produce our product candidates;
- the costs of producing the product candidates;
- the costs of hiring additional personnel appropriate for the development program;
- the cost of technology transfer, scale-up and optimization;
- the scope, progress, results, and cost of pre-clinical development, clinical trials, and regulatory review of any new product candidates for which we may initiate development;
- the cost of filing regulatory applications for our product candidates;
- the costs of preparing, filing, and prosecuting patent applications and maintaining, enforcing, and defending intellectual property-related claims;
- our ability to establish research collaborations and strategic collaborations and licensing or other arrangements on terms favorable to us;
- the costs to satisfy our obligations under potential future collaborations; and
- the timing, receipt, and amount of sales, milestone payments, licensing fees or royalties, if any, from any approved product candidates.

**Research and Development, Patents and Licenses**

Our research and development expenditures were approximately $3,869,000 and $540,000 in the nine months ended September, 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 in the nine month ended September 30, 2015 and 2014:

| | Nine Months ended September 30, | |
|---|---|---|
| | 2015 | 2014 |
| Direct Expenses: | | |
| Coversin | $ 2,348,000 | $ - |
| Other | 512,000 | 149,000 |
| Total direct expenses | $ 2,860,000 | $ 149,000 |
| Indirect Expenses: | | |
| Staffing | 620,000 | 169,000 |
| Other indirect | 389,000 | 222,000 |
| Total indirect expenses | $ 1,009,000 | $ 391,000 |
| Total Research and Development | $ 3,869,000 | $ 540,000 |

**Off-balance Sheet Arrangements**

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

**Certain Factors That May Affect Future Results of Operations**

The Securities and Exchange Commission, or SEC, encourages companies to disclose forward-looking information so that investors can better understand a company's future prospects and make informed investment decisions. This Quarterly Report on Form 10-Q contains such "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995.

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. All forward-looking statements are management's present expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those described in the forward-looking statements. These risks include, but are not limited to those set forth under the heading "Risk Factors" contained in this Quarterly Report on Form 10-Q.

In light of these assumptions, risks and uncertainties, the results and events discussed in the forward-looking statements contained in this Quarterly Report on Form 10-Q might not occur. Stockholders are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date of this Quarterly Report on Form 10-Q. 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 Akari or to any person acting on its behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section.

**Item 3. Quantitative and Qualitative Disclosures About Market Risk.**

As a "smaller reporting company" as defined by Item 10 of Regulation S-K, the Company is not required to provide information required by this Item.

**Item 4. Controls and Procedures.**

(a) *Evaluation of Disclosure Controls and Procedures*. Our principal executive officer and principal financial officer evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on this evaluation, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures were not 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 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. The material weakness in the Company's internal control over financial reporting identified by management relates to the lack of internal expertise and resources to analyze and timely record under US GAAP certain non-routine complex transactions that were directly related to and arose as a result of the Acquisition. Prior to the completion of the Acquisition, Volution, as a private company, lacked sufficient resources to properly analyze and record non-routine complex transactions. Management has begun to implement certain remediation measures to address these issues, including having the Company's Chief Financial Officer perform a rigorous and timely review of non-routine complex agreements prior to their execution and the hiring of additional accounting and legal personnel, that is intended to reasonably assure management that its disclosure controls and procedures are effective. In the event we enter into non-routine complex transactions, we intend to retain an accounting consultant or other expert advice to assist in the review of the accounting treatment: detailing the facts, circumstances, research and conclusions concerning the accounting treatment of such transaction and communicate its findings to senior management for resolution as needed.

(b) *Changes in Internal Controls*. There were no changes in our internal control over financial reporting, identified in connection with the evaluation of such internal control that occurred during our last fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting with the exception of the material weakness associated with controls over non-routine complex transactions.

## PART II - OTHER INFORMATION

**Item 1. Legal Proceedings.**

We are currently not a party to any material legal proceedings.

**Item 1A. Risk Factors.**

The following risk factors could cause our actual business and financial results to differ materially from those contained in forward-looking statements made in this Quarterly Report on Form 10-Q or elsewhere by management from time to time.

### 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 $51,789,822 for the nine months ended September 30, 2015, and $1,947,553 and $1,095,596 for the years ended December 31, 2014 and 2013, respectively. In addition, our accumulated deficit as of September 30, 2015 and December 31, 2014 was $63,268,903 and $11,479,081, respectively. To date, we have not commercialized any products or generated any revenues from the sale of products, and absent the realization of sufficient revenues from product sales, we may never attain profitability in the future. Our losses have resulted principally from costs incurred in our discovery and development activities.

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

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

As of September 30, 2015, we had existing cash and cash equivalents of $78,772,888. We will require additional capital in order to develop and commercialize our current product candidates or any product candidates that we acquire, if any. There can be no assurance that additional funds will be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available on a timely basis, we may be required to terminate or delay development for one or more of our product candidates.

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

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

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

**Risks Related to our Business**

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

We have incurred significant operating losses since inception and expect to incur significant losses for the foreseeable future as we continue our clinical trial and development programs for Coversin. As of June 30, 2015, Akari Therapeutics, Plc (formerly known as Celsus Therapeutics Plc) had an accumulated deficit of approximately $14.5 million and, on a pro forma basis, $18.3 million as set forth in our Form 8-K/A filed with the SEC on October 16, 2015. Losses have principally resulted from costs incurred in our clinical trials, research and development programs and general and administrative expenses. We have funded our operations primarily through the private placement of equity securities and debt financing. As of September 30, 2015, following the consummation of the Acquisition and the Financing, we had cash and cash equivalents of $78.8 million. We expect to incur significant losses for the foreseeable future as we continue to conduct research and development, clinical testing, regulatory compliance activities and, if Coversin or other future product candidates receive regulatory approval, sales and marketing activities.

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

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

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

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

- the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA, EMA or comparable foreign regulatory bodies for marketing approval;

- patients in our clinical trials may die or suffer other adverse effects for reasons that may or may not be related to Coversin, which could delay or prevent further clinical development;

- the standards implemented by clinical or regulatory agencies may change at any time;

- the FDA, EMA or foreign clinical or regulatory agencies may require efficacy endpoints for a Phase 2 clinical trial for the treatment of PNH, aHUS, GBS and in conditions such as antibody mediated transplant rejection that differ from the endpoints of our planned current or future trials, which may require us to conduct additional clinical trials;

- the mechanism of action of Coversin is complex and we do not know the degree to which it will translate into a medical benefit in certain indications;

- if approved for PNH, aHUS, myasthenia gravis, GBS, keratoconjunctivitis sicca secondary to Sjogren's or antibody mediated transplant rejection, Coversin will likely compete with the off-label use of currently marketed products and other therapies in development;

- our intellectual property rights may not be patentable, valid or enforceable; and

- we may not be able to obtain, maintain or enforce our patents and other intellectual property rights.

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

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

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

Patient enrollment is affected by other factors, including:

- severity of the disease under investigation;

- design of the clinical trial protocol;

- size and nature of the patient population;

- eligibility criteria for the trial in question;

- perceived risks and benefits of the product candidate under trial;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- ineffective marketing and distribution support of our products.

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

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

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

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

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

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

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

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

- diversion of management and scientific resources from our business operations; and
- the inability to commercialize our product candidates.

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

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

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

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

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

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

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

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

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

## Risks Related to Our Reliance on Third Parties

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

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

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

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

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

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

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

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

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

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

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

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

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

**Risks Related to Owning Our Ordinary Shares and ADSs**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**Risks Relating to the Acquisition**

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

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

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

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

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

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

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

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

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

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

**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.**

None.

**Item 3. Defaults Upon Senior Securities.**

None.

**Item 4. Mine Safety Disclosures.**

Not applicable.

**Item 5. Other Information.**

None.

**Item 6. Exhibits.**

(a) *Exhibits*

2.1 Share Exchange Agreement, dated as of July 10, 2015, by and between the Registrant and RPC Pharma Limited (incorporated by reference to Exhibit 2.1 of the Registrant's Current Report on Form 8-K filed with the SEC on July 13, 2015).

10.1 Relationship Agreement, dated as of July 10, 2015, by and between the Registrant and RPC Pharma Limited (incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed with the SEC on July 13, 2015).

10.2 Form of Working Capital Agreement, by and between the Registrant and RPC Pharma Limited (incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed with the SEC on July 13, 2015).

10.3 Form of Lock-Up Agreement, by and among the Registrant and RPC Pharma Limited (incorporated by reference to Exhibit 10.3 of the Registrant's Current Report on Form 8-K filed with the SEC on July 13, 2015).

10.4 Form of Securities Purchase Agreement, dated August 17, 2015 by and among the Registrant and the Buyers (as defined therein) (incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed with the SEC on August 18, 2015).

10.5 Form of Registration Rights Agreement, dated August 17, 2015 by and among the Registrant and the Buyers (as defined therein) (incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed with the SEC on August 18, 2015).

10.6 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 with the SEC on September 9, 2015).

10.7 Amended and Restated 2014 Equity Incentive Plan (incorporated by reference to the Exhibit previously filed with the Registrant's Definitive Proxy Statement on Schedule 14A (File No. 001-36288) filed with the SEC on August 3, 2015).

10.8 Executive Employment Agreement, dated as of September 21, 2015, by and between the Registrant and Gur Roshwalb, M.D. (incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed with the SEC on September 22, 2015).

10.9 Executive Employment Agreement, dated as of September 21, 2015, by and between the Registrant and Dov Elefant (incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed with the SEC on September 22, 2015).

10.10 Employment Contract, dated as of September 21, 2015, by and between the Registrant and Clive Richardson (incorporated by reference to Exhibit 10.3 of the Registrant's Current Report on Form 8-K filed with the SEC on September 22, 2015).

31.1 Certification of principal executive officer under Section 302(a) of the Sarbanes-Oxley Act of 2002.

31.2 Certification of principal financial officer under Section 302(a) of the Sarbanes-Oxley Act of 2002.

32.1 Certifications of the principal executive officer and the principal financial officer under Section 906 of the Sarbanes-Oxley Act of 2002.

101 The following materials from Akari Therapeutics PLC's Quarterly Report on Form 10-Q for the quarter and nine months ended September 30, 2015, formatted in XBRL (eXtensible Business Reporting Language): (i) the Unaudited Condensed Consolidated Balance Sheets, (ii) the Unaudited Condensed Consolidated Statements of Operations, (iii) the Unaudited Condensed Consolidated Statements of Comprehensive Loss, (iv) the Unaudited Condensed Consolidated Statements of Cash Flows, and (v) Notes to Unaudited Condensed Consolidated Financial Statements.

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

AKARI THERAPEUTICS, PLC

Date: November 23, 2015

By: /s/ Gur Roshwalb
Gur Roshwalb
Chief Executive Officer
(principal executive officer)

**Exhibit 31.1**

**CERTIFICATIONS UNDER SECTION 302**

I, Gur Roshwalb, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Akari Therapeutics, PLC;

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

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

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

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

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

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

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

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

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

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

Date: November 23, 2015

/s/ Gur Roshwalb
Gur Roshwalb
Chief Executive Officer
(principal executive officer)

**Exhibit 31.2**

**CERTIFICATIONS UNDER SECTION 302**

I, Dov Elefant, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Akari Therapeutics, PLC;

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

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

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

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

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

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

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

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

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

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

Date: November 23, 2015

/s/ Dov Elefant
Dov Elefant
Chief Financial Officer
(principal accounting and financial officer)

**Exhibit 32.1**

**CERTIFICATIONS UNDER SECTION 906**

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

The Quarterly Report on Form 10-Q for the period ended September 30, 2015 (the "Form 10-Q") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 23, 2015

/s/ Gur Roshwalb
Chief Executive Officer
(principal executive officer)

Dated: November 23, 2015

/s/ Dov Elefant
Dov Elefant
Chief Financial Officer
(principal accounting and financial officer)

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.